GREENEVILLE CITY BOARD OF EDUCATION

AGENDA

Date of Meeting: December 10, 2024 Time: 5:00 PM

Location: Professional Development Center at the Kathryn W. Leonard Administrative Office

{{Name: Agenda Item Name}} {{AnticipatedTime: Agenda Item Time}}

I. **Call to Order**

II. **Pledge to the Flag**

III. **Recognition of Visitors**

IV. **Special Recognition**
- **Maggie Moore**
- **Larry Blalock**
- **Trey Bailey**

V. (5 minutes)

VI. **Public Comment Period** (20 Minutes)

VII. **Report from Crystal Jessee** (5 minutes)

VIII. **Report from Daniel Lewis** (5 Minutes)

IX. **Conflict of Interest Statement** (5 Minutes)

Chair to Board Members:

- "If you have any relative who is employed by the Board of Education, meaning a spouse, parent, parent-in-law, child, son-in-law, daughter-in-law, grandparent, grandchild, brother, sister, uncle, aunt, nephew, niece, or any person who resides in the same household as you, please acknowledge the same at this time by raising your hand."

Chair to Board Members:

2. "To those board members who just raised their hands, do you hereby certify that any and all votes you will cast during this meeting are in the best interest of the school system? If so, please say, 'Aye.'"

Chair to Board Secretary:

3. "Please reflect within the minutes that possible conflicts were acknowledged, with board members present confirming their intent to act in the best interest of the school system."

X. **Approval of Agenda** (5 Minutes)

XI. **Consent Agenda** (5 minutes)

A. Consideration of Approving Minutes of October 24, 2024, Board Meeting

B. Consideration of Accepting Personnel Report

C. Consideration of Approving Board Policy Revisions (2nd Reading)

D. Consideration of Approving Board Policy Revisions - No Changes (1st Reading)

E. Consideration of Approving School Trip Request

F. Consideration of Approving Report on Compliance, School Approval Process

G. Consideration of Approving Resolution Supporting Public Schools

XII. **Action Items**

A. Consideration of Accepting October 2024 Financial Statements (5 minutes)

B. Consideration of Approving Board Policy Revisions - 1st Reading (5 minutes)

C. Consideration of Joining Lawsuit Against Insulin Manufacturers and PBM's (5 minutes)

D. Consideration of Approving Board Policy Revisions (1st and Final Reading) (5 Minutes)

E. Consideration of Approving Resolution Authorizing Participation in the Public Entity Partners "Driver Safety" (5 Minutes)

F. Consideration of Approving Door Preventative Maintenance Work (5 Minutes)

G. Consideration of Approving School Bus Purchase (5 Minutes)

H. Consideration of Approving Web Filtering License Renewal and Refreshing Hardware Appliance (5 Minutes)

XIII. **Director's Report** (5 minutes)

XIV. **Legislative Update** (5 Minutes)

XV. **Adjournment**

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
NORTHEASTERN DISVISION

HAMBLEN COUNTY, TENNESSEE,

Plaintiff,

v.

ELI LILLY AND COMPANY; NOVO NORDISK INC.; SANOFI-AVENTIS U.S. LLC; CVS HEALTH CORPORATION; CVS PHARMACY, INC.; CAREMARKPCS HEALTH, LLC; CAREMARK, LLC; CAREMARK RX, LLC; EVERNORTH HEALTH, INC. (F/K/A EXPRESS SCRIPTS HOLDING COMPANY); EXPRESS SCRIPTS, INC.; EXPRESS SCRIPTS ADMINISTRATORS, LLC; MEDCO HEALTH SOLUTIONS, INC.; ESI MAIL PHARMACY SERVICES, INC.; EXPRESS SCRIPTS PHARMACY, INC.; UNITEDHEALTH GROUP, INC.; OPTUM, INC.; OPTUMRX INC.; OPTUMRX HOLDINGS I LLC; OPTUMINSIGHT, INC.,

Defendants.

Civil Action No. _____

COMPLAINT

JURY TRIAL DEMANDED

Complaint and Demand for Jury Trial

TABLE OF CONTENTS

INTRODUCTION 1

PARTIES 10

A. Plaintiff 10

B. Manufacturer Defendants 11

C. PBM Defendants 15

JURISDICTION AND VENUE 38

ADDITIONAL FACTUAL ALLEGATIONS 39

A. Diabetes and Insulin Therapy 39

- The Diabetes Epidemic 39
- Insulin: A Century-Old Drug 40
- The Current Insulin Landscape 42
- Insulin Adjuncts: Type 2 Medications 42

B. The Dramatic Rise in the Price of Diabetes Medications in the U.S. 45

- The Defendant-Manufacturers Have Increased Prices in Lockstep 48

C. Pharmaceutical Payment and Supply Chain 52

D. The PBMs' Role in the Pharmaceutical Payment Chain 53

- The Rise of the PBMs in the Pharmaceutical Supply Chain 55
- The Insular Nature of the Pharmaceutical Industry 57

E. The Insulin Pricing Scheme 61

F. Defendants Play Down the Insulin Pricing Scheme and Its Harms 65

G. Defendant Profit from the Insulin Pricing Scheme 72

- The PBMs Pocket a Substantial Share of Manufacturer Payments 73
- The Insulin Pricing Scheme Allows the PBMs to Profit Off Pharmacies 80

- The Insulin Pricing Scheme Increases PBM Mail-Order Profits 84

H. Plaintiff Purchases the At-Issue Drugs Directly from Defendants 85

I. Defendants Deceived Plaintiff 87

J. The Insulin Pricing Scheme Has Damaged Plaintiff 100

K. Defendants' Recent Efforts in Response to Rising Insulin Prices 102

CLAIMS FOR RELIEF 105

FIRST CLAIM FOR RELIEF (Violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962(c)) (against Defendants Eli Lilly, Novo Nordisk, Sanofi, CVS Caremark, and Express Scripts) 105

A. Defendants Are Culpable "Persons" Under RICO. 105

B. The Manufacturer-PBM RICO Enterprises 106

C. The Enterprises Misrepresent and Fail to Disclose Material Facts in Furtherance of the Insulin Pricing Scheme. 110

D. Defendants' Use of the U.S. Mails and Interstate Wire Facilities 112

E. Conduct of the Manufacturer-PBM Enterprises' Affairs 114

F. Defendants' Pattern of Racketeering Activity 115

G. The RICO Defendants' Motive 117

H. The Manufacturer-PBM Enterprises' Insulin Pricing Scheme Injured Plaintiff.....117

SECOND CLAIM FOR RELIEF (Violations of RICO, 18 U.S.C. § 1962(d) By Conspiring to Violate 18 U.S.C. § 1962(c))(against all Defendants).....119

THIRD CLAIM FOR RELIEF (Unlawful Restraint of Trade, Tenn. Code Ann. §§ 47-25-101, *et seq*) (against all Defendants) 121

FOURTH CLAIM FOR RELIEF (Violation of Tennessee Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101, *et seq*) (against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark) 122

FIFTH CLAIM FOR RELIEF (Breach of Contract) (against Defendants Express Scripts, and CVS Caremark) 125

.
SIXTH CLAIM FOR RELIEF (Unjust Enrichment) (against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark) 126

MOTION FOR INJUNCTION 128

PRAYER FOR RELIEF 128

JURY DEMAND 130

Plaintiff, Hamblen County, Tennessee ("Plaintiff," the "County" or "Hamblen County"), by and through undersigned counsel, brings this lawsuit against the above-named Defendants and alleges as follows:

INTRODUCTION

1. The cost of diabetes medications has risen more than tenfold over the past 20 years. Over the same period of time, the average cost of consumer goods and services has risen just 1.75-fold. The skyrocketing prices of diabetes medications are not tethered the rising cost of goods, production costs, investment in research and development, or competitive market forces. Instead, Defendants engineered these price increases via an opaque, conspiratorial kickback scheme (referred to herein as the "Insulin Pricing Scheme"), which has exponentially increased their profits at the expense of payors like Plaintiff and its plan members. The Insulin Pricing Scheme is a multibillion-dollar industry.

2. Diabetes is widespread. The total estimated cost of diabetes in the U.S. in 2017, according to the American Diabetes Association, was $327 billion. One in four healthcare dollars is spent caring for people with diabetes.

3. As of 2020, more than 13% of adults in Tennessee have been diagnosed with diabetes.[1] An additional 9.9% of the Tennessee adult population are prediabetic, with blood glucose levels higher than normal but not yet high enough to be diagnosed as diabetic.[2] In Hamblen, approximately 11.4%, of adult residents are living with diabetes.[3] In Tennessee alone,

[1] Tennessee Diabetes Action Legislative Report, Feb. 2021, https://www.capitol.tn.gov/Archives/senate/112GA/committees/health-welfare/2021/Diabetes%20Legislative%20Report_FinalDraft.%2001-29-2021%208%2045%20pm.pdf.

[2] *Id.*

[3] United States Diabetes Surveillance System, https://gis.cdc.gov/grasp/diabetes/diabetesatlas-analysis.html# (last visited January 26, 2024).

diabetes costs an estimated $5.2 billion per year in direct medical costs attributed to diabetes.[4] An additional $2.1 billion is spent on indirect costs from attributed to diabetes.[5]

4. Diabetics in Tennessee generally rely on daily insulin treatments, oral medications, or a combination of both to treat and control diabetes. Defendants Eli Lilly, Novo Nordisk, and Sanofi (collectively, the "Manufacturer Defendants" or the "Manufacturers") manufacture the vast majority of insulins and other diabetic medications available in the United States. In 2020, as in the years preceding, the Manufacturer Defendants controlled 92% by volume, and 96% by revenue, of the global market for diabetes drugs.

5. Defendants CVS Caremark, Express Scripts, and OptumRx (collectively, the "PBM Defendants" or the "PBMs") are pharmacy benefit managers that work with the Manufacturer Defendants to dictate the availability and price of the at-issue drugs for most of the U.S. market.[6] The PBM Defendants are, at once, (1) the three largest pharmacy benefit managers in the United States (controlling more than 80% of the PBM market); (2) the largest pharmacies in the United States (comprising three of the top five dispensing pharmacies in the U.S.); and (3) housed within the same corporate families as three of the largest insurance companies in the United States—Aetna (CVS Health), Cigna (Express Scripts), and UnitedHealthcare (OptumRx).

6. These corporate conglomerate Defendants sit at 4th (CVS Health), 5th (UnitedHealth Group), and 12th (Cigna) on the Fortune 500 list as of year-end 2022.

[4] Tennessee Diabetes Profile, https://www.cdc.gov/diabetes/programs/stateandlocal/state-diabetes-profiles/tennessee.html (last visited January 26, 2024).

[5] *Id.*

[6] In the context of this Complaint, the "at-issue drugs" or "at-issue medications" are: Apidra, Basaglar, Humalog, Humulin N, Humulin R, Humulin R 500, Humulin 70/30, Lantus, Levemir, Novolin N, Novolin R, Novolin 70/30, Novolog, Ozempic, Soliqua, Toujeo, Tresiba, Trulicity, and Victoza.

Figure 1: Manufacturers, PBMs & PBM-Affiliated Insurers

Manufacturers	PBMs	PBM-Affiliated Insurer
Eli Lilly		
Novo Nordisk		
Sanofi		
	CVS	Aetna
	Express Scripts	Cigna
	Optum	UnitedHealthcare

7. For transactions in which the PBM Defendants control the insurer, the PBM, and the pharmacy (e.g., Aetna–Caremark–CVS Pharmacy), these middlemen capture as much as half of the money spent on each insulin prescription (up from 25% in 2014), even though they contribute nothing to the development, manufacture, innovation, or production of the drugs.

8. As part of this work, the PBM Defendants establish national formulary offerings (i.e., approved drug lists), which, among other things, set the baseline for which diabetes medications are covered and which are not covered by nearly every payor in the United States, including in Tennessee and, more specifically, Hamblen County.

9. The Manufacturers and PBMs understand that the PBMs' national formularies drive drug utilization. The more accessible a drug is on the PBMs' national formularies, the more that drug will be purchased throughout the United States. Conversely, exclusion of a drug from one or more of the PBMs' formularies can render the drug virtually inaccessible for millions of covered persons.

10. Given the PBMs' market power and the crucial role their standard formularies play in the pharmaceutical pricing chain, both Defendant groups understand that the PBM Defendants wield enormous control over drug prices and purchasing behavior.

11. The unfair and deceptive conspiracy at the root of this complaint—the Insulin Pricing Scheme—was borne from this mutual understanding.

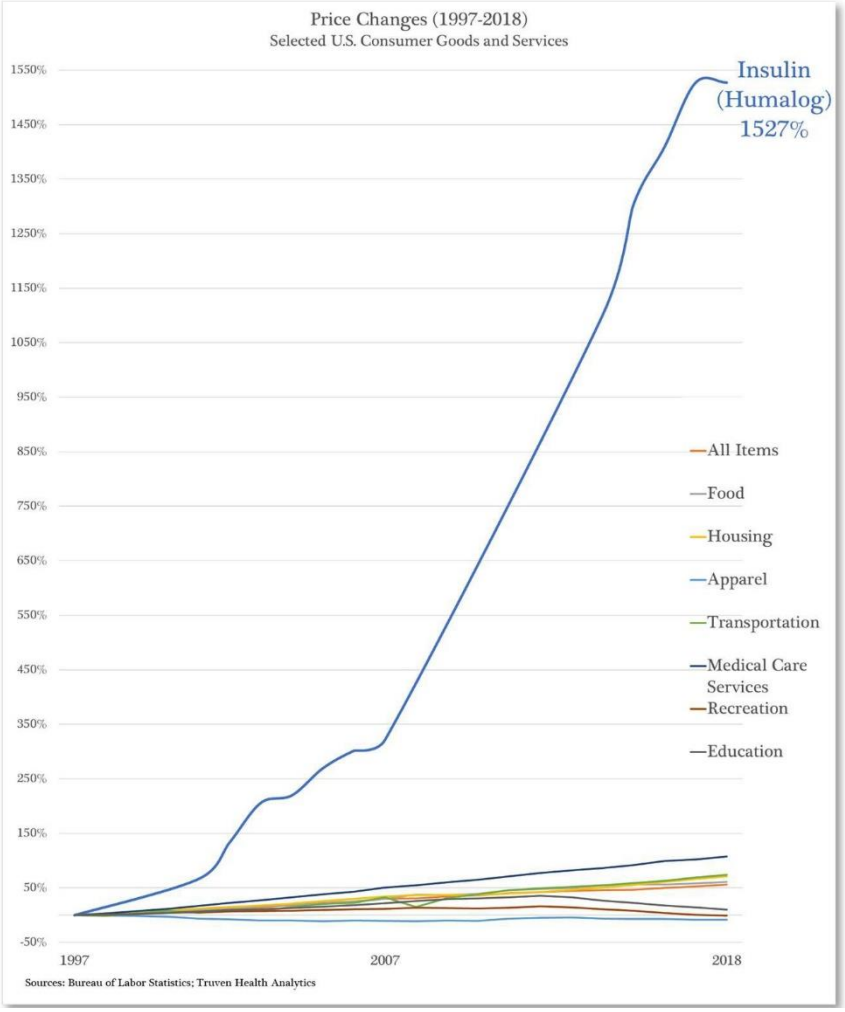
12. The Manufacturers set the initial list (wholesale) price for their respective insulin medications. Over the last 20 years, list prices have sharply increased in lockstep, even though the cost to produce these drugs decreased during that period.

13. Insulins, which today cost Manufacturers as little as $2 to produce, and which were originally priced at $20 the 1990s, now range in price from $300 to $700.

14. The Manufacturer Defendants have in tandem increased the prices of their insulins up to 1,000%, taking the same increase down to the decimal point within a few days of one another and, according to a U.S. Senate Finance Committee investigation, "sometimes mirroring" one another in "days or even hours."[7] Figure 2 shows the rate at which Defendant Eli Lilly raised the list price of its analog insulin, Humalog, compared to the rate of inflation for other consumer goods and services during the period from 1997- 2018.

[7] Charles E. Grassley & Ron Wyden, *Staff Report on Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug, Sen. Fin. Comm.*, at 6, 54, 55 (Jan. 2021), https://www.finance.senate.gov/imo/media/doc/GrassleyWyden%20Insulin%20Report%20 FINAL%201). Pdf (hereinafter "Grassley & Wyden" or "January 2021 Senate Insulin Report").

Figure 2: Price Increase of Insulin vs. Selected Consumer Goods, 1997-2018



15. Today's exorbitant prices do not accord with insulin's origins. The discoverers sold the original patent for $1 to ensure that the medication would remain affordable. But today, insulin is the poster child for skyrocketing pharmaceutical prices.

16. Nothing about these medications has changed over the past 100 years; today's $350 insulin is the same product Defendants once sold for $20.

How the Insulin Pricing Scheme Works

17. In the simplest terms, there are three important participants in the insulin medication chain.

a. **Hamblen County.** During the relevant period, Plaintiff Hamblen County operated a health plan for its employees and their dependents. The plan includes pharmacy benefits, meaning Plaintiff purchased the at-issue drugs for its beneficiaries. Operators of self-funded plans, like Plaintiff, may be referred to as payors or plan sponsors (or PBM "clients").

b. **PBMs.** Payors routinely engage pharmacy benefit managers to manage their prescription benefits, which includes negotiating prices with drug manufacturers and (ostensibly) helping payors manage drug spending. Each pharmacy benefit manager maintains a formulary—a list of covered medications. A pharmacy benefit manager's power to include or exclude a drug from its formulary theoretically should incentivize manufacturers to lower their list price. Pharmacy benefit managers also contract with pharmacies to reimburse them for medications purchased by the plan's beneficiaries. Pharmacy benefit managers are compensated by retaining a portion of what should—again in theory—be shared savings on the cost of medications.

c. **Manufacturers.** Manufacturers produce the at-issue insulin medications.[8] Each sets a list price for each of its products. The terms "list price" often is used interchangeably with the Wholesale Acquisition Cost (WAC) (defined by federal law as the undiscounted list price for a drug or biological to wholesalers or direct purchasers). The manufacturers self-report

[8] There are three types of insulin medications. First are *biologics*, which are manufactured insulins derived from living organisms. Second are *biosimilars*, which are "highly similar" copies of biologics. They are similar in concept to "generic" drugs; but in seeking approval they use biologics (rather than drugs) as comparators. Third, the confusingly-named *authorized generics* are not true generics—they are an approved brand-name drug marketed without the brand name on the label. FDA approved the original insulins as drug products rather than biologics, so although there was a regulatory pathway to introduce biosimilars generally (copies of biologics), companies could not introduce insulin biosimilars because their comparators were "drugs" rather than "biologics." In 2020, FDA moved insulin to the biologic regulatory pathway, thus opening the door to approval of biosimilars through an abbreviated approval process.

list prices to publishing compendiums such as First DataBank, Medi-Span, or Redbook, who then publish those prices.[9]

18. Given the PBMs' purchasing power and their control over formularies that govern the availability of drugs, their involvement should theoretically drive down list prices. Instead, to gain access to the PBMs' formularies, the Manufacturers artificially inflate their list prices and then pay a significant, but undisclosed, portion of the inflated price back to the PBMs (the "Manufacturer Payments").[10] The Manufacturer Payments bear a variety of dubious labels—rebates, discounts, credits, inflation/price protection fees, administrative fees, etc. By whatever name, the inflated list prices and resulting Manufacturer Payments are a quid pro quo for inclusion and favorable placement on the PBMs' formularies.[11]

19. Contracts between PBM Defendants and payors like Plaintiff tie the definition of "rebates" to patient drug utilization. But the contracts between PBMs and Manufacturers define "rebates" and other Manufacturer Payments differently—e.g., calling rebates for formulary placement "administrative fees." Defendants thus profit from the "rebates" and other Manufacturer Payments, and the payments are beyond a payor's contractual audit right to verify the accuracy of "rebate" payments they receive.

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[9] The related term Average Wholesale Price (AWP) is the published price for a drug sold by wholesalers to retailers.

[10] In this Complaint, "Manufacturer Payments" is defined as all payments or financial benefits of any kind conferred by the Manufacturer Defendants to PBM Defendants (or a subsidiary, affiliated entity, or group purchasing organization or rebate aggregator acting on a PBM's behalf), either directly via contract or indirectly via Manufacturer-controlled intermediaries. Manufacturer Payments includes rebates, administrative fees, inflation fees, pharmacy supplemental discounts, volume discounts, price or margin guarantees, and any other form of consideration exchanged.

[11] Favorable or preferred placement may, for example, involve placing a branded product in a lower cost-sharing tier or relaxing utilization controls (such as prior authorization requirements or quantity limits). Favorable placement of a relatively more expensive drug encourages use of that drug and leads to higher out-of-pocket costs for payors and copayors.

20. The PBMs' staggering revenues vastly exceed the fair market value of the services they provide and, specifically, the amount of Manufacturer Payments the PBMs receive in connection with the at-issue drugs vastly exceeds the fair market value of the services they provide with respect to those drugs.

21. The Manufacturers' list prices are not the result of free-market competition for payors' business. The Manufacturers' list prices are so untethered from the net prices that the Manufacturers ultimately realize that the Manufacturers know the list price constitutes a false price. It does not reflect the Manufacturers' actual costs to produce the at-issue drugs or the fair market value of the drugs.[12]

22. The PBMs grant formulary status based upon the highest inflated price—a price that the PBMs know is false—and based upon which diabetes medications will generate the largest profits for themselves.

23. The Insulin Pricing Scheme creates a "best of both worlds" scenario for Defendants. The Manufacturer Defendants buy formulary access and increase their revenues while the PBM Defendants receive significant secret Manufacturer Payments.

24. The PBM Defendants profit off the Insulin Pricing Scheme in numerous ways, including by: (1) retaining a significant, but undisclosed, share of the Manufacturer Payments, either directly or through rebate aggregators, (2) using the price produced by the Insulin Pricing Scheme to generate unwarranted profits from pharmacies, and (3) relying on those same artificial

[12] "Net price" refers to the price the manufacturer ultimately realizes, i.e., the list price less rebates, discounts, etc. (net sales divided by volume). At times, Defendants' representatives use "net price" to refer to the amount payors or plan members pay for medications. In this Complaint, "net price" refers to the former—the amount that the Defendant Manufacturers realize for the at-issue drugs, which is roughly the List Price less Manufacturer Payments.

list prices to drive up the PBMs' margins and pharmacy related fees, including those relating to their mail-order pharmacies.

25. As detailed below, although the PBM Defendants represent both publicly and directly to their client payors that they use their market power to drive down prices for diabetes medications, these representations are false and deceptive. Instead, the PBMs intentionally incentivize the Manufacturers to inflate list prices, and the PBMs' "negotiations" intentionally drive up the price of the at-issue drugs and are directly responsible for the skyrocketing price of diabetes medications, which confers unearned benefits upon the PBMs and Manufacturers alike.

26. Because the purchase price of every at-issue diabetes medication flows from the false list price generated by Defendants' unfair and deceptive scheme, every payor in the United States that purchases these life-sustaining drugs, including Plaintiff, has been directly harmed by the Insulin Pricing Scheme.

27. Even if temporary reductions in Plaintiff's costs for the at-issue drugs occurred from time to time, those costs remained higher than the prices that would have resulted from a transparent exchange in an open and competitive market.

28. As a payor for and purchaser of the at-issue drugs, and, as a direct result of the Insulin Pricing Scheme, Hamblen County has spent exorbitant amounts of capital on the at-issue diabetes medications.

29. A substantial portion of this exorbitant amount is attributable to Defendants' artificially inflated prices that did not arise from transparent or competitive market forces; rather, these inflated costs can be attributed to undisclosed dealings between the Manufacturer Defendants and the PBM Defendants as further described herein.

30. This action alleges that Defendants violated the Racketeer Influenced and Corrupt Organizations Act, Tennessee Consumer Protection Act, and Tennessee common law by engaging in the Insulin Pricing Scheme. The Insulin Pricing Scheme directly and foreseeably caused and continues to cause harm to Plaintiff.

31. This action seeks injunctive relief, restitution, disgorgement, actual damages, treble damages, punitive damages, and attorneys' fees and costs to address and abate the harm caused by the Insulin Pricing Scheme.

32. The relevant period for damages alleged in this Complaint is from 2003 through the present.

PARTIES

A. Plaintiff

33. Plaintiff Hamblen County is a body corporate and politic under the laws of the State of Tennessee.

34. Plaintiff, as a government entity, provides vital services to its population of over 64,000 residents including public safety, emergency management, and health services.

35. Any increase in spending has a detrimental effect on Plaintiff's overall budget and, in turn, negatively impacts its ability to provide necessary services to the community.

36. The Insulin Pricing Scheme has had such an effect.

37. Additionally, as a government employer, Plaintiff provides health benefits to its employees, retirees, and their dependents ("Beneficiaries"). These benefits include paying for Beneficiaries' pharmaceutical drugs, including the at-issue diabetes medications. Plaintiff also purchases the at-issue diabetes medications for use in county-run facilities.

38. Plaintiff maintains a self-insured health plan for its Beneficiaries.

39. Exclusive of the costs associated with providing diabetes medications at county-run facilities, such as correctional facilities, Plaintiff spends thousands of dollars per year on the costs of providing diabetes medications for its health-plan members. Accordingly, during the relevant period, and to the detriment of its Beneficiaries and taxpayers, Plaintiff has paid millions of dollars more for insulin than it otherwise would have paid absent Defendants' conduct.

40. Plaintiff seeks to recover for the losses it has suffered due to Defendants' illegal Insulin Pricing Scheme.

B. Manufacturer Defendants

41. **Defendant Eli Lilly and Company ("Eli Lilly")** is an Indiana corporation with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

42. Eli Lilly is registered to do business in the State of Tennessee. Eli Lilly may be served through its registered agent: National Registered Agents, Inc., 300 Montvue Road, Knoxville, Tennessee 37919-5546.

43. In Tennessee and nationally, Eli Lilly manufactures, promotes, and distributes several at-issue diabetes medications: Humulin N, Humulin R, Humalog, Trulicity, and Basaglar.

44. Eli Lilly's global revenues in 2019 were $4.13 billion from Trulicity, $2.82 billion from Humalog, $1.29 billion from Humulin and $1.11 billion from Basaglar.

45. Eli Lilly's global revenues in 2018 were $3.2 billion from Trulicity, $2.99 billion from Humalog, $1.33 billion from Humulin and $801 million from Basaglar.

46. Eli Lilly transacts business in Tennessee and in Hamblen County, targeting these markets for its products, including the at-issue diabetes medications.

47. Eli Lilly employs sales representatives throughout Tennessee to promote and sell Humulin N, Humulin R, Humalog, Trulicity, and Basaglar.

48. Eli Lilly also directs advertising and informational materials to Tennessee and Hamblen County physicians and potential users of Eli Lilly's products.

49. At all times relevant hereto, in furtherance of the Insulin Pricing Scheme, Eli Lilly published its prices for the at-issue diabetes medications throughout Tennessee with the express knowledge that payment and reimbursement by Plaintiff would be based on those false list prices.

50. During the relevant time period, Plaintiff purchased Eli Lilly's at-issue drugs at a price based on false list prices generated by the Insulin Pricing Scheme through its employee health plans and for use in county-run facilities.

51. All of the Eli Lilly diabetes medications related to the at-issue transactions were paid for and/or reimbursed in Tennessee based on the specific false and inflated prices Eli Lilly caused to be published in Tennessee in furtherance of the Insulin Pricing Scheme.

52. **Defendant Sanofi-Aventis U.S. LLC ("Sanofi")** is a Delaware limited liability company with its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

53. Sanofi may be served through its registered agent: Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808.

54. Sanofi manufactures, promotes, and distributes pharmaceutical drug both in Tennessee and nationally, including several at-issue diabetes medications: Lantus, Toujeo, Soliqua, and Apidra.

55. Sanofi's global revenues in 2019 were $3.50 billion from Lantus and $1.03 billion from Toujeo, $400 million from Apidra and $144 million from Soliqua.

56. Sanofi's global revenues in 2018 were $3.9 billion from Lantus, $923 million from Toujeo, $389 million from Apidra and $86 million from Soliqua.

57. Sanofi does business in Tennessee and in Hamblen County, targeting these markets for its products, including the at-issue diabetes medications.

58. Sanofi employs sales representatives throughout Tennessee and in this District to promote and sell Lantus, Toujeo, Soliqua, and Apidra.

59. Sanofi also directs advertising and informational materials to Tennessee physicians and potential users of Sanofi's products for the specific purpose of selling the at-issue drugs in Tennessee and Hamblen County and profiting from the Insulin Pricing Scheme.

60. At all times relevant hereto, in furtherance of the Insulin Pricing Scheme, Sanofi published its prices of its at-issue diabetes medications throughout Tennessee for the purpose of payment and reimbursement by payors, including Plaintiff.

61. During the relevant time period, Plaintiff Hamblen County purchased Sanofi's at-issue drugs at prices based on false list prices generated by the Insulin Pricing Scheme through its employee health plans and for use in county-run facilities.

62. All of the Sanofi diabetes medications related to the at-issue transactions were paid for and/or reimbursed in Tennessee and Hamblen County based on the specific false and inflated prices Sanofi caused to be published in Tennessee in furtherance of the Insulin Pricing Scheme.

63. **Defendant Novo Nordisk Inc. ("Novo Nordisk")** is a Delaware corporation with its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

64. Novo Nordisk is registered to do business in the State of Tennessee. Novo Nordisk may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

65. Novo Nordisk manufactures, promotes, and distributes pharmaceutical drugs both in Tennessee and nationally, including at-issue diabetic medications: Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic.

66. Nordisk's global revenues in 2019 were $2.89 billion from Novolog, $973 million from Levemir, $968 million from Tresiba, $2.29 billion from Victoza and $1.17 billion from Ozempic.[13]

67. Novo Nordisk's global revenues in 2018 were $4.19 billion from Novolog, $1.66 billion from Levemir, $1.19 billion from Tresiba, $3.61 billion from Victoza and $185 million from Ozempic.

68. Novo Nordisk transacts business in Tennessee and in Hamblen County, targeting these markets for its products, including the at-issue diabetes medications.

69. Novo Nordisk employs sales representatives throughout Tennessee and Hamblen County to promote and sell Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic.

70. Novo Nordisk also directs advertising and informational materials to Tennessee and Hamblen County physicians and potential users of Novo Nordisk's products.

71. At all times relevant hereto, in furtherance of the Insulin Pricing Scheme, Novo Nordisk published its prices of its at-issue diabetes medications throughout Tennessee for the purpose of payment and reimbursement by Plaintiff.

72. During the relevant time period, Plaintiff purchased Novo Nordisk's at-issue diabetes medications at prices based on false list prices generated by the Insulin Pricing Scheme through its employee health plans and for use in county-run facilities.

[13] Novo Nordisk, Annual Report (Form 20-F) (Dec. 31, 2019).

73. All Novo Nordisk diabetes medications related to the at-issue transactions were paid for and/or reimbursed in Tennessee based on the specific false and inflated prices Novo Nordisk caused to be published in Tennessee in furtherance of the Insulin Pricing Scheme.

74. Collectively, Defendants Eli Lilly, Novo Nordisk, and Sanofi are referred to as the "Manufacturer Defendants" or the "Manufacturers."

C. PBM Defendants

75. **Defendant CVS Health Corporation ("CVS Health")** is a Delaware corporation with its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895. CVS Health transacts business and has locations throughout the United States and Tennessee.

76. CVS Health may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

77. CVS Health—through its executives and employees, including its CEO, Chief Medical Officer, Executive Vice Presidents, Senior Executives in Trade Finance, Senior Vice Presidents, and Chief Communication Officers—is directly involved in creating and implementing the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs involved in the Insulin Pricing Scheme.

78. CVS Health's conduct had a direct effect in Tennessee and damaged Plaintiff Hamblen County as a payor and purchaser.

79. On a regular basis, CVS Health executives and employees communicate with and direct its subsidiaries related to the at-issue PBM services and formulary activities.

80. In each annual report for at least the last decade, CVS Health (or its predecessor) has repeatedly and explicitly stated that CVS Health:

- designs pharmacy benefit plans that minimize the costs to the client while prioritizing the welfare and safety of the clients' members;

- negotiates with pharmaceutical companies to obtain discounted acquisition costs for many of the products on CVS Health's drug lists, and these negotiated discounts enable CVS Health to offer reduced costs to clients; and

- utilizes an independent panel of doctors, pharmacists, and other medical experts, referred to as its Pharmacy and Therapeutics Committee, to select drugs that meet the highest standards of safety and efficacy for inclusion on its drug lists.

81. CVS Health publicly represents that it constructs programs that lower the cost of the at-issue diabetes medications. For example, in 2016, CVS Health announced a new program to "reduce overall spending in diabetes" that is available in all states, including Tennessee, stating:

> *CVS Health* introduced a new program available to help the company's pharmacy benefit management (PBM) clients to improve the health outcomes of their members, *lower pharmacy costs [for diabetes medications]* through aggressive trend management and decrease medical costs . . . [and that] participating clients could save between $3000 to $5000 per year for each member who successfully improves control of their diabetes" (emphasis supplied).[14]

82. In 2017, CVS Health stated that "*CVS Health* pharmacy benefit management (PBM) strategies reduced trend for commercial clients to 1.9 percent per member per year the lowest in five years. Despite manufacturer price increases of near 10 percent, *CVS Health* kept drug price growth at a minimal 0.2 percent."

83. In November 2018, CVS Health acquired Aetna for $69 billion and became the first combination of a major health insurer, PBM, and mail-order and retail pharmacy chain. As a result, CVS Health controls the health plan/insurer, the PBM, and the pharmacies utilized by approximately 40 million Aetna members in the United States, including in Tennessee. CVS Health controls the entire drug pricing chain for these 40 million Americans.

[14] CVS HEALTH, *CVS Health Introduces New "Transform Diabetes Care" Program to Improve Health Outcomes and Lower Overall Health Care Costs* (Dec. 13, 2016), https://cvshealth.com/newsroom/press-releases/cvs-health-introduces-newtransform-diabetes-care-program-improve-health.

84. CVS Health is the immediate or indirect parent of many pharmacy subsidiaries that own and operate hundreds of pharmacies throughout Tennessee that dispensed and received payment for the at-issue diabetes medications throughout the relevant time period.

85. **Defendant CVS Pharmacy, Inc. ("CVS Pharmacy")** is a Rhode Island corporation whose principal place of business is at the same location as CVS Health. CVS Pharmacy is a wholly owned subsidiary of CVS Health.

86. CVS Pharmacy is the immediate or indirect parent of many pharmacy subsidiaries that own and operate hundreds of pharmacies throughout Tennessee and is directly involved in these pharmacies dispensing and payment policies related to the at issue diabetes medications.

87. CVS Pharmacy is also the immediate and direct parent of Defendant Caremark Rx, LLC.

88. CVS Pharmacy is registered to do business in Tennessee and has been since at least 1997.

89. CVS Pharmacy is registered to do business in the State of Tennessee. CVS Pharmacy may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

90. During the relevant time period, CVS Pharmacy provided retail pharmacy services in Tennessee that gave rise to the Insulin Pricing Scheme, which damaged Plaintiff.

91. **Defendant Caremark Rx, LLC** is a Delaware limited liability company and an immediate or indirect parent of many subsidiaries, including pharmacy benefit management and mail-order subsidiaries that engaged in the activities in Tennessee that gave rise to this Complaint.

92. Caremark Rx, LLC is a wholly owned subsidiary of Defendant CVS Pharmacy and its principal place of business is at the same location as CVS Pharmacy and CVS Health.

93. Caremark Rx, LLC is registered to do business in Tennessee and has been since at least 2007. Caremark Rx, LLC may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

94. During the relevant time period, Caremark Rx, LLC provided PBM and mail order pharmacy services in Tennessee that gave rise to the Insulin Pricing Scheme and damaged payors in Tennessee, including Plaintiff.

95. Defendant Caremark, LLC is a California limited liability company whose principal place of business is at the same location as CVS Health. Caremark, LLC is a wholly owned subsidiary of Caremark Rx, LLC.

96. Caremark, LLC is registered to do business in Tennessee and has been since at least 2007. Caremark, LLC may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

97. During the relevant time period, Caremark, LLC provided PBM and mail order pharmacy services in Tennessee and Hamblen County that gave rise to the Insulin Pricing Scheme, which damaged Plaintiff.

98. **Defendant CaremarkPCS Health, LLC** is a Delaware limited liability company whose principal place of business is at the same location as CVS Health. CVS Health is the direct or indirect parent company of CaremarkPCS Health LLC.

99. CaremarkPCS Health, LLC, doing business as CVS Caremark, provides pharmacy benefit management services.

100. CaremarkPCS Health, LLC is registered to do business in Tennessee and has been since at least 2009. CaremarkPCS Health, LLC may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

101. During the relevant time period, CaremarkPCS Health, LLC provided PBM services in the State of Tennessee, which gave rise to the Insulin Pricing Scheme and damaged Plaintiff Hamblen.

102. Defendants CaremarkPCS Health, LLC and Caremark, LLC are agents and/or alter egos of Caremark Rx, LLC, CVS Pharmacy, and CVS Health.

103. As a result of numerous interlocking directorships and shared executives, Caremark Rx, LLC, CVS Pharmacy, and CVS Health are directly involved in the conduct of and control CaremarkPCS Health, LLC and Caremark, LLC's operations, management, and business decisions related to the at-issue formulary construction; Manufacturer Payments; and mail-order and retail pharmacy services—to the ultimate detriment of Plaintiff. For example:

a. During the relevant time period, these parent and subsidiaries have had common officers and directors, including:

- Thomas S. Moffatt, Vice President and Secretary of Caremark Rx, LLC, CaremarkPCS Health LLC, and Caremark, LLC, is also a Vice President, Assistant Secretary, and Senior Legal Counsel at CVS Health and the Vice President, Secretary and Senior Legal Counsel of CVS Pharmacy;

- Melanie K. Luker, Assistant Secretary of Caremark Rx, LLC, CaremarkPCS Health, LLC, and Caremark, LLC, is also a Manager of Corporate Services at CVS Health;

- Carol A. Denale, Senior Vice President and Treasurer of Caremark Rx, LLC, is also Senior Vice President, Treasurer and Chief Risk Officer at CVS Health Corporation;

- John M. Conroy has been Vice President of Finance at CVS Health since 2011, and was also President and Treasurer of Caremark, LLC and CaremarkPCS Health LLC in 2019; and

- Sheelagh Beaulieu has been the Senior Director of Income Tax at CVS Health while also acting as the Assistant Treasurer at CaremarkPCS Health LLC and Caremark LLC.

b. CVS Health owns all the stock of CVS Pharmacy, which, in turn, owns all the stock of Caremark Rx, LLC, which, in turn, owns all the stock of Caremark LLC. CVS Health also directly or indirectly owns all the stock of CaremarkPCS Health LLC.

c. CVS Health, as a corporate family, does not operate as separate entities. The public filings, documents, and statements of CVS Health present its subsidiaries, including CVS Pharmacy, CaremarkPCS Health, LLC, Caremark, LLC and Caremark Rx, LLC as divisions or departments of one unified "diversified health services company" that "works together across our disciplines" to "create unmatched human connections to transform the health care experience." The day-to-day operations of this corporate family reflect these public statements. These entities are a single business enterprise and should be treated as such as to all legal obligations discussed in this Complaint.[15]

d. All executives of CaremarkPCS Health, LLC, Caremark, LLC, Caremark Rx, LLC, and CVS Pharmacy ultimately report to the executives at CVS Health, including the President and CEO of CVS Health.

e. As stated above, CVS Health's CEO, Chief Medical Officer, Executive Vice Presidents, Senior Executives in Trade Finance, Senior Vice Presidents, and Chief Communication Officers are directly involved in the policies and business decisions of CaremarkPCS Health, LLC and Caremark, LLC that gave rise to Plaintiff Hamblen County's claims in this Complaint.

[15] CVS Caremark/CVS Health, Annual Report (Form 10-K) (Dec. 31, 2009-2019); CVS Health, *Our Purpose*, https://cvshealth.com/about-cvs-health/our-purpose (last visited Sept. 9, 2022); CVS Health, *Quality of Care*, https://cvshealth.com/health-withheart/improving-health-care/quality-of-care (last visited Sept. 9, 2022).

104. Collectively, Defendants CVS Health, CVS Pharmacy, Caremark Rx, LLC, Caremark, LLC and CaremarkPCS Health, LLC, including all predecessor and successor entities, are referred to as "CVS Caremark."

105. CVS Caremark is named as a Defendant in its capacities as a PBM and pharmacy.

106. In its capacity as a PBM, CVS Caremark coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the price of the at-issue diabetes medications, as well as for the placement of these Manufacturers' diabetes medications on CVS Caremark's formularies.

107. CVS Caremark has the largest PBM market share based on total prescription claims managed, representing approximately 40% of the national market. CVS Caremark's pharmacy services segment generated $141.5 billion in total revenues last year.

108. At all times relevant hereto, CVS Caremark offered pharmacy benefit services nationwide and to Tennessee payors, and derived substantial revenue therefrom, and, in doing so, made the at-issue misrepresentations (discussed below) and utilized the false prices generated by the Insulin Pricing Scheme to unlawfully profit off of payors like Plaintiff.

109. At all times relevant hereto, CVS Caremark offered pharmacy benefit management services nationwide and maintained standard formularies that are used nationwide, including in Tennessee. During the relevant time period, those formularies included diabetes medications, including all of those at issue in this Complaint.

110. CVS Caremark purchases drugs directly from manufacturers and through drug wholesalers for dispensing through its mail-order pharmacy.

111. During the relevant time period, CVS Caremark provided PBM services to Plaintiff and, in doing so, CVS Caremark set the price that Plaintiff paid for the at-issue drugs based on the

false list prices generated by the Insulin Pricing Scheme. Plaintiff paid CVS Caremark for the at-issue drugs.

112. In its capacity as a retail pharmacy, CVS Caremark further and knowingly profited from the false list prices produced by the Insulin Pricing Scheme by pocketing the spread between acquisition cost for the drugs at issue (an amount well below the list price generated by the Insulin Pricing Scheme), and the amounts it received from payors (which amounts were based on the false list prices and, in many cases, were set by CVS Caremark in its capacity as a PBM).

113. During the relevant time period, CVS Caremark provided mail-order and retail pharmacy services to Plaintiff and, in doing so, Plaintiff paid CVS Caremark for the at-issue drugs at prices based on the false list prices generated by the Insulin Pricing Scheme.

114. At all times relevant hereto, CVS Caremark dispensed the at-issue medications nationwide and directly to Plaintiff through its mail-order and retail pharmacies and derived substantial revenue from these activities in Tennessee.

115. At all times relevant hereto, CVS Caremark had express agreements with Defendants Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid by the Manufacturer Defendants to CVS Caremark, as well as agreements related to the Manufacturers' at-issue drugs sold through CVS Caremark's mail-order pharmacies.

116. **Defendant Evernorth Health, Inc. ("Evernorth")**, formerly known as Express Scripts Holding Company, is a Delaware corporation with its principal place of business at 1 Express Way, St. Louis, Missouri 63121.[16]

[16] Until 2021, Evernorth Health, Inc. conducted business under the name Express Scripts Holding Company. For the purposes of this Complaint "Evernorth" refers to Evernorth Health, Inc and Express Scripts Holding Company.

117. Evernorth may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

118. Evernorth, through its executives and employees, including its CEO and Vice Presidents, is directly involved in shaping the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs, related to the Insulin Pricing Scheme.

119. Evernorth's conduct had a direct effect in Tennessee and with respect to Plaintiff Hamblen County.

120. On a regular basis, Evernorth executives and employees communicate with and direct Evernorth's subsidiaries related to the at-issue PBM services and formulary activities.

121. Evernorth is the immediate or indirect parent of pharmacy and PBM subsidiaries that operate throughout Tennessee, which engaged in the activities that gave rise to this Complaint.

122. In December 2018, Evernorth merged with Cigna in a $67 billion deal to consolidate their businesses as a major health insurer, PBM, and mail-order pharmacy. As a result, the Evernorth corporate family controls the health plan/insurer, the PBM, and the mail-order pharmacies utilized by approximately 15 million Cigna members in the United States, including in Tennessee. Evernorth controls the entire drug pricing chain for these 15 million Americans.

123. In each annual report for at least the last decade, Evernorth has repeatedly and explicitly:

- Acknowledged that it is directly involved in the company's PBM services, stating "[Evernorth is] the largest stand-alone PBM company in the United States."

- Stated that Evernorth: "provid[es] products and solutions that focus on improving patient outcomes and assist in controlling costs; evaluat[es] drugs for efficacy, value and price to assist clients in selecting a cost-effective formulary; [and] offer[s] cost-effective home delivery pharmacy and specialty services that result in cost savings for plan sponsors and better care for members."

124. **Defendant Express Scripts, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. Express Scripts, Inc.'s principal place of business is the same location as Evernorth.

125. Express Scripts, Inc. is registered to do business in Tennessee and has been since at least 2017. Express Scripts, Inc. may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 39719-5546.

126. Express Scripts, Inc. is the immediate or indirect parent of pharmacy and PBM subsidiaries that operate throughout Tennessee that engaged in the conduct that gave rise to this Complaint.

127. During the relevant time period, Express Scripts Inc. was directly involved in the PBM and mail-order pharmacy services that gave rise to the Insulin Pricing Scheme and damaged Plaintiff.

128. Indeed, Express Scripts, Inc. provided pharmacy benefit services to Plaintiff, based on Plaintiff's reliance upon Express Scripts, Inc.'s response to Plaintiff's Request for Proposals.

129. **Defendant Express Scripts Administrators, LLC**, doing business as Express Scripts and formerly known as Medco Health, LLC, is a Delaware limited liability company and is a wholly owned subsidiary of Evernorth. Express Scripts Administrators, LLC's principal place of business is at the same location as Evernorth.

130. Express Scripts Administrators, LLC is registered to do business in Tennessee and may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

131. During the relevant time period, Express Scripts Administrators, LLC provided the PBM services in Tennessee discussed in this Complaint that gave rise to the Insulin Pricing Scheme that damaged Plaintiff.

132. **Defendant Medco Health Solutions, Inc. ("Medco")** is a Delaware Corporation with its principal place of business located at 100 Parsons Pond Road, Franklin Lakes, New Jersey.

133. Medco is registered to do business in Tennessee and may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

134. In 2012, Express Scripts acquired Medco for $29 billion.

135. Prior to the merger, Express Scripts and Medco were two of the largest PBMs in the United States and in Tennessee.

136. Prior to the merger, Medco provided the at-issue PBM and mail-order services, which gave rise to the Insulin Pricing Scheme and damaged Plaintiff, within Tennessee.

137. Following the merger, all of Medco's PBM and mail-order pharmacy functions were combined into Express Scripts. The combined company (Medco and Express Scripts) continued under the name Express Scripts with all of Medco's payor customers becoming Express Scripts' customers. The combined company covered over 155 million lives at the time of the merger.

138. At the time of the merger, on December 6, 2011, in his testimony before the Senate Judiciary Committee, David B. Snow, the then-CEO of Medco, publicly represented that "the merger of Medco and Express Scripts will result in immediate savings to our clients and, ultimately, to consumers. This is because our combined entity will achieve even greater [Manufacturer Payments] from drug manufacturers and other suppliers."

139. The then-CEO of Express Scripts, George Paz, during a Congressional subcommittee hearing in September 2011, echoed these sentiments: "A combined Express Scripts and Medco will be well-positioned to protect American families from the rising cost of prescription medicines."

140. **Defendant ESI Mail Pharmacy Service, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. ESI Mail Pharmacy Service, Inc.'s principal place of business is the same location as Evernorth.

141. ESI Mail Pharmacy Service, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

142. During the relevant time period, ESI Mail Pharmacy Services provided the mail-order pharmacy services in Tennessee discussed in this Complaint, which gave rise to the Insulin Pricing Scheme and damaged Plaintiff.

143. **Defendant Express Scripts Pharmacy, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. Express Scripts Pharmacy, Inc.'s principal place of business is at the same location as Evernorth.

144. Express Scripts Pharmacy, Inc. is registered to do business in Tennessee and has been since 2021. Express Scripts Pharmacy, Inc. may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

145. During the relevant time period, Express Scripts Pharmacy, Inc. provided the mail-order pharmacy services in Tennessee discussed in this Complaint, which gave rise to the Insulin Pricing Scheme and damaged Plaintiff.

146. As a result of numerous interlocking directorships and shared executives, Evernorth and Express Scripts, Inc. control Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., and Express Scripts Pharmacy, Inc's operations, management, and business decisions related to the at-issue formulary construction, negotiations, and mail-order pharmacy services to the ultimate detriment of Plaintiff. For example:

a. During the relevant time period, these parent and subsidiaries have had common officers and directors:

- Officers and/or directors shared between Express Scripts, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; David Queller, President; Jill Stadelman, Managing Counsel; and Scott Lambert, Treasury Manager Director;
- Executives shared between Express Scripts Administrators, LLC and Evernorth include Bradley Phillips, Chief Financial Officer; and Priscilla Duncan, Associate Senior Counsel;
- Officers and/or directors shared between ESI Mail Pharmacy Service, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; Priscilla Duncan, Associate Senior Counsel; and Joanne Hart, Treasury Director; and
- Officers and/or directors shared between Express Scripts Pharmacy, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; Jill Stadelman, Managing Counsel; Scott Lambert, Treasury Manager Director; and Joanne Hart, Treasury Director.

b. Evernorth directly or indirectly owns all the stock of Express Scripts Administrators, LLC, Medco Health Solutions, Inc., ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc. and Express Scripts, Inc.

c. The Evernorth corporate family does not operate as separate entities. The public filings, documents, and statements of Evernorth present its subsidiaries, including Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc. and Express Scripts, Inc., as divisions or departments of a single company that "unites businesses that have as many as 30+ years of experience . . . to

take health services further with integrated data and analytics that help us deliver better care to more people." The day-to-day operations of this corporate family reflect these public statements. All of these entities comprise a single business enterprise and should be treated as such as to all legal obligations detailed in this Complaint. All of the executives of Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc., and Express Scripts, Inc. ultimately report to the executives, including the CEO, of Evernorth.

d. As stated above, Evernorth's CEO and other executives and officers are directly involved in the policies and business decisions of Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., Express Scripts Pharmacy, Inc., and Express Scripts, Inc. that gave rise to Plaintiff's claims in this Complaint.

147. Collectively, Defendants Evernorth Health, Inc., Express Scripts, Inc., Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., and Express Scripts Pharmacy, Inc., including all predecessor and successor entities, are referred to as "Express Scripts."

148. Express Scripts is named as a Defendant in its capacities as a PBM and mail order pharmacy.

149. In its capacity as a PBM, Express Scripts coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the price of the at-issue diabetes medications, as well as for the placement of these Manufacturers' diabetes medications on Express Script's formularies.

150. Prior to merging with Cigna in 2019, Express Scripts was the largest independent PBM in the United States. During the relevant period of this Complaint, Express Scripts controlled

30% of the PBM market in the United States. Express Scripts has only grown larger since the Cigna merger.

151. In 2017, annual revenue for Express Scripts was over $100 billion.

152. As of December 31, 2018, more than 68,000 retail pharmacies, representing over 98% of all retail pharmacies in the nation, participated in one or more of Express Scripts' networks.

153. Express Scripts transacts business throughout the United States and Tennessee.

154. At all times relevant hereto, Express Scripts derived substantial revenue providing pharmacy benefits in Tennessee.

155. At all times relevant hereto, and contrary to their express representations, Express Scripts knowingly insisted that its payor clients use the false list prices produced by the Insulin Pricing Scheme as the basis for reimbursement of the at-issue drugs.

156. At all times relevant hereto, Express Scripts concealed its critical role in the generation of those false list prices.

157. At all times relevant hereto, Express Scripts maintained standard formularies that are used nationwide, including in Tennessee. During the relevant time period, those formularies included drugs produced by the Manufacturer Defendants, including the at-issue diabetes medications.

158. During the relevant time period, Express Scripts provided PBM services to Plaintiff and, in doing so, Express Scripts set the price that Plaintiff paid for the at-issue drugs, at prices based on the false list prices generated by the Insulin Pricing Scheme, and Plaintiff paid Express Scripts for the at-issue drugs.

159. In its capacity as a mail-order pharmacy, Express Scripts received payments from Tennessee payors for, and set the out-of-pocket price paid for, the at-issue drugs based on the falsely inflated prices generated by the Insulin Pricing Scheme and, as a result, damaged Plaintiff.

160. At all times relevant hereto, Express Scripts offered pharmacy benefit management services nationwide and maintained standard formularies that are used nationwide, including in Tennessee. During the relevant time period, those formularies included diabetes medications, including all of those at issue in this Complaint.

161. Express Scripts purchases drugs directly from manufacturers for dispensing through its mail-order pharmacy.

162. At all times relevant hereto, Express Scripts dispensed the at-issue medications nationwide and directly to Plaintiff through its mail-order pharmacies and derived substantial revenue from these activities in Tennessee.

163. During the relevant time period, in addition to its critical role in the Insulin Pricing Scheme, which detrimentally affected all payors and purchasers of the at-issue drugs, Express Scripts also provided PBM services directly to Plaintiff Hamblen County.

164. During the years when some of the largest at-issue price increases occurred, Express Scripts worked directly with OptumRx to negotiate Manufacturer Payments on behalf of OptumRx and its clients in exchange for preferred formulary placement.

165. For example, in a February 2014 email released by the U.S. Senate in conjunction with its January 2021 report titled "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug" ("January 2021 Senate Insulin Report"), Eli Lilly describes a "Russian nested

doll situation" in which Express Scripts was negotiating rebates on behalf of OptumRx related to the at-issue drugs for Cigna (who later would become part of Express Scripts).[17]

166. At all times relevant hereto, Express Scripts had express agreements with Defendants Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid by the Manufacturer Defendants to Express Scripts, as well as agreements related to the Manufacturers' at-issue drugs sold through Express Scripts' mail-order pharmacies.

167. **Defendant UnitedHealth Group, Inc**. is a corporation organized under the laws of Delaware with its principal place of business at 9900 Bren Road East, Minnetonka, Minnesota, 55343.

168. UnitedHealth Group, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

169. UnitedHealth Group, Inc. is a diversified managed healthcare company. In 2015, UnitedHealth Group reported revenue in excess of $257 billion, and the company is currently ranked sixth on the Fortune 500 list. UnitedHealth Group, Inc. offers a spectrum of products and services including health insurance plans through its wholly owned subsidiaries and prescription drugs through its PBM, OptumRx.

170. Over one-third of the overall revenues of UnitedHealth Group come from OptumRx.

[17] CHARLES E. GRASSLEY & RON WYDEN, STAFF REPORT ON INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG, S. FIN. COMM., https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf; Letter from Joseph B. Kelley, Eli Lilly Vice President, Global Gov. Affairs, to Charles E. Grassley & Ron Wyden, S. Fin. Comm. (Mar. 8, 2019), https://www.finance.senate.gov/imo/media/doc/Eli%20Lilly_Redacted%20v1.pdf

171. UnitedHealth Group, through its executives and employees, is directly involved in the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs and related to the Insulin Pricing Scheme. For example, UnitedHealth Group executives structure, analyze, and direct the company's overarching policies, including with respect to PBM and mail-order services, as a means of maximizing profitability across the corporate family.

172. UnitedHealth Group's Sustainability Report states that "OptumRx works directly with pharmaceutical manufacturers to secure discounts that lower the overall cost of medications and create tailored formularies – or drug lists – to ensure people get the right medications. [*UnitedHealth Group*] then negotiate[s] with pharmacies to lower costs at the point of sale . . . [*UnitedHealth Group*] also operate[s] [mail-order pharmacies] . . .. [*UnitedHealth Group*] work[s] directly with drug wholesalers and distributors to ensure consistency of the brand and generic drug supply, and a reliance on that drug supply."

173. In addition to being a PBM and a mail-order pharmacy, UnitedHealth Group owns and controls a major health insurance company, UnitedHealthcare. As a result, UnitedHealth Group controls the health plan/insurer, the PBM, and the mail-order pharmacies utilized by approximately 26 million UnitedHealthcare members in the United States, including those in Tennessee. UnitedHealth Group controls the entire drug pricing chain for these 26 million Americans.

174. UnitedHealth Group's conduct had a direct effect in Tennessee and damaged Plaintiff.

175. UnitedHealth Group states in its Annual Reports that UnitedHealth Group "utilizes Optum's capabilities to help coordinate patient care, improve affordability of medical care, analyze

cost trends, manage pharmacy benefits, work with care providers more effectively and create a simpler consumer experience."

176. **Defendant Optum, Inc.** is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. Optum, Inc. is a health services company managing subsidiaries that administer pharmacy benefits, including Defendant OptumRx, Inc.

177. Optum, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

178. Optum, Inc. is directly involved, through its executives and employees, in the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs and related to the Insulin Pricing Scheme, which had a direct effect in Tennessee and damaged Plaintiff.

179. For example, according to Optum Inc.'s press releases, Optum, Inc. is "UnitedHealth Group's information and technology-enabled health services business platform serving the broad healthcare marketplace, including care providers, plan sponsors, payors, life sciences companies and consumers."[18] In this role Optum, Inc. is directly responsible for the "business units – OptumInsight, OptumHealth and OptumRx"[19] and the CEOs of all these companies report directly to Optum, Inc. regarding their policies, including those that inform the at-issue formulary construction and mail order activities.

180. Defendant OptumRx, Inc. is a California corporation with its principal place of business at 2300 Main Street, Irvine, California, 92614.

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[18] UNITEDHEALTH GROUP, https://www.unitedhealthgroup.com/ (last visited on Sept. 9, 2022); *UnitedHealth Group Announces "Optum" Master Brand for Its Health Services Businesses*, FIERCE HEALTHCARE (Apr. 11, 2011, 9:21 AM), https://www.fiercehealthcare.com/healthcare/unitedhealth-group-announces-optummaster-brand-for-its-health-services-businesses.

[19] *Id.*; UNITEDHEALTH GROUP, *UnitedHealth Group Announces "Optum" Master Brand for Its Health Services Businesses* (Apr. 11, 2011), https://www.unitedhealthgroup.com/newsroom/2011/0411optum.html.

181. OptumRx, Inc. operates as a subsidiary of OptumRx Holdings I, LLC, which, in turn, operates as a subsidiary of Defendant Optum, Inc.

182. OptumRx, Inc. is registered to do business in Tennessee and has been since at least 2008. OptumRx, Inc. may be served through its registered agent: 300 Montvue Road, Knoxville, Tennessee 37919-5546.

183. During the relevant time period, OptumRx, Inc. provided the PBM and mail order pharmacy services in Tennessee that gave rise to the Insulin Pricing Scheme, which damaged Plaintiff.

184. **Defendant OptumInsight, Inc**. is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota.

185. OptumInsight, Inc. is registered to do business in Tennessee and has been since at least 1997. OptumInsight, Inc. may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

186. OptumInsight, Inc. is an integral part of the Insulin Pricing Scheme and, during the relevant time period coordinated directly with the Manufacturer Defendants in furtherance of the conspiracy. OptumInsight analyzed data and other information from the Manufacturer Defendants to advise the other Defendants with regard to the profitability of the Insulin Pricing Scheme to the benefit of all Defendants.

187. As a result of numerous interlocking directorships and shared executives, UnitedHealth Group, OptumRx Holdings I, LLC, and Optum, Inc are directly involved in the conduct of and control OptumInsight and Optum Rx's operations, management, and business decisions related to the at-issue formulary construction, negotiations, and mail order pharmacy services to the ultimate detriment of Plaintiff. For example:

a. These parent and subsidiaries have common officers and directors, including:

- Sir Andrew Witty is president of UnitedHealth Group and CEO of Optum, Inc.;
- Dan Schumacher is president of Optum, Inc and is also named to the Office of the Chief Executive at UnitedHealth Group, Inc.;
- Terry Clark is a senior vice president and chief marketing officer at UnitedHealth Group and also oversees the branding, marketing and advertising for UnitedHealth Group and Optum, Inc.;
- Tom Roos serves as chief accounting officer for UnitedHealth Group and Optum, Inc.;
- Heather Lang is Deputy General Counsel, Subsidiary Governance at UnitedHealth Group, Inc. and also Assistant Secretary at OptumRx, Inc.;
- Peter Gill is Vice President at UnitedHealth Group, Inc. and also Treasurer at OptumRx, Inc.;
- John Santelli leads Optum Technology, the leading technology division of Optum, Inc serving the broad customer base of Optum and UnitedHealthcare and also serves as UnitedHealth Group's chief information officer; and
- Eric Murphy is the Chief Growth and Commercial Officer for Optum, Inc. and has also led OptumInsight, Inc.

b. UnitedHealth Group directly or indirectly owns all the stock of Optum, Inc., OptumRx, Inc., and OptumInsight, Inc.;

c. The UnitedHealth Group corporate family does not operate as separate entities. The public filings, documents, and statements of UnitedHealth Group present its subsidiaries, including Optum, Inc., OptumRx, Inc., and OptumInsight as divisions or departments of a single company that is "a diversified family of businesses" and that "leverages core competencies" to "help[] people live healthier lives and help[] make the health system work better for everyone." The day-to-day operations of this corporate family reflect these public statements. These entities are a single business

enterprise and should be treated as such as to all legal obligations detailed in this Complaint.[20]

d. All the executives of Optum, Inc., OptumRx, Inc., and OptumInsight ultimately report to the executives, including the CEO, of UnitedHealth Group.

e. As stated above, UnitedHealth Group's executives and officers are directly involved in the policies and business decisions of Optum, Inc., OptumRx, Inc., and OptumInsight that gave rise to Plaintiff's claims in this Complaint.

188. Collectively, Defendants UnitedHealth Group, Inc., OptumRx, Inc., OptumInsight, Inc. and Optum, Inc., including all predecessor and successor entities, are referred to as "OptumRx."

189. OptumRx is named as a Defendant in its capacities as a PBM and mail-order pharmacy.

190. OptumRx is a pharmacy benefit manager and, as such, coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the price of the at-issue diabetes medications, as well as for the placement of these Manufacturers' diabetes medications on OptumRx's drug formularies.

191. OptumRx provides pharmacy care services to more than 65 million people in the nation through a network of more than 67,000 retail pharmacies and multiple delivery facilities.[21]

192. In 2018, OptumRx managed more than $91 billion in pharmaceutical spending, representing 23% of the PBM market in the United States. OptumRx's 2018 revenue was $69 billion.

[20] UnitedHealth Group, Quarterly Report (Form 10-Q) (Mar. 31, 2017).
[21] UnitedHealth Group, Annual Report (Form 10-K) (Dec. 31, 2018).

193. In 2019, OptumRx managed more than $96 billion in pharmaceutical spending, with a revenue of $74 billion.[22]

194. At all times relevant hereto, OptumRx derived substantial revenue providing pharmacy benefits in Tennessee.

195. At all times relevant hereto, OptumRx offered pharmacy benefit management services nationwide and maintained standard formularies that are used nationwide, including in Tennessee. During the relevant time period, those formularies included diabetes medications, including all of those at issue in this Complaint.

196. At all times relevant hereto, and contrary to their express representations, OptumRx knowingly insisted that its payor clients use the false list prices produced by the Insulin Pricing Scheme as the basis for reimbursement of the at-issue drugs.

197. At all times relevant hereto, OptumRx concealed its critical role in the generation of those false list prices.

198. In its capacity as a mail-order pharmacy, OptumRx received payments from payors for, and set the out-of-pocket price paid for, the at-issue drugs based on the falsely inflated prices produced by the Insulin Pricing Scheme and, as a result, damaged Plaintiff.

199. At all times relevant hereto, OptumRx dispensed the at-issue medications nationwide and directly to Plaintiff and Plaintiff's Beneficiaries in Tennessee through its mail-order pharmacies and derived substantial revenue from these activities in Tennessee.

200. OptumRx purchases the Manufacturer Defendants' drugs, including the at issue diabetes medications, for dispensing through its mail-order pharmacies.

[22] UnitedHealth Group, Annual Report (Form 10-K) (Dec. 31, 2019).

201. At all times relevant hereto, OptumRx had express agreements with Defendants Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid by the Manufacturer Defendants to OptumRx, as well as agreements related to the Manufacturers' at-issue drugs sold through OptumRx's mail-order pharmacies.

202. Collectively, CVS Caremark, Optum Rx, and Express Scripts are referred to as the "PBM Defendants" or the "PBMs."

JURISDICTION AND VENUE

203. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1331 and pursuant to 18 U.S.C. § 1964(c) because this action alleges violations of the Racketeer influenced and Corrupt Organizations Act, 18 U.S.C. § 1962, which raises a federal question. This Court has supplemental jurisdiction over the state law claims in this action pursuant to 28 U.S.C. § 1367.

204. There is also federal subject matter jurisdiction over this action because complete diversity exists among the parties, 28 U.S.C. § 1332. The parties are citizens of different states, and the amount in controversy, exclusive of interests or costs, exceeds the sum or value of $75,000.

205. This Court also has personal jurisdiction over all Defendants under 18 U.S.C. § 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the Court in a single trial.

206. Venue is proper pursuant to 18 U.S.C. § 1965 because Defendants Sanofi, Novo Nordisk and Medco reside, are found, have an agent, or transact their affairs in this District, and the ends of justice require that any Defendant residing elsewhere be brought before this Court.

207. Venue is also proper in this District pursuant to 28 U.S.C. § 1391(b) and (c) because all Defendants transact business in, are found in, and/or have agents in this District, and because some of the actions giving rise to the Complaint took place within this District.

ADDITIONAL FACTUAL ALLEGATIONS

A. Diabetes and Insulin Therapy

The Diabetes Epidemic

208. Diabetes occurs when a person's blood glucose is too high. In people without diabetes, the pancreas secretes the hormone insulin, which controls the rate at which food is converted to blood glucose. When insulin is lacking or when cells stop responding to insulin, however, blood sugar stays in the bloodstream. Over time, this can cause serious health problems, including heart disease, blindness, and kidney disease.

209. There are two basic types of diabetes: Type 1 and Type 2. Roughly 90-95% of diabetics are Type 2, which develops when a person does not produce enough insulin or has become resistant to the insulin they produce. While Type 2 patients can initially be treated with tablets, in the long term most patients switch to insulin injections.

210. Diabetes has been on the rise for decades. In 1958, only 1.6 million Americans had diabetes. By the turn of the century, that number had grown to over ten million. Fourteen years later, the number had tripled. Today, more than 37 million Americans—approximately 11% of the country—live with the disease.

211. The prevalence of diabetes in Tennessee has increased as well. Over 760,000 Tennessee adults now live with diabetes and hundreds of thousands more have prediabetes.[23]

[23] https://www.cdc.gov/diabetes/programs/stateandlocal/state-diabetes-profiles/tennessee.html; Tennessee Diabetes Action Legislative Report, Feb. 2021, https://www.capitol.tn.gov/Archives/senate/112GA/committees/health-welfare/2021/Diabetes%20Legislative%20Report_FinalDraft.%2001-29-2021%208%2045%20pm.pdf.

Insulin: A Century-Old Drug

212. Despite its potentially deadly impact, diabetes is highly treatable. Patients able to follow a prescribed treatment plan consistently may avoid the health complications associated with the disease. Unlike many high-burden diseases, treatment for diabetes has been available for almost a century.

213. In 1922, Frederick Banting and Charles Best, while working at the University of Toronto, pioneered a technique for removing insulin from an animal pancreas that could then be used to treat diabetes. After discovery, Banting and Best obtained a patent and then sold it to the University of Toronto for $1 (equivalent of $14 today), explaining "[w]hen the details of the method of preparation are published anyone would be free to prepare the extract, but no one could secure a profitable monopoly."[24]

214. After purchasing the patent, the University of Toronto contracted with Defendants Eli Lilly and Novo Nordisk to scale their production. Under this arrangement, Eli Lilly and Novo Nordisk were allowed to apply for patents on variations to the manufacturing process.

215. Although early iterations of insulin were immediately perceived as lifesaving, there have been numerous incremental improvements since its discovery.

216. The earliest insulin was derived from animals and, until the 1980s, was the only diabetes treatment.

217. While effective, animal-derived insulin created the risk of allergic reaction. This risk was lessened in 1982 when synthetic insulin, known as human insulin, was developed by Defendant Eli Lilly. Eli Lilly marketed this insulin as Humulin. The development of human insulin

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[24] Jessica DiGiacinto & Valencia Higuera, *Everything You Need to Know About Insulin*, HEALTHLINE (Oct. 5, 2021), http://www.healthline.com/health/type-2-diabetes/insulin; M. BLISS, THE DISCOVERY OF INSULIN (2013).

benefited heavily from government and non-profit funding through the National Institute of Health and the American Cancer Society.

218. Over a decade later, Eli Lilly released the first analog insulin.

219. Analog insulin is laboratory-grown and genetically altered insulin. Analogs are slight variations on human insulin that make the injected treatment act more like the insulin naturally produced and regulated by the body.

220. Defendant Eli Lilly developed the first analog insulin, Humalog, in 1996.

221. Other rapid-acting analogs are Defendant Novo Nordisk's Novolog and Defendant Sanofi's Apidra, which have similar profiles. Diabetics use these rapid-acting insulins in combination with longer-acting insulins, such as Sanofi's Lantus and Novo Nordisk's Levemir.

222. The Manufacturer Defendants introduced these rapid-acting and long-acting analog insulins between 1996 and 2007.

223. In 2015, Sanofi introduced Toujeo, another long-acting insulin similar to Lantus; however, Toujeo is highly concentrated, making injection volume smaller than Lantus.

224. In 2016, Eli Lilly introduced Basaglar, which is a long-acting insulin biologically similar to Sanofi's Lantus.

225. Even though insulin was first extracted 100 years ago, and despite its profitability, only Defendants Eli Lilly, Novo Nordisk, and Sanofi manufacture insulin for the United States market. This did not occur by chance.

226. Many of the at-issue medications are now off-patent.

227. The Manufacturers maintain market domination through patent "evergreening." Drugs usually face generic competition when their 20-year patents expire. While original insulin formulas may technically be available for generic use, the Manufacturers "stack" patents around

the original formulas, making new competition more costly and risky. For example, Sanofi has filed more than 70 patents on Lantus—more than 95% were filed after the drug was approved by the FDA—potentially providing more than three additional decades of patent "protection" for the drug. The market therefore remains highly concentrated.

The Current Insulin Landscape

228. While insulin today is generally safer and more convenient to use than when originally developed in 1922, there remain questions about whether the overall efficacy of insulin has significantly improved over the last twenty years.

229. For example, while long-acting analogs may have certain advantages over human insulins, such as affording more flexibility around mealtime planning, it has yet to be shown that analogs lead to better long-term outcomes. Recent work suggests that older human insulins may work just as well for patients with Type 2 diabetes.

230. Moreover, all insulins at issue have either been available in the same form since the late 1990s/early 2000s or are biologically equivalent to insulins available then.

231. As Dr. Kasia Lipska, a Yale researcher, explained in the Journal of the American Medical Association:

> We're not even talking about rising prices for better products here. I want to make it clear that we're talking about rising prices for the same product . . . there's nothing that's changed about Humalog. It's the same insulin that's just gone up in price and now costs ten times more.[25]

232. Production costs have also decreased in recent years. A September 2018 study calculated that, based on production costs, a reasonable price for a year's supply of human insulin

[25] Natalie Shure, *The Insulin Racket*, American Prospect (June 24, 2019), https://prospect.org/health/insulin-racket/ (last visited Jan. 14, 2023).

is $48 to $71 per person and $78 to $133 for analog insulins. Another recent study found that the Manufacturers could profit at as little as $2 per vial.

233. United States diabetics spent an average of $5,705 each for insulin in 2016. According to a 2020 RAND report, the 2018 list price per vial across all forms of insulin was just $12 in Canada and less than $7 in Australia. In the U.S., it was $98.70.

234. While R&D costs often contribute significantly to a drug's price, the initial basic insulin research occurred 100 years ago and its costs have long-since been recouped. Other costs, such as developing the recombinant DNA-fermentation process and the creation of insulin analogs, were incurred decades ago.

Insulin Adjuncts: Type 2 Medications

235. The Manufacturer Defendants have released several non-insulin diabetes medications over the past decade. Novo Nordisk released Victoza in 2010, followed by Trulicity (Eli Lilly), Soliqua (Sanofi), and Ozempic (Novo Nordisk).[26] The following is a list of diabetes medications at issue in this lawsuit:

[26] Victoza, Trulicity, and Ozempic are glucagon-like peptide-1 receptor agonists ("GLP-1") and mimic the GLP-1 hormone produced in the body. Soliqua is a combination long-acting insulin and GLP-1 drug. Each of these drugs can be used in conjunction with insulins to control diabetes.

Table 1: Diabetes medications at issue in this case

Insulin Type	Action	Name	Company	FDA Approval	Current/Recent List Price
Human	*Rapid-Acting*	Humulin R	Eli Lilly	1982	$178 (vial)
		Humulin R 500	Eli Lilly	1982	$1784 (vial), $689 (pens)
		Novolin R	Novo Nordisk	1991	$165 (vial), $312 (pens)
	Intermediate	Humulin N	Eli Lilly	1982	$178 (vial), $566 (pens)
		Humulin 70/30	Eli Lilly	1989	$178 (vial), $566 (pens)
		Novolin N	Novo Nordisk	1991	$165 (vial), $312 (pens)
		Novolin 70/30	Novo Nordisk	1991	$165 (vial), $312 (pens)
Analog	*Rapid-Acting*	Humalog	Eli Lilly	1996	$342 (vial), $636 (pens)
		Novolog	Novo Nordisk	2000	$347 (vial), $671 (pens)
		Apidra	Sanofi	2004	$341 (vial), $658 (pens)
	Long-Acting	Lantus	Sanofi	2000	$340 (vial), $510 (pens)
		Levemir	Novo Nordisk	2005	$370 (vial), $555 (pens)
		Basaglar (Kwikpen)	Eli Lilly	2015	$392 (pens)
		Toujeo (Solostar)	Sanofi	2015	$466 (pens), $622 (max pens)
		Tresiba	Novo Nordisk	2015	$407 (vial) $610 (pens – 100u) $732 (pens – 200u)
Type 2 Medications		Trulicity	Eli Lilly	2014	$1013 (pens)
		Victoza	Novo Nordisk	2010	$813 (2 pens) $1220 (3 pens)
		Ozempic	Novo Nordisk	2017	$1022 (pens)
		Soliqua	Sanofi	2016	$928 (pens)

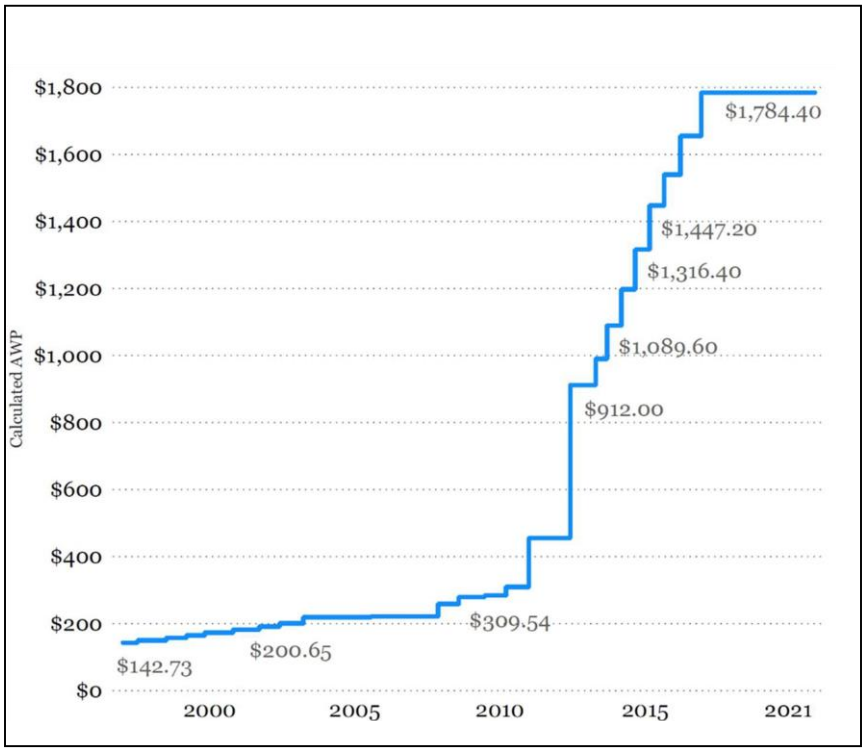
B. The Dramatic Rise in the Price of Diabetes Medications in the U.S.

236. Over the past 25 years, the list price of certain insulins has increased in some cases by more than 1000% (10x).

237. According to the U.S. Bureau of Labor Statistics, $165 worth of consumer goods and services in 1997 dollars would, in 2021, have cost $289 (1.75x).[27]

238. Since 1997, Eli Lilly has raised the list price of a vial of Humulin R (500U/mL) from $165 to $1784 in 2021 (10.8x).

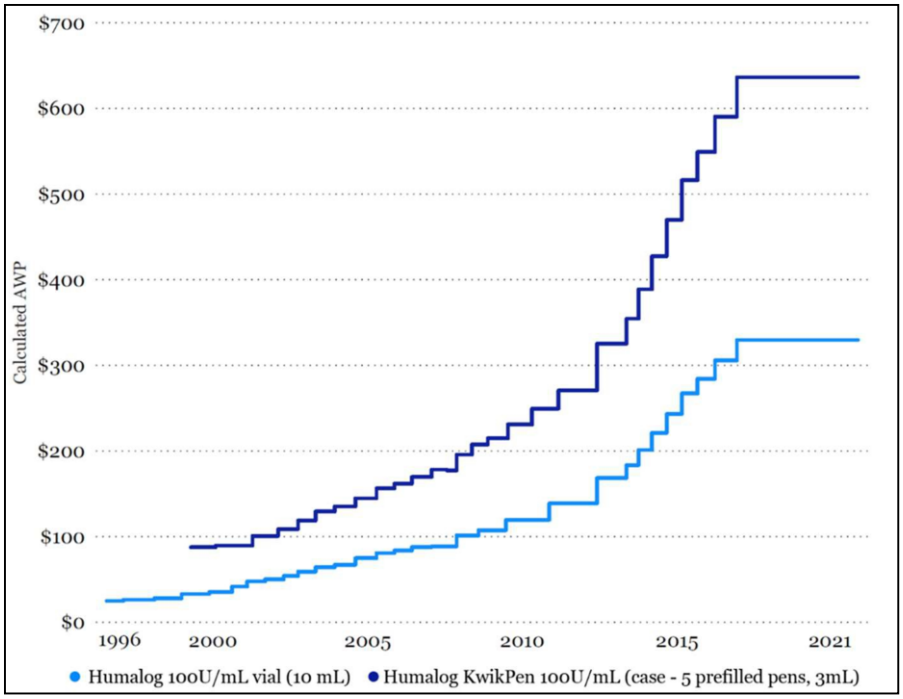
Figure 3: Rising list prices of Humulin R (500U/mL) from 1997-2021



239. Since 1996, Eli Lilly has raised the price for a package of Humalog pens from less than $100 to $663 (6.6x) and from less than $50 per vial to $342 (6.8x). (See Fig. 4.)

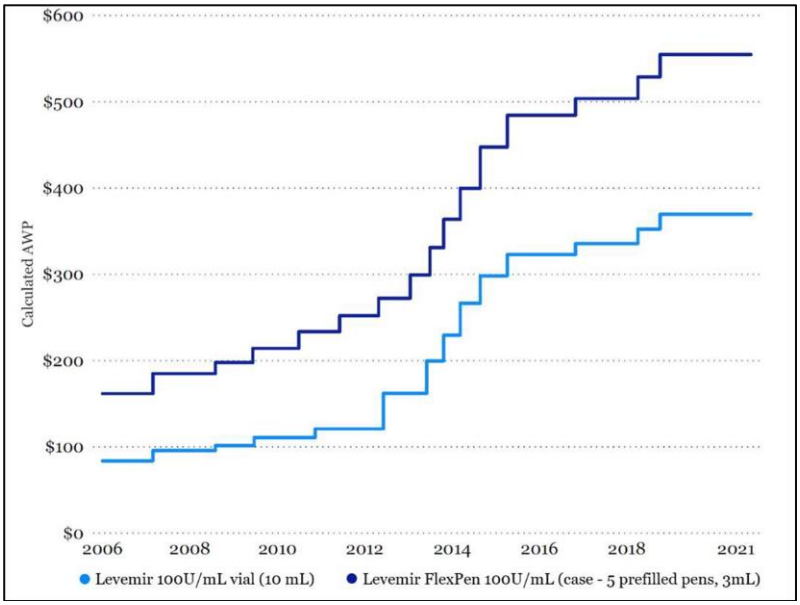
Figure 4: Rising list prices of Humalog vials and pens from 1996-2021

[27] https://www.bls.gov/data/inflation_calculator.htm (last visited Aug. 23, 2023). The Consumer Price Index (CPI) measures "the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services." (https://www.bls.gov/cpi/).



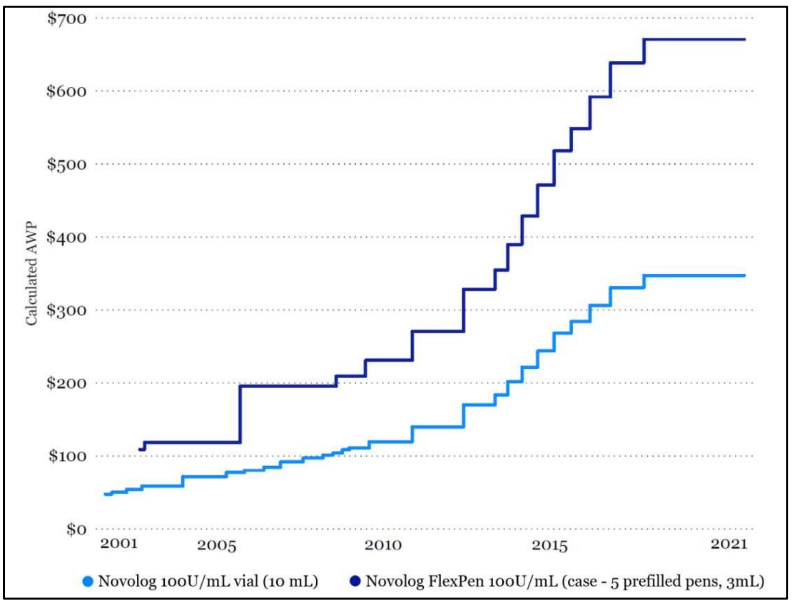
240. From 2006 to 2020, Novo Nordisk has raised Levemir's list price from $162 to $555 (3.4x) for pens and from under $100 to $370 per vial (3.7x).

Figure 5: Rising list prices of Levemir from 2006-2021



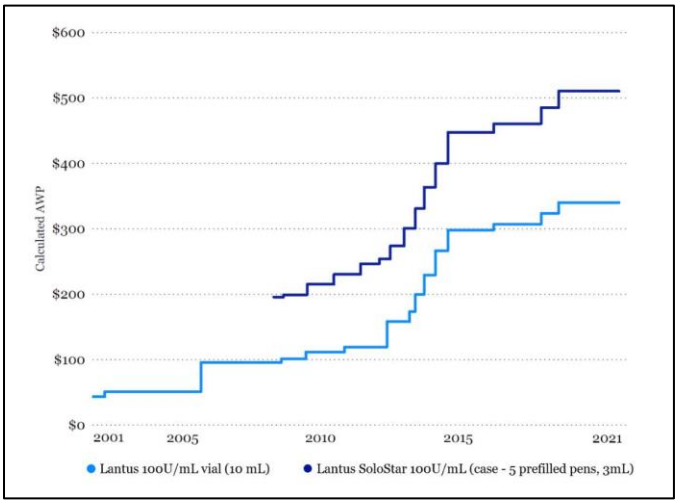
241. From 2002 to 2021, Novo Nordisk raised the list price of Novolog from $108 to $671 (6.2x) for a package of pens and from less than $50 to $347 (6.9x) for a vial.

Figure 6: Rising list prices of Novolog vials and pens from 2002-2021



242. Defendant Sanofi has kept pace. It manufactures a top-selling analog insulin—Lantus—which has been and remains a flagship brand for Sanofi. It has been widely prescribed nationally and within Tennessee, including to Plaintiff's Beneficiaries. Sanofi has raised the list prices for Lantus from less than $200 in 2006 to over $500 in 2020 (2.5x) for a package of pens and from less than $50 to $340 for a vial (6.8x). (See Fig. 7.)

Figure 7: Rising list prices of Lantus vials and pens from 2001-2021



243. The Manufacturer Defendants have similarly ballooned the prices for noninsulin diabetes medications.

244. Driven by these price hikes, payors' and diabetics' spending on these drugs has steadily increased with totals in the tens of billions of dollars. The Defendant-Manufacturers Have Increased Prices in Lockstep

245. The timing of the price increases reveals that the Manufacturer Defendants have not only dramatically increased prices for the at-issue diabetes treatments, but have done so in lockstep.

246. Between 2009 and 2015, for example, Sanofi and Novo Nordisk raised the list prices of their insulins in tandem 13 times, taking the same price increase down to the decimal point within a few days of each other (sometimes within a few hours).[28]

247. This conduct is known as "shadow pricing," which communicates between competitors their intention not to price compete against one another.

[28] Grassley & Wyden, *supra* note 2.

248. In 2016, Novo Nordisk and Sanofi's lockstep increases for the at-issue drugs represented the highest drug price increases in the pharmaceutical industry.

249. Eli Lilly and Novo Nordisk have engaged in the same lockstep behavior with respect to their rapid-acting analog insulins, Humalog and Novolog. Figure 8 demonstrates this collusive behavior with respect to Lantus and Levemir. Figure 9 demonstrates this behavior with respect to Novolog and Humalog.

Figure 8: Rising list prices of long-acting insulins

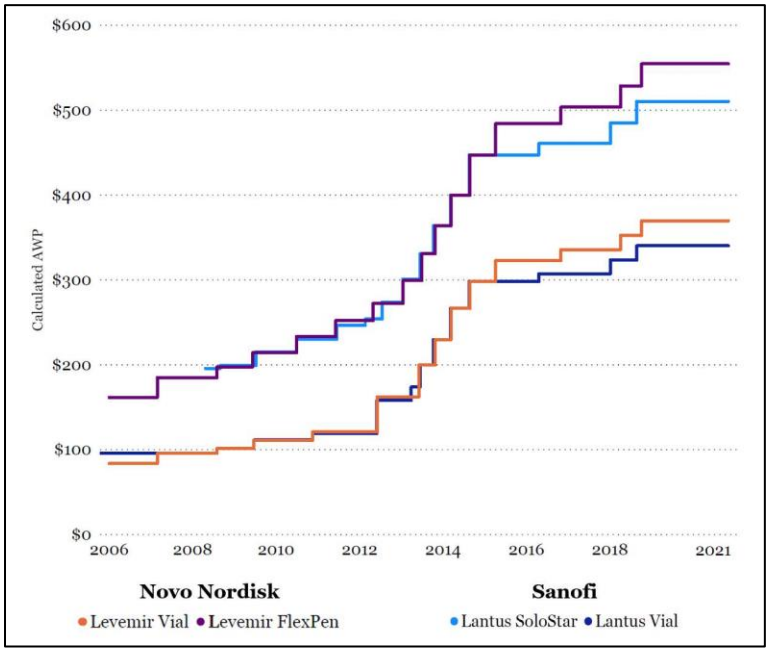
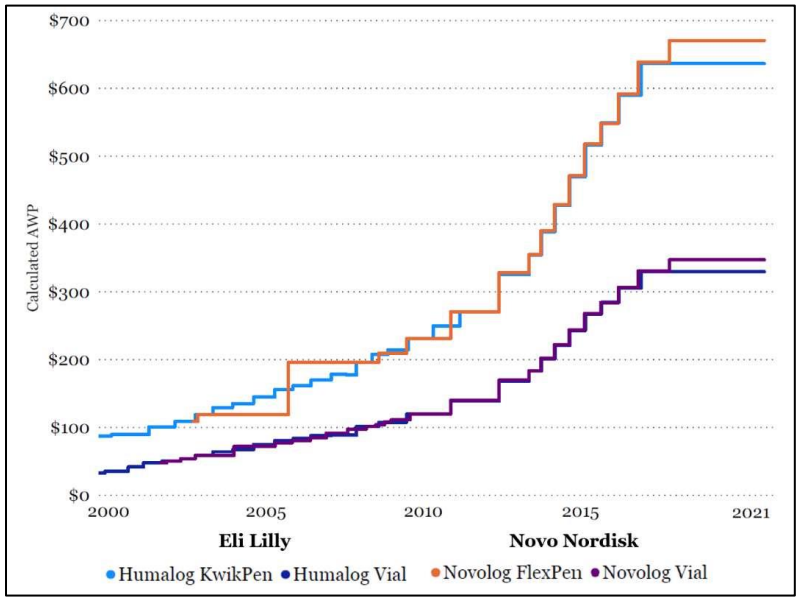
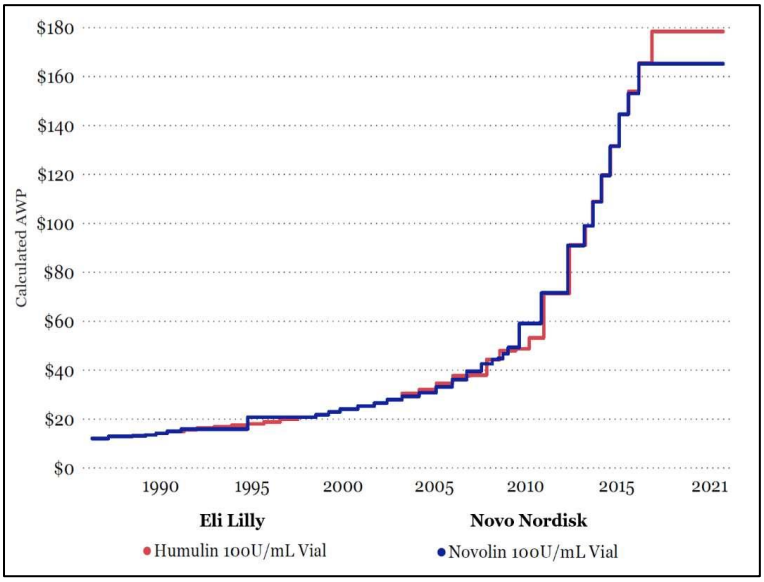


Figure 9: Rising list prices of rapid-acting insulins



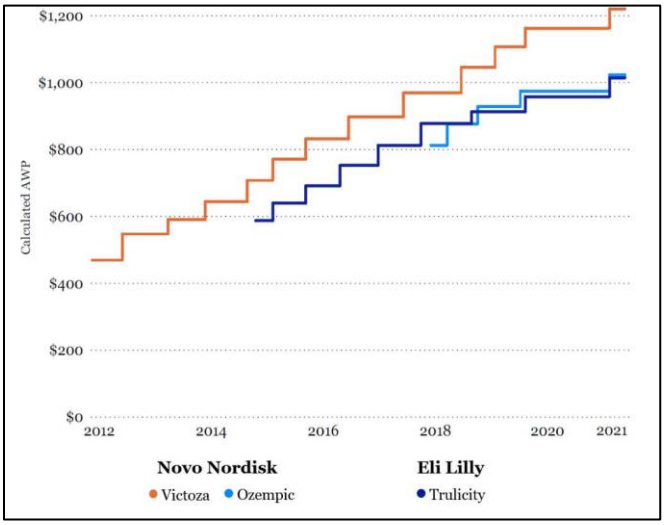
250. Figure 10 below demonstrates this behavior with respect to the human insulins—Eli Lilly's Humulin and Novo Nordisk's Novolin.

Figure 10: Rising list price increases for human insulins



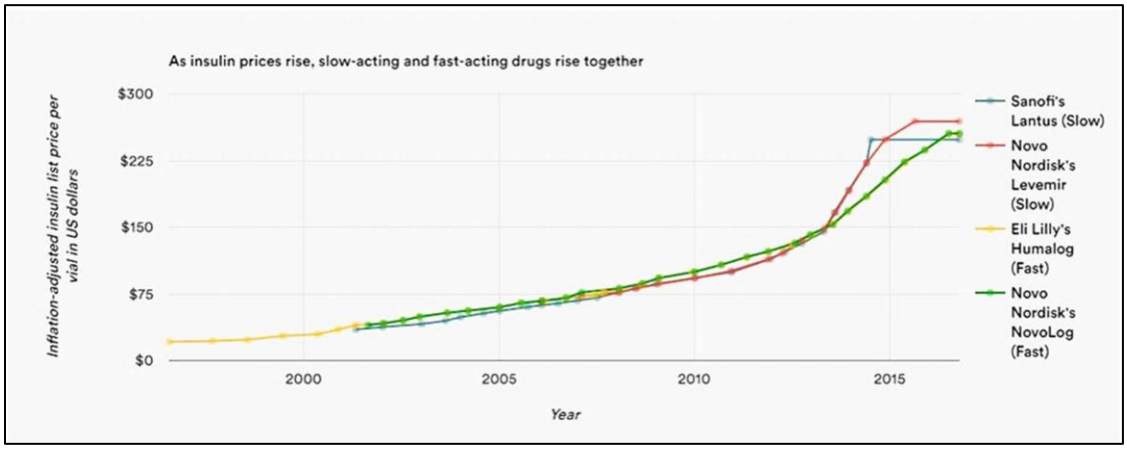
251. Figure 11 below demonstrates Novo Nordisk and Eli Lilly's lockstep price increases for their Type 2 drugs Trulicity, Victoza, and Ozempic.

Figure 11: Rising list prices of Type 2 drugs



252. Figure 12 below shows how, collectively, the Manufacturer Defendants have exponentially raised the prices of insulin products in near-perfect unison.

Figure 12: Lockstep insulin price increases



253. Because of the Manufacturer Defendants' collusive price increases, nearly a century after the discovery of insulin, diabetes medications have become unaffordable for many diabetics.

C. Pharmaceutical Payment and Supply Chain

254. The prescription drug industry is comprised of a deliberately opaque network of entities engaged in multiple distribution and payment structures. These entities include drug manufacturers, wholesalers, pharmacies, health plans/third-party payors, PBMs, and patients.

255. Given the complexities of the different parties involved in the pharmaceutical industry, there are many ways in which pharmaceutical drugs are distributed. Generally speaking, branded prescription drugs, such as the at-issue diabetes medications, are often distributed in one of three ways: (1) from manufacturer to wholesaler (distributor), wholesaler to pharmacy, and pharmacy to patient; (2) from manufacturer to mail-order pharmacy to patient; and (3) from manufacturer to mail-order pharmacy, mail-order pharmacy to self-insured payor, and then self-insured payor to patient.

256. The pharmaceutical industry, however, is unique in that the pricing chain is distinct from the distribution chain. The prices for the drugs distributed in the pharmaceutical chain are different for each participating entity, i.e., different actors pay different prices set by different entities for the same drugs. The unifying factor is that the price that each entity in the pharmaceutical chain pays for a drug is inexorably tied to the price set by the manufacturer. The pricing chain includes self-insured payors paying PBMs directly.

257. There is no transparency in this pricing system. Typically, only a brand drug's list price—also known as its Average Wholesale Price (AWP) or the mathematically related Wholesale Acquisition Cost (WAC)—is available.

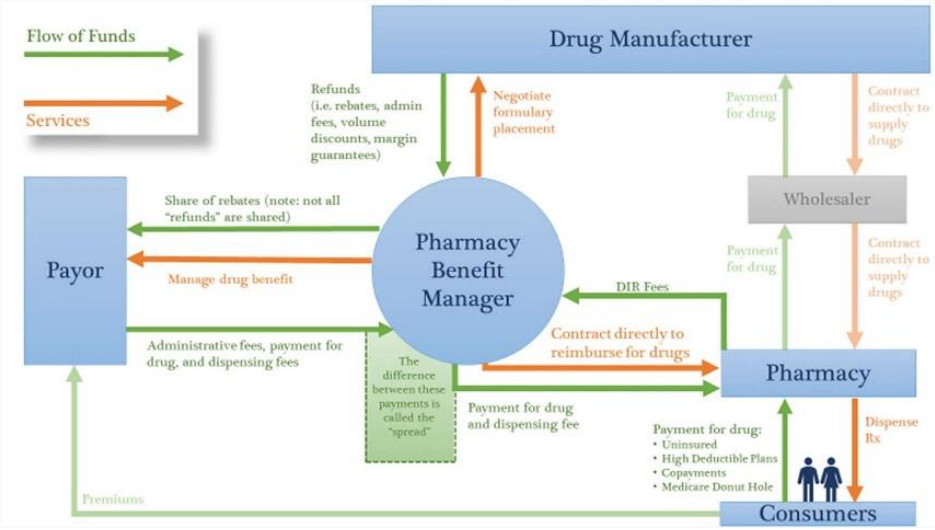
258. Drug manufacturers self-report AWP, or other prices upon which AWP is based, to publishing compendiums such as First DataBank, Redbook, and others who then publish those prices.

259. As a direct result of the PBMs' conduct, AWP persists as the most commonly and continuously used list price in reimbursement and payment calculations and negotiations for both payors and patients.

D. The PBMs' Role in the Pharmaceutical Payment Chain

260. The PBMs are at the center of this convoluted pharmaceutical payment chain, as illustrated in Figure 13 below.

Figure 13: Insulin distribution and payment chain



261. The PBM Defendants develop drug formularies, process claims, create a network of retail pharmacies, set the prices in coordination with the Manufacturers that the payor will pay for prescription drugs, and are paid by the payor to reimburse pharmacies for the drugs utilized by the payor's beneficiaries.

262. The PBMs also contract with a network of retail pharmacies. Pharmacies agree to dispense drugs to patients and pay fees back to the PBMs. The PBMs reimburse pharmacies for the drugs dispensed.

263. The PBM Defendants also own mail-order and specialty pharmacies, which purchase and take possession of prescription drugs, including those at-issue here, and directly supply those drugs to payors like Plaintiff Hamblen County, their Beneficiaries, and other patients, by mail.

264. Often, the PBM Defendants purchase drugs directly from the Manufacturers and distribute them directly to the patients. The prices that the PBM Defendants pay are significantly less than the purchase prices paid by payors.

265. Even where PBM Defendant mail-order pharmacies purchase drugs from wholesalers, their costs are set by direct contracts with the manufacturers.

266. In addition, and of particular significance here, the PBM Defendants contract with pharmaceutical manufacturers, including the Manufacturer Defendants. The PBMs extract from the Manufacturers rebates, fees, and other consideration that are paid back to the PBMs, including the Manufacturer Payments related to the at-issue drugs.

267. The Manufacturers also interact with the PBMs related to other services outside the scope of the Insulin Pricing Scheme, such as health and educational programs and patient and prescriber outreach with respect to drugs not at issue here.

268. These relationships allow PBMs to exert tremendous influence over what drugs are available throughout the United States, including in Hamblen County, on what terms, and at what prices.

269. Thus, PBMs are at the center of the flow of pharmaceutical money. Historically and today PBMs:

- negotiate the price that payors pay for prescription drugs (based on prices generated by the Insulin Pricing Scheme);

- separately negotiate a different (and often lower) price that pharmacies in their networks receive for the same drug;
- set the amount in fees that the pharmacy pays back to the PBM for each drug sold (based on prices generated by the Insulin Pricing Scheme);
- set the price paid for each drug sold through their mail-order pharmacies (based on prices generated by the Insulin Pricing Scheme); and
- negotiate the amount that the Manufacturers pay back to the PBM for each drug sold (based on prices generated by the Insulin Pricing Scheme).

270. Yet, for most of these transactions, only the PBMs are privy to the amount that any other entity in this supply chain is paying or receiving for the same drugs. The contracts between the PBMs and Manufacturers are undisclosed to Plaintiff. Payors, including Plaintiff, do not know and cannot learn the terms of those contracts.

271. This lack of transparency affords Defendants the opportunity to extract billions of dollars from this payment and supply chain without detection.

272. In every interaction that the PBMs have within the pharmaceutical pricing chain, they stand to profit from the prices generated by the Insulin Pricing Scheme.

The Rise of the PBMs in the Pharmaceutical Supply Chain

273. At first, in the 1960s, pharmacy benefit managers functioned largely as claims processors. Over time, however, they have taken on increasingly larger roles.

274. One of the roles the pharmacy benefit managers have taken on, as discussed above, was negotiating with drug manufacturers—ostensibly on behalf of payors. In so doing, the PBMs affirmatively represented that they were using their leverage to drive down drug prices.

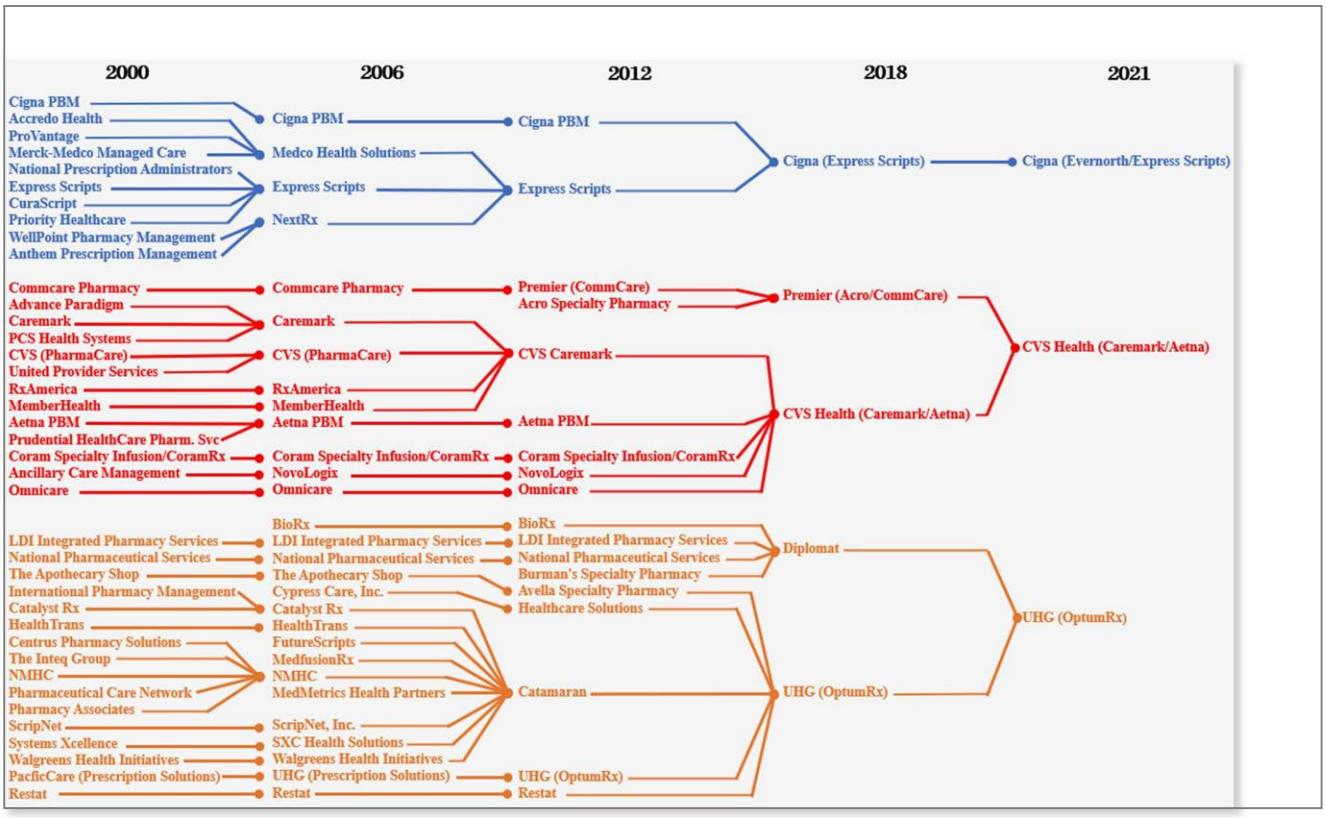
275. In the early 2000s, the PBMs started buying pharmacies, thus creating an additional incentive to collude with manufacturers to keep certain prices high.

276. These perverse incentives still exist today with respect to both retail and mail-order pharmacies housed within the PBMs' corporate families. Further recent consolidation in the industry has given the pharmacy benefit managers disproportionate market power.

277. Nearly forty pharmacy benefit manager entities have combined into what are now the three PBM Defendants. Moreover, each PBM Defendant now is owned by other significant players in the pharmaceutical chain, e.g., Express Scripts merged with Cigna; CVS bought Caremark, which now also owns Aetna; and UnitedHealth Group acquired OptumRx.

278. Figure 14 depicts this consolidation within the pharmacy benefit manager market.

Figure 14: PBM consolidation



279. After merging with or acquiring all of their competitors, and now backed by multibillion-dollar corporations, the PBM Defendants have taken over the market in the past

decade, controlling more than 80% of the market and managing pharmacy benefits for more than 270 million Americans.

280. Together, the PBM Defendants report more than $300 billion in annual revenue.

281. The PBMs use this market consolidation and the resulting purchasing power as leverage when negotiating with other entities in the pharmaceutical pricing chain.

The Insular Nature of the Pharmaceutical Industry

282. The insular nature of the pharmaceutical industry has provided Defendants with ample opportunity to contact and communicate with the other PBM and Manufacturer Defendants and to devise, coordinate, and carry out the Insulin Pricing Scheme.

283. The Manufacturer Defendants are all members of the industry-funded Pharmaceutical Research and Manufacturers of America ("PhRMA") and routinely communicate through PhRMA meetings and platforms in furtherance of the Insulin Pricing Scheme. According to PhRMA's 2019 IRS Form 990, it received $515,420,431 in "membership dues." All members are pharmaceutical companies.[29]

284. David Ricks (CEO of Eli Lilly), Paul Hudson (CEO of Sanofi), and Douglas Langa (President of Novo Nordisk and EVP of North American Operations), serve on the PhRMA board of directors and/or part of the PhRMA executive leadership team.

285. The PBM Defendants also routinely communicate through direct interaction with their competitors and the Manufacturers at trade associations and industry conferences.

[29] PhRMA 2019 Form 990, https://projects.propublica.org/nonprofits/organizations/530241211/202043189349300519/full; PhRMA, About PhRMA, https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/About-PhRMA2.pdf (last visited Aug.23,2023).

286. Each year during the relevant period, the main PBM trade association, the industry-funded Pharmaceutical Care Management Association ("PCMA"), held several yearly conferences, including its Annual Meeting and its Business Forum conferences.[30]

287. The PCMA is governed by PBM executives. The current (July 2023) board of the PCMA includes David Joyner (Executive Vice President and President of Pharmacy Services of PBM Defendant CVS Caremark); Adam Kautzner (President of PBM Defendant Express Scripts); and Heather Cianfrocco (CEO of PBM Defendant OptumRx).

288. In 2022, Former Express Scripts President Amy Bricker was the Chair of the PCMA board of directors and the only Express Scripts employee on the board. But when Ms. Bricker left Express Scripts in late 2022/early 2023, she was removed from the PCMA board. On February 3, 2023, PCMA issued a press release naming Mr. Kautzner to the board and appointing him Chairman of the Board of Directors. Mr. Kautzner was not on the board as of late 2022. Mr. Kauztner was added to the PCMA board and named Chair of the board to ensure that the PCMA board has directors from all three PBM Defendants and to facilitate the Insulin Pricing Scheme.

289. All PBM Defendants are members of the PCMA and, due to their leadership positions, have substantial control over that association.

290. Additionally, the Manufacturer Defendants are affiliate members of the PCMA.

291. Every year, high-level representatives and corporate officers from both the PBM and Manufacturer Defendants attend these conferences to meet in person and engage in discussions, including those in furtherance of the Insulin Pricing Scheme.

[30] The PCMA's industry funding in the form of "membership dues" is set out in its 2019 Form 990, https://projects.propublica.org/nonprofits/organizations/383676760/202042969349301134/full (last visited Aug, 23, 2023).

292. In fact, for at least the last eight years, all Manufacturer Defendants have been "Partners," "Platinum Sponsors," or "Presidential Sponsors" of these PBM conferences.

293. Notably, many of the forums at these conferences are specifically advertised as offering opportunities for private, non-public communications. For example, as Presidential Sponsors of these conferences, Manufacturer Defendants each hosted "private meeting rooms" that offer "excellent opportunities for . . . one-on-one interactions between PBM and pharma executives."[31]

294. Representatives from each Manufacturer Defendant have routinely met privately with representatives from each PBM Defendant during the Annual Meetings and Business Forum conferences that the PCMA holds (and the manufacturers sponsor) each year.

295. In addition, all PCMA members, affiliates and registered attendees of these conferences are invited to join PCMA-Connect, "invitation only LinkedIn group and online networking community."[32]

296. As PCMA members, the PBM and Manufacturer Defendants clearly utilized both PCMA-Connect, as well as the private meetings at the PCMA conferences, to exchange information and to reach agreements in furtherance of the Insulin Pricing Scheme.

297. Key at-issue lockstep price increases occurred shortly after the Defendants had convened at PCMA meetings. For example, on September 26 and 27, 2017, the PCMA held its annual meeting where each of the Manufacturer Defendants hosted private rooms and executives from each Defendant engaged in several meetings throughout the conference. Mere days after the

[31] PCMA, *The PCMA Annual Meeting 2021 Will Take Place at the Broadmoor in Colorado Springs, CO September 20 and 21*, https://www.pcmanet.org/pcmaevent/annual-meeting-2021/ (an event "tailored specifically for senior executives from PBMs and their affiliated business partners" with "private reception rooms" and "interactions between PBM members, drug manufacturers, and other industry partners") (last visited Aug 23, 2023).

[32] PCMA, *PCMA-Connect*, https://www.pcmanet.org/contact/pcma-connect/ (last visited Sept. 9, 2022).

conference, on October 1, 2017, Sanofi increased Lantus's list price by 3% and Toujeo's list by 5.4%. Novo Nordisk also recommended that their company make a 4% list price increase effective on January 1, 2018, to match the Sanofi increase.

298. Likewise, on May 30, 2014, Novo Nordisk raised the list price of Levemir a matter of hours after Sanofi made its list price increase on Lantus. These price hikes occurred just weeks after the 2014 PCMA spring conference in Washington, D.C., attended by representatives from all the PBM Defendants.

299. The PBMs control the PCMA and have exploited it to further their interests and to conceal the Insulin Pricing Scheme. The PCMA has brought numerous lawsuits and lobbying campaigns aimed at blocking drug-pricing transparency efforts, including recently suing the Department of Health and Human Services (HHS) to block the finalized HHS "rebate rule," which would eliminate anti-kickback safe harbors for Manufacturer Payments and instead offer them as direct-to-consumer discounts.

300. Notably, the PCMA's 2019 tax return reports more than a million dollars in revenue for "litigation support." Prior tax returns available at ProPublica reveal millions of dollars in revenue for "litigation support" (and tens of millions in revenue for "industry relations") year after year.[33]

301. Communications among the PBM Defendants are facilitated by the fluidity and frequency with which executives relocate from one PBM Defendant to another. For example:

- Mark Thierer worked as an executive at Caremark Rx (now CVS Caremark) prior to becoming the CEO of OptumRx in 2016 (he also served as Chairman of the Board for PCMA starting in 2012);

- Bill Wolfe was the President of the PBM Catalyst Rx (now OptumRx) prior to becoming the President of Aetna Rx in 2015 (he also served as a PCMA board member from 2015-2017 while with Aetna Rx);

[33] *See, e.g.*, PCMA 2019 Form 990, *supra* note 24, and prior years' returns on ProPublica.

- Derica Rice, former EVP for CVS Health and President of CVS Caremark, previously served as EVP and CFO for Eli Lilly;

- Duane Barnes was the Vice President of Medco (now Express Scripts) before becoming division President of Aetna Rx in 2006 (he also served as a PCMA board member);

- Everett Neville was the division President of Aetna Rx before becoming Senior Vice President of Express Scripts;

- Albert Thigpen was a Senior Vice President at CVS Caremark for 11 years before becoming a Senior Vice President at OptumRx in 2011;

- Harry Travis was the Chief Operating Officer at Medco (now Express Scripts) before becoming a Vice President at Aetna Rx in 2008; he served as SVP Member Services Operations for CVS Caremark from 2020-2022; and

- Bill Kiefer was a Vice President of Express Scripts for 14 years before becoming Senior Vice President of Strategy at OptumRx in 2013.

E. The Insulin Pricing Scheme

302. The market for the at-issue diabetes medications is unique in that it is highly concentrated with no true generics and few biosimilar options. The drugs and biosimilars have similar efficacy and risk profiles.

303. This affords the PBMs great leverage that, in theory, could be used to negotiate with the Manufacturer Defendants to drive down list prices for the at-issue drugs through open competition.

304. But the PBMs do not want the prices for diabetes medications to go down. A 2022 report by the Community Oncology Alliance put it this way:

> Among the different sources of revenue, the most prolific by far is in the form of rebates from pharmaceutical manufacturers that PBMs extract in exchange for placing the manufacturer's product drug on a plan sponsor's formulary or encouraging utilization of the manufacturer's drugs . . . . [T]he growing number and scale of rebates is the primary fuel of today's high drug prices. The truth is that PBMs have a vested interest to have drug prices remain high, and to extract rebates

> off of these higher prices. PBM formularies tend to favor drugs that offer higher rebates over similar drugs with lower net costs and lower rebates.[34]

305. The Manufacturer Defendants understand that PBM Defendants make more money as prices increase. This is confirmed by the January 2021 Senate Insulin Report after review of internal documents produced by the Manufacturers: [B]oth Eli Lilly and Novo Nordisk executives, when considering lower list prices, were sensitive to the fact that PBMs largely make their money on rebates and fees that are based on a percentage of a drug's list price.[35]

306. The documents eventually released by the Senate also show how the Manufacturers' pricing strategy focuses on *the PBMs' profitability*. In an internal August 6, 2015, email, Novo Nordisk executives debated delaying increasing the price of an at-issue drug in order to make the increase more profitable for *CVS Caremark*, stating:

> Should we take 8/18 [for a price increase], as agreed to by our [pricing committee], or do we recommend pushing back due to the recent CVS concerns on how we take price? . . . We know CVS has stated their disappointment with our price increase strategy (ie taking just after the 45th day) and how it essentially results in a lower price protection, admin fee and rebate payment for that quarter/time after our increase . . . it has been costing CVS a good amount of money. [36]

307. The Manufacturer Defendants also understand that because of the PBMs' market dominance, most payors, including Plaintiff Hamblen County and its Beneficiaries, accept the baseline national formularies offered by the PBMs with respect to the at-issue drugs.

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[34] Community Oncology Alliance & Frier Levitt, *Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers* (Feb. 2022), https://communityoncology.org/wpcontent/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf (last visited Jan. 14, 2023).

[35] Grassley & Wyden, *supra* note 2 at 89.

[36] Letter from Raphael A. Prober, Counsel for Novo Nordisk Inc., to Charles E. Grassley & Ron Wyden, S. Fin. Comm. (Mar. 8, 2019), https://www.finance.senate.gov/imo/media/doc/Novo_ Redacted.pdf (last visited Jan. 15, 2023).

308. The Insulin Pricing Scheme was borne from these understandings. Both sets of Defendants realized that if the Manufacturers artificially inflate their list prices while paying large, undisclosed Manufacturer Payments back to the PBMs, both the PBMs and Manufacturers would generate billions of unearned dollars. The plan worked.

309. Over the past several years the Manufacturers have raised prices in unison and have paid correspondingly larger Manufacturer Payments to the PBMs.

310. In exchange for the Manufacturers artificially inflating their prices and paying the PBMs substantial amounts in Manufacturer Payments, the PBM Defendants grant the Manufacturer Defendants' diabetes medications elevated prices and preferred status on their national formularies. During the relevant period, the rebate amounts (as a proportion of the list price) grew year-over-year while list prices themselves increased.

311. Beyond increased rebate demands, the PBMs also have sought and received larger and larger administrative fee payments and other Manufacturer Payments from the Manufacturers during the relevant period.

312. A recent study by the Pew Charitable Trust estimated that, between 2012 and 2016, the amount of administrative and other fees that the PBMs requested and received from the Manufacturers tripled, reaching more than $16 billion. The study observed that, although rebates were sent to payors during this period, PBMs retained the same volume of rebates in pure dollars, given the overall growth in rebate volume while administrative fees and spread pricing (charging a client payor more for a drug than the PBM pays the pharmacy) further offset reductions in retained rebate volumes.

313. Thus—and contrary to their public representations—the PBM Defendants' negotiations and agreements with the Manufacturer Defendants (and the formularies that result

from these agreements) have caused and continue to cause precipitous price increases for the at-issue drugs.

314. As a result of the Insulin Pricing Scheme, every payor, including Plaintiff, that pays for and/or reimburses for the at-issue drugs has been overcharged.

315. Moreover, the PBMs use this false price to misrepresent the amount of "savings" they generate for diabetics, payors, and the healthcare system. For example, in January 2016, Express Scripts' president Tim Wentworth stated at the 34th annual JP Morgan Healthcare Conference that Express Scripts "saved our clients more than $3 billion through the Express Scripts National Preferred Formulary."[37] Likewise, in April 2019, CVS Caremark President Derica Rice stated: "Over the last three years . . . CVS Caremark has helped our clients save more than $141 billion by blunting drug price inflation, prioritizing the use of effective, lower-cost drugs and reducing the member's out-of-pocket spend."[38]

316. In making these representations, the PBMs fail to disclose that the amount of "savings" generated is calculated based on the false list price, which is not paid by any entity in the pharmaceutical pricing chain and which all Defendants are directly responsible for artificially inflating.

317. The Insulin Pricing Scheme is a coordinated effort among the Manufacturer and PBM Defendants in which each agreed to, and did, participate, and which created enormous profits for all. For example:

a. The Manufacturers and the PBMs are in constant communication and regularly meet and exchange information to construct and refine the PBM formularies that

[37] Surabhi Dangi-Garimella, *PBMs Can Help Bend the Cost Curve: Express Scripts' Tim Wentworth*, AJMC (Jan. 12, 2016), https://www.ajmc.com/view/pbms-can-help-bendthe-cost-curve-express-scripts-tim-wentworth (last visited Jan. 15, 2023).

[38] CVS Health, *CVS Health PBM Solutions Blunted the Impact of Drug Price Inflation, Helped Reduce Member Cost, and Improved Medication Adherence in 2018* (Apr. 11, 2019), https://www.cvshealth.com/news-and-insights/press-releases/cvs-health-pbmsolutions-blunted-the-impact-of-drug-price (last visited Jan. 11, 2023).

form and fuel the scheme. As part of these communications, the Manufacturers are directly involved in determining not only where their own diabetes medications are placed on the PBMs' formularies and with what restrictions, but also in determining the same for competing products;

b. The Manufacturers and the PBMs share confidential and proprietary information with each other in furtherance of the Insulin Pricing Scheme, such as market data gleaned from the PBMs' drug utilization tracking efforts and mail-order pharmacy claims, internal medical efficacy studies, and financial data. Defendants then use this information in coordination to set the false prices for the at-issue medications and to construct their formularies in the manner that is most profitable for both sets of Defendants. The data that is used to further this coordinated scheme is compiled, analyzed, and shared either by departments directly housed within the PBM or by subsidiaries of the PBM, as is the case with OptumRx, which utilizes OptumInsight and Optum Analytics; and

c. The Manufacturers and the PBMs engage in coordinated outreach programs directly to patients, pharmacies, and prescribing physicians to convince them to switch to the diabetes medications that are more profitable for the PBMs and Manufacturers, even drafting and editing letters in tandem to send out to diabetes patients on behalf of the PBMs' clients. For example, the Grassley-Wyden Senate committee recently released an email where Eli Lilly discussed paying Defendant UnitedHealth Group and OptumRx additional rebates for every client that was converted to formularies that exclusively preferred Eli Lilly's at-issue drugs, including Humalog. The email continued: "United's leadership committee made one ask of Lilly – that we are highly engaged in the communication/pull through plan.[39] I of course indicated we fully expect to support this massive patient transition [to Eli Lilly's at-issue drugs favored by United] and provider education with the full breadth of Lilly resources. UHC also proactively thanked Lilly for our responsiveness, solution generation and DBU execution."

318. Rather than using their prodigious bargaining power to lower drug prices as they claim, Defendants instead used their dominant positions to conspire to generate billions of dollars in illicit profits at the expense of payors like Plaintiff.

F. Defendants Play Down the Insulin Pricing Scheme and Its Harms

319. On April 10, 2019, the United States House of Representatives Committee on Energy and Commerce held a hearing on industry practices titled, "Priced Out of a Lifesaving

[39] "Pull through" is an industry term that refers to an integrated process between PBMs and Manufacturers aimed at moving market share and increasing sales for a certain product following the PBM granting that product preferred placement on its formulary.

Drug: Getting Answers on the Rising Cost of Insulin."[40]

320. Representatives from all Defendants testified at the hearing, and each acknowledged before Congress that the price for insulin has increased exponentially in the past 15 years.

321. Further, each Defendant conceded that the price that diabetics pay out-of-pocket for insulin is too high. For example:

- Dr. Sumit Dutta, SVP and Chief Medical Officer of OptumRx since 2015, stated: "A lack of meaningful competition allows the [M]anufacturers to set high [list] prices and continually increase them which is odd for a drug that is nearly 100 years old and which has seen no significant innovation in decades. These price increases have a real impact on consumers in the form of higher out-of-pocket costs."

- Thomas Moriarty, Chief Policy and External Affairs Officer and General Counsel for CVS Health testified: "A real barrier in our country to achieving good health is cost, including the price of insulin products which are too expensive for too many Americans. Over the last several years, [list] prices for insulin have increased nearly 50 percent. And over the last ten years, [list] price of one product, Lantus, rose by 184 percent."

- Mike Mason, Senior Vice President of Eli Lilly when discussing how much diabetics pay out-of-pocket for insulin stated: "it's difficult for me to hear anyone in the diabetes community worry about the cost of insulin. Too many people today don't have affordable access to chronic medications . . ."

- Kathleen Tregoning, Executive Vice President External Affairs at Sanofi, testified: "Patients are rightfully angry about rising out-of-pocket costs and we all have a responsibility to address a system that is clearly failing too many people. . . we recognize the need to address the very real challenges of affordability . . . Since 2012, average out-of-pocket costs for Lantus have risen approximately 60 percent for patients . . ."

- Doug Langa, Executive Vice President of Novo Nordisk, stated: "On the issue of affordability . . . I will tell you that at Novo Nordisk we are accountable for the [list] prices of our medicines. We also know that [list] price matters to many, particularly those in high-deductible health plans and those that are uninsured."

[40] https:// www.congress.gov/event/116th-congress/house-event/109299?s=1&r=3 (last visited Jan. 9, 2023) (hereinafter *Priced Out of a Lifesaving Drug*).

322. None of the testifying Defendants claimed that the significant increase in the price of insulin was related to competitive factors such as increased production costs or improved clinical benefit.

323. Instead, Novo Nordisk's President Doug Langa's written testimony for the April 2019 hearing recognized "misaligned incentives" that have led to higher drug costs, including for insulin: "Chief among these misaligned incentives is the fact that the rebates pharmaceutical companies pay to PBMs are calculated as a percentage of WAC [list] price. That means a pharmaceutical company fighting to remain on formulary is constrained from lowering WAC price, or even keeping the price constant, if a competitor takes an increase. This is because PBMs will then earn less in rebates and potentially choose to place a competitor's higher-priced product on their formulary to the exclusion of others." Likewise, Mr. Langa's responses to questions for the record conceded that "[t]he disadvantage of a system in which administrative fees are paid as a percentage of the list price is that there is increased pressure to keep list prices high. . . ." The hearing transcript records Mr. Langa's further comments in this regard:

> So as you heard from Dr. Cefalu last week of the ADA [American Diabetes Association], there is this perverse incentive and misaligned incentives and this encouragement to keep list prices high. And *we've been participating in that system* because the higher the list price, the higher the rebate . . . There is a significant demand for rebates…. *We're spending almost $18 billion a year in rebates*, discount, and fees, and *we have people with insurance with diabetes that don't get the benefit of that*. (emphasis added)

324. Eli Lilly admitted that it raises list prices as a quid pro quo for formulary positions. At the April 2019 Congressional hearing, Mike Mason, Senior Vice President of Eli Lilly, testified:

> Seventy-five percent of our list price is paid for rebates and discounts . . . . $210 of a vial of Humalog is paid for discounts and rebates. . . . We have to provide rebates [to PBMs] in order to provide and compete for that [formulary position] so that people can use our insulin. In the very next question, Mr. Langa of Novo Nordisk was asked, "[H]ave you ever lowered a list price? His answer: "We have not."

325. Sanofi's Executive Vice President for External Affairs, Kathleen Tregoning, testified:

> The rebates is [sic] how the system has evolved. . . . I think the system became complex and rebates generated through negotiations with PBMs are being used to finance other parts of the healthcare system and not to lower prices to the patient.

Her written response to questions for the record acknowledged that "it is clear that payments based on a percentage of list price result in a higher margin [for PBMs] for the higher list price product than for the lower list price product."

326. The PBM Defendants also conceded at the April 2019 Congressional hearing that they grant preferred, or even exclusive, formulary position because of higher Manufacturer Payments paid by the Manufacturer Defendants.

327. In her responses to questions for the record, Amy Bricker, former SVP of Express Scripts and PCMA board member, confirmed that "manufacturers lowering their list prices" would give patients "greater access to medications;" yet when asked to explain why Express Scripts did not grant an insulin with a lower list price preferred formulary status, answered, "Manufacturers do give higher discounts [i.e., payments] for exclusive [formulary] position . . ." When asked why the PBM would not include both costly and lower-priced insulin medications on its formulary, Ms. Bricker stated plainly, "We'll receive less discount in the event we do that."[41]

328. As Dr. Dutta, SVP of OptumRx, perversely reasoned, the cheaper list-priced alternative Admelog is not given preference on the formulary because "it would cost the payer more money to do that . . . because the list price is not what the payer is paying. They are paying

[41] Buried in Express Scripts' 2017 10-K is the following: "We maintain contractual relationships with numerous pharmaceutical manufacturers, which provide us with, among other things administrative fees for managing rebate programs, including the development and maintenance of formularies that include particular manufacturer's products . . . ." That is, the Manufacturers pay the PBMs to effectively participate in the creation of formularies that payors are required to adopt as a condition for obtaining PBM services. Express Scripts Annual Report (Form 10-K) (FYE Dec. 31, 2017) at 24. It also notes that its business would be "adversely affected" if it were to "lose [its] relationship with one or more key pharmaceutical manufacturers." *Id.*

the net price."[42] In other words, under the pricing scheme, PBMs and manufacturers can make a drug with a lower list price effectively more expensive for payors and then ostensibly save payors from that artificially inflated price by giving preference to drugs that had higher list prices to begin with (yielding higher Manufacturer Payments to the PBMs).

329. While all Defendants acknowledged before Congress their participation in conduct integral to the Insulin Pricing Scheme, none revealed its inner workings or the connection between their coordination and the economic harm that payors, like Plaintiff, and Beneficiaries were unwittingly suffering. Instead, in an effort to obscure the true reason for precipitous price increases, each Defendant group pointed the finger at the other as the more responsible party.

330. The PBM Defendants testified to Congress that the Manufacturer Defendants are solely responsible for their list price increases and that the Manufacturer Payments that the PBMs receive are not correlated to rising insulin prices.

331. This testimony is false. The amounts Manufacturers pay back to the PBMs is *directly correlated* to an increase in list prices. On average, a $1 increase in Manufacturer Payments is associated with a $1.17 increase in list price. Reducing or eliminating Manufacturer Payments would lower prices and reduce out-of-pocket expenditures.

332. Further, in large part because of the increased list prices and related Manufacturer Payments, the PBMs' profit per prescription has grown substantially over the same time period that insulin prices have steadily increased. For example, since 2003, Defendant Express Scripts has seen its profit per prescription increase more than 500% per adjusted prescription.[43]

[42] *Id.* As noted in the hearing, even the "cheaper" alternative Admelog "costs over $200 a bottle."

[43] David Balto, *How PBMs Make the Drug Price Problem Worse*, Hill (Aug. 31, 2016, 5:51 PM), https://thehill.com/blogs/pundits-blog/healthcare/294025-how-pbms-make-thedrug-price-problem-worse (last visited Jan. 15, 2023).

333. Novo Nordisk's President, Doug Langa, submitted written testimony to Congress acknowledging "there is no doubt that the WAC [list price] is a significant component" of "what patients ultimately pay at the pharmacy counter." Yet, the Manufacturers urged upon Congress the fiction that the PBMs were solely to blame for insulin prices because of their demands for rebates in exchange for formulary placement. The Manufacturers claimed their hands were tied and sought to conceal their misconduct by suggesting that they have not profited off rising insulin prices.

334. Given the Manufacturers' claims that rebates were the sole reason for rising prices, each was asked directly during the Congressional hearing to guarantee it would decrease list prices if rebates were restricted or eliminated. The spokespersons for Eli Lilly, Novo Nordisk and Sanofi all said only that they would "consider it."

335. In addition, a 2020 study from the Institute of New Economic Thinking titled, "Profits, Innovation and Financialization in the Insulin Industry," demonstrates that during the time insulin price increases were at their steepest, distributions to the Manufacturers' shareholders in the form of cash dividends and share repurchases totaled $122 billion. In fact, during this period the Manufacturers spent a significantly lower proportion of profits on R&D compared to shareholder payouts. The paper also notes that "[t]he mean price paid by patients for insulin in the United States almost tripled between 2002 and 2013" and that "per-person spending on insulin by patients and insurance plans in the United States doubled between 2012 and 2016, despite only a marginal increase in insulin use."[44]

336. The 2022 Community Oncology Alliance report found:[45]

[44] Rosie Collington, *Profits, Innovation and Financialization in the Insulin Industry*, Inst. for New Econ. Thinking (Apr. 2020), https://www.ineteconomics.org/research/research-papers/ profits-innovation-and-financialization-in-the-insulin-industry (last visited Jan. 15, 2023).

[45] Community Oncology Alliance, *supra* note 29.

> [T]here are several important ways that PBM rebates increase the costs of drugs for both plan sponsors and patients. . . . PBMs employ exceedingly vague and ambiguous contractual terms to recast monies received from manufacturers outside the traditional definition of rebates, which in most cases must be shared with plan sponsors. Rebate administration fees, *bona fide* service fees, and specialty pharmacy discounts/fees are all forms of money received by PBMs and rebate aggregators which may not be shared with (or even disclosed to) the plan sponsor. These charges serve to increase the overall costs of drugs, while providing no benefit whatsoever to plan sponsors. . . . The total drug spend of a plan sponsor, regardless of whether it is a federal or state governmental program or a self-funded employer, will inevitably increase because PBMs are incentivized to favor expensive drugs that yield high rebates. . . .

337. In January 2021, the Senate Finance Committee (Grassley-Wyden) issued a report titled "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug,"[46] which detailed Congress's findings after reviewing more than 100,000 pages of internal company documents from Sanofi, Novo Nordisk, Eli Lilly, CVS Caremark, Express Scripts, OptumRx, and Cigna. The report concluded, among other things:

- The Manufacturer Defendants retain more revenue from insulin than in the 2000s—for example, Eli Lilly has reported a steady increase in Humalog revenue for more than a decade—from $1.5 billion in 2007 to $3 billion in 2018;
- The Manufacturer Defendants have aggressively raised the list price of their Insulin products absent significant advances in the efficacy of the drugs; and
- The Manufacturer Defendants only spend a fraction of their revenue related to the at-issue drugs on research and development—Eli Lilly spent $395 million on R&D costs for Humalog, Humulin, and Basaglar between 2014-2018, during which time the company generated $22.4 billion in revenue on these drugs.

[46] Grassley & Wyden, *supra* note 2 at 5, 7.

338. The truth is that, despite their finger pointing in front of Congress, the Manufacturers and PBMs are *both* responsible for their concerted efforts in creating the Insulin Pricing Scheme.

G. Defendants Profit from the Insulin Pricing Scheme

339. The Insulin Pricing Scheme affords the Manufacturer Defendants the ability to pay the PBM Defendants secret but significant Manufacturer Payments in exchange for formulary placement, which garners the Manufacturer Defendants greater revenues from sales without decreasing their profit margins. During the relevant period, the PBM Defendants granted national formulary position to each at-issue drug in exchange for large Manufacturer Payments and inflated prices.

340. The Manufacturer Defendants also use the inflated price to earn hundreds of millions of dollars in additional tax breaks by basing their deductions for donated insulins on the inflated list price.

341. Because of the increased list prices and related Manufacturer Payments, the PBMs' profit per prescription has grown exponentially during the relevant period as well. A recent study published in the Journal of the American Medical Association concluded that the amount of money that goes to the PBM Defendants for each insulin prescription increased more than 150% from 2014 to 2018. In fact, for transactions where the PBM Defendants control the PBM and the pharmacy (e.g., Caremark-CVS pharmacy) these Defendants were capturing an astonishing 40% of the money spent on each insulin prescription (up from only 25% just four years earlier), despite the fact that they do not contribute to the development, manufacture, innovation or production of the product.[47]

[47] Karen Van Nuys, et al., *Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans From 2014 to 2018*,

342. The PBM Defendants profit from the artificially inflated prices created by the Insulin Pricing Scheme in a number of ways, including by: (1) retaining a significant, yet undisclosed, percentage of the Manufacturers Payments, (2) using the inflated list price to generate profits from pharmacies, and (3) relying on the inflated list price to drive up the PBMs' margins through their own mail-order pharmacies.

The PBMs Pocket a Substantial Share of Manufacturer Payments

343. The first way in which the PBMs profit from the Insulin Pricing Scheme is by keeping a significant portion of the secret Manufacturer Payments.

344. The amount that the Manufacturers pay back to the PBMs has increased over time both in real dollars and as a proportion of the ever-increasing list prices.

345. Historically, contracts between PBMs and payors allowed the PBMs to keep most or all of the rebates they received, rather than forwarding them to the payor.

346. Over time, payors secured contract provisions guaranteeing payment to them of all or some portion of the rebates paid by the Manufacturers to the PBMs. Critically, however, "rebates" are only one aspect of the total Manufacturer Payments, particularly as "rebates" are narrowly defined and qualified by vague exceptions in the PBM contracts with payors.

347. Indeed, as described in the January 2021 Senate Insulin Report, the PBMs and Manufacturers coordinate to determine the contract options made available to payors: "Contracts between PBMs and manufacturers provide a menu of options from which their health plan clients can choose certain terms and conditions."[48] The contracts between the PBMs and Manufacturers also "stipulate terms the plans must follow regarding factors such as formulary placement and

JAMA Network (Nov. 5, 2021), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2785932 (last visited Aug. 23, 2023).

[48] Grassley & Wyden, *supra* note 2 at 40.

competition from other drugs in the therapeutic class."[49] Thus, the Manufacturers ultimately played a role in dictating the terms and conditions of the contracts that payors like Plaintiff entered into with PBMs. Of course, the payors were not involved in the coordination or the negotiation of the contracts between the PBMs and Manufacturers and the PBMs disclosed only the fact that such relationships may exist—the terms of the contracts, the consideration exchanged between the PBMs and Manufacturers, and the means of reaching these determinations all were and remain shrouded in secrecy.

348. The PBM and Manufacturer Defendants thus created a "hide-the-ball" system where payors like Plaintiff are not privy to rebate negotiations or contracts between the Manufacturers and the PBMs. The consideration exchanged between them (and not shared with payors) is labeled and relabeled. As more payors moved to contracts that required PBMs to remit some or all of the manufacturer "rebates" through to the payor, the PBMs rechristened Manufacturer Payments to shield them from scrutiny and from their payment obligations. Payments once called "rebates" now include administrative fees, volume discounts, service fees, inflation fees, or other industry monikers designed to obfuscate the substantial sums being secretly exchanged between the PBMs and the Manufacturers.

349. Just last year, the Senate Commerce, Science and Transportation Committee released testimony from David Balto—a former antitrust attorney with the DOJ and Policy Director for the FTC's Bureau of Competition—from a hearing on fairness and transparency in drug pricing:

> The PBM rebate system turns competition on its head with PBMs seeking higher, not lower prices to maximize rebates and profits. In the past decade, PBM profits have increased to $28 billion annually. . . . PBMs establish tremendous roadblocks to prevent payors from knowing the amount of rebates they secure. Even sophisticated buyers are unable to secure specific drug by drug rebate information.

[49] *Id.* at 44.

> PBMs prevent payors from being able to audit rebate information. As the Council of Economic Advisors observed, the PBM market lacks transparency as "[t]he size of manufacturer rebates and the percentage of the rebate passed on to health plans and patients are secret." Without adequate transparency, plan sponsors cannot determine if the PBMs are fully passing on any savings, or whether their formulary choices really benefit the plan and subscribers.

350. The renamed, undisclosed Manufacturer Payments are substantial. "Administrative fees" are one example. A heavily redacted complaint filed by Defendant Express Scripts in 2017 revealed that Express Scripts retains up to 13 times more in "administrative fees" than it remits to payors in rebates.[50]

351. These so-called administrative fees typically are based on a percentage of the drug price—as opposed to a flat fee—such that even if the actual "administrative" cost associated with processing two drugs is the same, the "administrative fee" would be correspondingly higher for the higher-priced drug, which creates (by design) a perverse incentive to give preference to more expensive drugs. Moreover, the PBM Defendants' contracts with payors, including those with Plaintiff, narrowly define "rebates" by tying them to patient drug utilization, so rebates for formulary placement are characterized as "administrative fees" that are not remitted to payors and are beyond a payor's contractual audit right to verify the accuracy of "rebate" payments under the contracts.

352. The opaque nature of these arrangements between the Manufacturers and PBM Defendants also makes it impossible for a given payor to discover, much less assess or confront, conflicts of interest that may affect it or its members. The January 2021 Senate Insulin Report observed with respect to these arrangements: "Relatively little is publicly known about these financial relationships and the impact they have on insulin costs borne by consumers."[51]

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[50] *Express Scripts, Inc. v. Kaleo, Inc.*, No. 4:17-cv-01520-RLW (E.D. Mo. 2017).
[51] Grassley & Wyden, *supra* note 2 at 4.

353. Unsurprisingly, the PBMs have gone to great lengths to obscure these renamed Manufacturer Payments in order keep them for themselves and to avoid scrutiny from payors and others.

354. For example, with regard to the Manufacturer Payments now known as "inflation fees," the PBMs often create a hidden gap between how much the Manufacturers pay them to increase their prices and the amount in "price protection guarantees" that the PBMs agree to pay back to their client payors.

355. In particular, the Manufacturer Defendants often pay the PBM Defendants "inflation fees" in order to increase the price of their diabetes medications. The thresholds for these payments are typically set at around 6% to 8%—if the Manufacturer Defendants raise their prices by more than the set percentage during a specified time period, they pay the PBM Defendants an additional "inflation fee" (based on a percentage of the list prices).

356. For many of their clients, the PBMs have separate "price protection guarantees" that state that if the overall drug prices for that payor increase by more than a set amount, then the PBMs will remit a portion of the amount to the client.

357. The PBMs set these "price protection guarantees" at a higher rate than the thresholds that trigger the Manufacturers' "inflation fees," usually around 10%-15%.

358. Thus, if the Manufacturers increase their list prices more than the 6% (or 8%) inflation fee rate but less than the 10%-15% client price protection guarantee rate, then the PBMs keep all of these "inflation fee" payments. This is a win-win for the Manufacturers and PBMs—they share and retain the entire benefit of these price increases while the PBM contracts with payors imply that payors are protected from price hikes by their price protection guarantees.

359. The PBMs also hide the renamed Manufacturer Payments with "rebate aggregators." Rebate aggregators, sometimes referred to as rebate group purchasing organizations ("GPOs"), are entities that negotiate for and collect payments from drug manufacturers, including the Manufacturer Defendants, on behalf of a large group of pharmacy benefit managers (including the PBM Defendants) and different entities that contract for pharmaceutical drugs.

360. These rebate aggregators are often affiliated with or owned by the PBM Defendants, such as Ascent Health Services (Express Scripts), Coalition for Advanced Pharmacy Services and Emisar Pharma Services (OptumRx), and Zinc (CVS Caremark).

361. The PBMs carefully guard the revenue streams from their rebate aggregator activities, hiding them in complex contractual relationships and not reporting them separately in their quarterly SEC filings.

362. Certain rebate-aggregator companies are located offshore, for example, in Switzerland (Express Scripts' Ascent Health) and Ireland (Emisar Pharma Services), making oversight even more difficult.

363. As summarized by the recent Community Oncology Alliance report:[52]

> PBMs have increasingly "delegated" the collection of manufacturer rebates to "rebate aggregators," which are often owned by or affiliated with the PBMs, without seeking authorization from plan sponsors and without telling plan sponsors. . . . Even some of the major PBMs (i.e., the "Big Three" PBMs) sometimes find themselves contracting with other PBMs' rebate aggregators for the collection of manufacturer rebates. . . . In both the private sector and with respect to government health care programs, the contracts regarding manufacturer rebates (i.e., contracts between PBMs and rebate aggregators, as well as contracts between PBMs/rebate aggregators and pharmaceutical manufacturers) are not readily available to plan sponsors.

364. For example, a 2017 audit conducted by a local governmental entity on Defendant OptumRx related to its PBM activities from 2013 to 2015 concluded that the auditor was unable

[52] Community Oncology Alliance, *supra* note 29.

to verify the percentage of rebates OptumRx remitted to its client payor because OptumRx would not allow the auditor access to its rebate contracts. The audit report explained:

> Optum[Rx] has stated that it engaged the services of an aggregator to manage its rebate activity. Optum[Rx] shared that under this model, they are paid by their aggregator a certain amount per prescription referred. Then, the aggregator, through another entity, seeks rebates from the drug manufacturers, based upon the referred [Payor Client] prescription utilization, and retains any rebate amounts that may be received. Optum[Rx] states that they have paid [Payor Client] all amounts it has received from its aggregator, and that they do not have access to the contracts between the aggregator (and its contractors) and the manufacturer. However, our understanding is that Optum[Rx] has an affiliate relationship with its aggregator.[53]

365. A footnote in the audit report clarifies that "Optum[Rx] contracted with Coalition for Advanced Pharmacy Services (CAPS), and CAPS in turn contracted with Express Scripts, Inc."

366. In other words, according to this report, OptumRx contracts with its own affiliate aggregator Coalition for Advanced Pharmacy Services, who then contracts with OptumRx's co-conspirator Express Scripts, who then contracts with the Manufacturers for rebates related to OptumRx's client's drug utilization. OptumRx then uses this complex relationship to obscure the amount of Manufacturer Payments that are being generated from its client's utilization.

367. A subsequent audit by the same local entity—covering the period September 2017 to September 2018, concluded:[54]

> Several material weaknesses in Broward's agreement with Optum were identified, many of which are commonplace across pharmacy benefit manager agreements in general. Due to contract weaknesses, comparison of Broward's PBM agreement, including rebate amounts received, to the Consultant's marketplace data is not feasible. Broward could save an estimated $1,480,000 per year in net prescription drug benefit expenses (based upon minimum rebate guarantees) by switching from

[53] Laura Rogers & Stacey Thomas, Broward County Florida, Audit of Pharmacy Benefit Management Services Agreement, No. 18-13 (Dec. 7, 2017), https://www.broward.org/Auditor/Reports/Documents/2017_1212%20Agenda%20Review%20of%20Pharmacy%20Benefit%20Management%20Services%20by%20StoneBridge/2017_1212%20Exh1_OptumRx.pdf (last visited Jan. 15, 2023).

[54] Broward County, Florida, *Analysis of Broward County's Prescription Drug Coverage*, https://www.broward.org/Auditor/Reports/Reports/082019_Exh1_BCRxDrug_19-15.pdf (last visited Aug. 23, 2023).

> its current flawed agreement with Optum, to an agreement with its Coalition, which offers clearly defined terms, increased rebate guarantees and cost saving requirements.

Among other "loopholes" discovered in the contract were a number of "flawed" (i.e., vague and manipulable) definitions—including the definition of Rebates, which "allows the exclusion of monies that should be included—and limitation with respect to "Pass Through Transparency Pricing."

368. The January 2021 Grassley-Wyden Senate Report summarizing findings of their two-year probe into the Insulin Pricing Scheme contained the following observation on these rebate aggregators[55]:

> [T]he recent partnership between Express Scripts and Prime Therapeutics may serve as a vehicle to avoid increasing legislative and regulatory scrutiny related to administrative fees by channeling such fees through a Swiss based group purchasing organization (GPO), Ascent Health. While there are several regulatory and legislative efforts underway to prohibit manufacturers from paying administrative fees to PBMs, there is no such effort to change the GPO safe harbor rules. New arrangements used by PBMs to collect fees should be an area of continued investigative interest for Congress.

369. Federal regulations governing Medicare attempt to capture all possible forms of Direct or Indirect Remuneration (DIR) to PBMs (and plan sponsors), defining DIR as "any form of price concession" received by a plan sponsor or PBM "from any source," including "discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, legal judgment amounts, settlement amounts from lawsuits or other legal action, and other price concessions or similar benefits. DIR also includes price concessions from and additional contingent payments to network pharmacies that cannot reasonably be determined at the point of sale."[56]

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[55] Grassley & Wyden, *supra* note 2 at 83.

[56] CMS, *Final Medicare Part D DIR Reporting Guidance for 2021* at 7, https://www.cms.gov/files/document/final2021dirreportingreqsmemo508v3.pdf (last visited Jan. 15, 2023).

370. The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) considers all of the following as DIR: rebates, grants, reduced price administrative services, PBM-retained rebates, PBM rebate guarantee amounts, all post-point of sale payments by pharmacies that are not included in the negotiating price including dispensing incentive payments, prompt pay discounts, and payment adjustments. On the other hand, "bona fide service fees from pharmaceutical manufacturers" and "remuneration for administrative services with no impact on the sponsor's or PBM's drug cost (e.g., PBM incentive payments)" are not considered DIR, but only to the extent they reflect fair market value for services rendered.[57]

371. Because the PBMs retain and conceal a majority of the secret Manufacturer Payments that they receive, they are able to reap significant profits on the Insulin Pricing Scheme.

372. Even where payor clients receive a portion of the Manufacturer Payments from their PBM, those payors still are significantly overcharged as a direct result of the Insulin Pricing Scheme given the extent to which Defendants have deceptively and egregiously inflated the prices of the at-issue drugs.

The Insulin Pricing Scheme Allows the PBMs to Profit Off Pharmacies

373. A second way the PBM Defendants profit off the Insulin Pricing Scheme is by using the Manufacturers' inflated price to derive profit from the pharmacies with whom they contract, including those in Hamblen County.

374. Each PBM Defendant decides which pharmacies are included in the PBM's network and how much it will reimburse these pharmacies for each drug dispensed.

375. The PBM Defendants, in coordination with the Manufacturers, directly reach out to patients, pharmacies, and prescribing physicians to convince them to switch to the diabetes

[57] *Id.* at 6-7.

medications that are more profitable for the PBMs and Manufacturers, even drafting and editing letters together to send to diabetes patients on behalf of the PBMs' clients [58]. The Defendants also petition these recipients to use the PBM Defendants' mail-order pharmacies and have succeeded in convincing patients, pharmacies, and prescribing physicians to do so.

376. The PBMs pocket the spread between the amount that the PBMs are paid by their clients for the at-issue drugs (which are based on the prices generated by the Insulin Pricing Scheme) and the amount the PBM reimburses the pharmacy (which often is less). In other words, the PBMs charge a client like Hamblen County more for a drug than the PBM pays the pharmacy and pockets the difference.

377. A bipartisan bill introduced in the Senate in 2022 (the Pharmacy Benefit Manager Transparency Act—S. 4293)—would have, criminalized spread pricing, which the bill defined as "[c]harg[ing] a health plan or payer a different amount for a prescription drug's ingredient cost or dispensing fee than the amount the pharmacy benefit manager reimburses a pharmacy for the prescription drug's ingredient cost or dispensing fee where the pharmacy benefit manager retains the amount of any such difference." The bill has not yet been enacted.[59]

378. Not coincidentally, the PBMs' industry-funded trade association PCMA spent $7.8 million on federal lobbying in 2021 and more $6 million through the third quarter of 2022.[60]

379. The PBMs often disclose the concept of spread pricing to payors, but only in vague terms that require no accountability and are not subject to the payors' audit rights because the revenue is not defined as a "rebate" in the PBM contracts with payors.

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[58] See supra 326(c).

[59] https://www.govtrack.us/congress/bills/117/s4293 (last visited Jan. 10, 2023).

[60] https://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2021&id=D000028342 (2021); https://www.opensecrets.org/federallobbying/clients/summary?cycle= 2022&id=D000028342 (2022) (last visited Jan. 10, 2023).

380. This spread pricing, like the secret Manufacturer Payment negotiation, happens behind closed doors. There is no transparency, no commitment from the PBM Defendants to account for the cost effectiveness of a drug, and no communication to either the payor or the pharmacy to let them know if they are getting a fair deal.

381. The higher the Manufacturers' list prices, the more money the PBMs make off this spread. At the same time, a Beneficiary's out-of-pocket co-pay or deductible cost often is more than if the client had simply paid cash outside of his or her plan. On top of this, the PBM contracts generally allow no rebates to payors where the Beneficiary is responsible for 100% of the drug cost, e.g., under his or her deductible.

382. The PBMs also use the Insulin Pricing Scheme to generate additional profits from pharmacies by charging the pharmacies post-purchase fees, including DIR (Direct or Indirect Remuneration) fees, based on the list prices—and again, the higher the list price for each diabetes medication sold, the more fees the PBMs generate—or by applying "retrospective" discounts. So, for example, a payor's (and member's co-pay or deductible) cost may be $100, but the price is discounted post-purchase (between the PBM and the (often self-owned) pharmacy) to $90 with the spread going to the PBM.

383. CMS addressed these and similar DIR issues in a proposed rule in 2017. While noting the growth of "pharmacy price concessions" that "are negotiated between pharmacies and their sponsors or PBMs," CMS nevertheless concluded:[61]

> When manufacturer rebates and pharmacy price concessions are not reflected in the price of a drug at the point of sale, beneficiaries might see lower premiums, but they do not benefit through a reduction in the amount they must pay in cost-sharing, and thus, end up paying a larger share of the actual cost of a drug. Moreover, given the increase in manufacturer rebates and pharmacy price concessions in recent

[61] Medicare Program; Contract Year 2019 Policy and Technical Changes, 82 Fed. Reg. 56336 (Nov. 29, 2017), https://www.govinfo.gov/content/pkg/FR-2017-11-28/pdf/2017-25068.pdf. Last visited Aug 23, 2023.

> years, the point-of-sale price of a drug that a Part D sponsor reports on a PDE record as the negotiated price is rendered less transparent . . . .

CMS expressed further concern that when rebates and other price concessions are not reflected in the negotiated point-of-sale drug price, it "can impede beneficiary access to necessary medications, which leads to poorer health outcomes and higher medical care costs for beneficiaries . . . ."

384. PBMs thus make money coming and going. In a pre-PBM world, a competitively priced drug might have a (hypothetical) net cost to a health plan $50 and that is what it paid. PBMs enter the picture and coordinate with Manufacturers to increase the list price to $150. The PBMs then "negotiate" the inflated price down to $100 and take a $50 rebate, some of which may be forwarded to the payor, whose net cost is less than the inflated list price, but whose real-world cost is considerably more than if the PBMs were not involved.

385. At the same time, the PBM receives "administrative fees" for including certain drugs on its formularies, which are not considered "rebates." The PBM also receives "service fees" or other payment for "administrative services" provided to the Manufacturers such as "formulary compliance initiatives," "education services," or "the sale of non-patient identifiable claim information." All of these revenues are outside the definition of "rebates."

386. The PBM then charges payors like the County for administrative fees for providing pharmacy benefit management services and charges for drug costs (i.e. ingredient costs) and per-prescription dispensing fees, as well as additional administrative fees for services not included in the PBM's general administrative obligations. The PBM also receives rebates and/or discounts (pre-purchase or post-purchase) from the pharmacies, which it often owns. These too are excluded from the definition of "rebates." These and other vaguely described revenue streams are sometimes disclosed but only in hazy, overly generalized terms. And they are beyond a payor's contractual

rights to audit for "transparency" purposes because they are not defined "rebates." Additionally, the PBM may take months to pay rebates to payors and the PBM retains all interest on, and the time-value of, the rebates pending payment.

387. Payors have no access to, and no knowledge of, the intricacies of the dealings between the PBM Defendants and the Manufacturers that are shrouded by such vague "disclosures" (which vary in detail, but not in substance, in all three of the PBM Defendants' adhesive contracts).

The Insulin Pricing Scheme Increases PBM Mail-Order Profit

388. Another way PBMs profit from the Insulin Pricing Scheme is through the PBM Defendants' own mail-order pharmacies. The higher the price that PBM Defendants are able to get customers, such as Plaintiff, to pay for diabetes medications, the higher the profits PBM Defendants realize through their mail-order pharmacies.

389. Because the PBMs base the price they charge for the at-issue diabetes medications on the Manufacturers' price, the more the Manufacturers inflate their prices, the more money the PBMs make. For example, the PBMs have colluded with the Manufacturers so that the PBMs often know when the Manufacturers are going to raise their prices. The PBMs use this opportunity to purchase a significant amount of the at- issue drugs prior to the price increase, at the lower rate. Then, after the Manufacturers raise their price, the PBMs charge their mail-order customers based on the higher, increased prices and pocket the difference. The PBMs make significant amounts of money through this arbitrage scheme.

390. The PBMs also charge the Manufacturer Defendants fees related to their mail-order pharmacies, such as pharmacy supplemental discount fees, that are directly tied to the

Manufacturers' price. Thus, once again, the higher the price, the more money the PBMs make on these fees.

391. In sum, every way in which the PBMs make money on diabetes medications is tied directly to creating higher prices and inducing larger secret Manufacturer Payments. The PBMs are not lowering the price of diabetes medications as they publicly represent; they are making billions of dollars by fueling these skyrocketing prices.

H. Plaintiff Purchases the At-Issue Drugs Directly from Defendants

392. As a government employer, Plaintiff serves its residents by providing public safety, emergency management, and health services, among other vital roles. As more federal and state responsibilities are mandated to local government, Plaintiff has a growing list of demands on a limited budget. Consequently, any significant increase in spending can have a severe detrimental effect on Plaintiff's overall budget and, in turn, negatively impact its ability to provide necessary services to the community.

393. One benefit Plaintiff provides the Beneficiaries of its healthcare plan is payment for a large portion of their pharmaceutical purchases. In this role, Plaintiff spent significant amounts on the at-issue diabetes medications during the relevant period.

394. Because Plaintiff maintains a self-funded plan for County employees, Plaintiff does not rely on a third-party insurer to pay for insured employees' medical care, pharmaceutical benefits, or prescription drugs. Rather, Plaintiff directly contracts with, and directly pays, PBMs (and their affiliated pharmacies) for pharmaceutical benefits and prescription drugs, including the at-issue medications.

395. Plaintiff also purchased, and still purchases, the at-issue drugs directly from these PBMs (and their affiliated pharmacies) for use in Plaintiff's county-run facilities.

396. In the context of Plaintiff's purchases of the at-issue drugs, Plaintiff and its Beneficiaries are the only victims of the Insulin Pricing Scheme. Plaintiff is the only named party that pays the full purchase price for the at-issue drugs, and the only named party that has not knowingly participated in the Insulin Pricing Scheme. Neither the PBM Defendants nor the Manufacturers Defendants suffer losses from the Insulin Pricing Scheme.

397. As part of purchasing the at-issue drugs from the PBMs, Plaintiff directly pays the PBMs artificially inflated costs resulting from the Insulin Pricing Scheme, including "administrative fees," "inflation fees," "discount fees," and more—all of which are associated with Plaintiff's purchase of the at-issue drugs from the PBM Defendants. Because the at-issue medications are potentially life-saving drugs, and because the Manufacturers control the market for these drugs, Plaintiff has no choice but to pay these exorbitant, artificially inflated prices directly to PBM Defendants.

398. Plaintiff also relies (and has relied) on CVS Caremark and Express Scripts as administrative agents, for the alleged purposes of limiting its administrative burden and controlling pharmaceutical drugs costs.

399. In providing PBM services to the County, including developing and offering formularies for Plaintiff's prescription plan, constructing and managing Plaintiff's pharmacy network (which included the PBMs' retail and mail-order pharmacies), processing pharmacy claims, and providing mail-order pharmacy services, Express Scripts and CVS Caremark set the amount Plaintiff paid in coordination with the Manufacturer Defendants and, utilizing the false prices, generated by the Insulin Pricing Scheme. Plaintiff paid Express Scripts and CVS Caremark directly for the at-issue drugs.

I. Defendants Deceived Plaintiff

400. At no time has either Defendant group disclosed the Insulin Pricing Scheme or the reasons for the false list prices produced by it.

The Manufacturer Defendants Deceived Plaintiff

401. At all times during the relevant period, the Manufacturer Defendants knew that the list prices, net prices, and payors' net costs (purchase prices) generated by the Insulin Pricing Scheme were false, excessive, and untethered to any legal, competitive, or fair market price.

402. The Manufacturer Defendants knew that these prices did not bear any rational relationship to the actual costs incurred or prices realized by Defendants, did not result from transparent or competitive market forces, and were artificially and arbitrarily inflated for the sole purpose of generating profits for Defendants.

403. The insulin market, and Defendants' business arrangement relating thereto, exhibit the key features of oligopolies (see Fig. 14)—concentration of numerous competitors into a small group of firms that dominates the market, high barriers to entry, ability to set and control prices, firm interdependence, and maximal revenues.

404. The Manufacturer Defendants also knew that payors, including Plaintiff, relied on the false list prices generated by the Insulin Pricing Scheme to pay for the at-issue drugs.

405. The Manufacturer and PBM Defendants further knew that Plaintiff—like any reasonable consumer, and particularly one with fiduciary obligations to its Beneficiaries—wanted and expected to pay a price reflecting the lowest fair market value for the drugs (which was not necessarily the same as the lowest price in the market, given that all prices were inflated due to the Insulin Pricing Scheme).

406. Despite this knowledge, the Manufacturer Defendants published the prices generated by the Insulin Pricing Scheme throughout the United States and Tennessee through

publishing compendia, in various promotional and marketing materials distributed by entities downstream in the drug supply chain, and directly to pharmacies which then used these prices to set the amount that the pharmacies charged for the at-issue drugs.

407. The Manufacturer Defendants also publish these prices to the PBMs and pharmacies, which then use them to charge diabetics and payors like Plaintiff for the at-issue drugs.

408. By publishing their prices throughout Tennessee, the Manufacturer Defendants held these prices out as a reasonable price upon which to base the prices that payors actually pay for the at-issue drugs.

409. These representations are false. The Manufacturer Defendants knew that their artificially inflated list prices were not remotely related to their cost, their fair market value in a competitive market, or the net price received for the at-issue drugs.

410. During the relevant period, the Manufacturer Defendants published prices in Tennessee at hundreds of dollars per dose for the same at-issue drugs that would have been profitable to Manufacturers at prices less than $10 per dose.

411. The Manufacturer Defendants also have publicly represented that they price the at-issue drugs according to each drug's value to the health care system and the need to fund innovation. For example, briefing materials prepared for Dave Ricks, Eli Lilly's CEO, as a panelist at the 2017 Forbes Healthcare Summit included "Reactive Key Messages" on pricing that emphasized the significant research and development costs for insulin. During the relevant period, executives from Sanofi and Novo Nordisk also falsely represented that research and development costs were key factors driving the at-issue price increases.[62]

[62] Drug Pricing Investigation, H.R. Comm. On Oversight and Reform, 117th Cong. (2021), https://web.archive.org/web/20211215170722/https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf (last visited Jan. 10, 2023).

412. To the contrary, between 2005 and 2018, Eli Lilly spent $680 million on R&D costs related to Humalog while earning $31.35 billion in net sales during that same time period. In other words, Eli Lilly made more than 46 times its reported R&D costs on Humalog during this portion of the relevant period, i.e., R&D costs amounted to about 2% of net sales (whereas R&D costs for pharmaceuticals typically amount to around 20% of total revenues). Novo Nordisk has spent triple the amount it spends on R&D on stock buyouts and shareholder dividend payouts in recent years.[63]

413. The January 2021 Senate Insulin Report found that the PBMs consider insulins to be "interchangeable" from "a clinical perspective" and that Manufacturers focus their R&D efforts on new insulin-related device, equipment, and other mechanical parts which are separate from insulin's formulation."[64]

414. A House Oversight Committee staff report concluded that "drug companies' claims that reducing U.S. prescription drug prices will harm innovation is overblown" and that "[m]any drug companies spent a significant portion of their R&D budget on finding ways to suppress generic and biosimilar competition while continuing to raise prices, rather than on innovative research."[65]

415. In sum, the Manufacturer Defendants affirmatively withheld the truth from Plaintiff and specifically made these misrepresentations in furtherance of the Insulin Pricing Scheme and

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[63] *Id.*

[64] Grassley & Wyden, *supra* note 2 at 5, 17.

[65] U.S. House of Reps., *Drug Pricing Investigation: Industry Spending on Buybacks, Dividends and Executive Compensation* (July 2021), https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/COR%20Staff%20Report%20-%20Pharmaceutical%20Industry%20Buybacks%20Dividends%20Compared%20to%20Research.pdf (last visited Aug. 23, 2023).

to induce Plaintiff's reliance to purchase the at-issue drugs. The PBM Defendants Deceived Plaintiff

416. The PBM Defendants ensured that the Manufacturer Defendants' artificially inflated list prices harmed diabetics and payors by selecting the highest price at-issue drugs for preferred formulary placement and by requiring that their contracts with both pharmacies and with payors include such prices as the basis for payment.

417. The PBM Defendants perpetuate the use of the artificially inflated insulin prices because it allows them to obscure the actual price any entity in the drug pricing chain is paying for the at-issue drugs. This lack of transparency affords Defendants the opportunity to construct and perpetuate the Insulin Pricing Scheme and to profit therefrom at the expense of Tennessee payors, including Plaintiff.

418. At all times throughout the relevant period, the PBMs have purposefully, consistently, and routinely misrepresented that they negotiate with Manufacturer Defendants and construct formularies for the benefit of payors and patients by lowering the price of the at-issue drugs and by promoting the health of diabetics. Representative examples include: [66]

- Defendant CVS Caremark has for the past decade consistently stated in its annual reports that its design and administration of formularies are aimed at reducing the costs and improving the safety, effectiveness, and convenience of prescription drugs. CVS Caremark has further stated that it maintains an independent panel of doctors, pharmacists, and other medical experts to review and approve the selection of drugs based on safety and efficacy for inclusion on one of Caremark's template formularies and that CVS Caremark's formularies lower the cost of drugs.

- Likewise, Defendant Express Scripts has consistently represented that it works with clients, manufacturers, pharmacists, and physicians to increase efficiency in the drug distribution chain, to manage costs in the pharmacy benefit chain, and to improve members' health outcomes. Its annual reports consistently claim that in making formulary recommendations, Express Scripts' Pharmacy & Therapeutics Committee considers the drug's safety and efficacy, without any information on or

[66] CVS Health Annual Reports (Form 10-K) (FY 2010-2019); OptumRx Annual Reports (Form 10-K) (FY 2010-2019); Express Scripts Annual Reports (Form 10-K) (FY 2010-2019).

consideration of the cost of the drug, including any discount or rebate arrangement that Express Scripts negotiates with the Manufacturer, and that Express Scripts fully complies with the P&T Committee's clinical recommendations regarding drugs that must be included or excluded from the formulary based on their assessment of safety and efficacy.

- Similarly, Defendant OptumRx has consistently stated in its annual reports over the past decade that OptumRx's rebate contracting and formulary management assist customers in achieving a low-cost, high-quality pharmacy benefit. It has consistently claimed that it promotes lower costs by using formulary programs to produce better unit costs, encouraging patients to use drugs that offer improved value and that OptumRx's formularies are selected for health plans based on their safety, cost and effectiveness.

419. In addition to these general misrepresentations, the PBM Defendants have during the relevant period purposefully, consistently, and routinely made misrepresentations about the at-issue diabetes medications. Representative examples include:

- In a public statement issued in November 2010, CVS Caremark represented that it was focused on diabetes to "help us add value for our PBM clients and improve the health of plan members . . . a PBM client with 50,000 employees whose population has an average prevalence of diabetes could save approximately $3.3 million a year in medical expenditures."[67]

- In 2010, Andrew Sussman, Chief Medical Officer of CVS Caremark, stated on national television that "CVS is working to develop programs to hold down [diabetes] costs."[68]

- In a public statement issued in November 2012, CVS Caremark represented that formulary decisions related to insulin products "is one way the company helps manage costs for clients."[69]

- In 2016, Glen Stettin, Senior Vice President and Chief Innovation Officer at Express Scripts, said in an interview with a national publication that "[d]iabetes is wreaking havoc on patients, and it is also a runaway driver of costs for payors . . .

[67] Chain Drug Review, *CVS Expands Extracare for Diabetes Products* (May 11, 2010), https://www.chaindrugreview.com/cvs-expands-extracare-for-diabetes-products/ (last visited Jan. 15, 2023).

[68] CBS News, Diabetes Epidemic Growing (June 22, 2010, 11:29 AM), https://www.cbsnews.com/news/diabetes-epidemic-growing/ (last visited Aug. 23, 2023).

[69] Jon Kamp & Peter Loftus, *CVS' PBM Business Names Drugs It Plans to Block Next Year*, WSJ (Nov. 8, 2012), https://www.wsj.com/articles/SB10001424127887324439804578 107040729812454 (last visited Jan. 15, 2023).

[Express Scripts] helps our clients and diabetes patients prevail over cost and care challenges created by this terrible disease."[70] Mr. Stettin also claimed that Express Scripts "broaden[s] insulin options for patients and bend[s] down the cost curve of what is currently the costliest class of traditional prescription drugs."[71]

- In a 2018 Healthline interview, Mark Merritt, longtime President of the PBM trade association PCMA, stated: "[Through their formulary construction], PBMs are putting pressure on drug companies to reduce insulin prices."[72]

- CVS Caremark's Chief Policy and External Affairs Officer claimed in the April 2019 hearings that CVS Caremark "has taken a number of steps to address the impact of insulin price increases. We negotiate the best possible discounts off the manufacturers' price on behalf of employers, unions, government programs, and beneficiaries that we serve."[73]

- Dr. Sumit Dutta, SVP and Chief Medical Officer of OptumRx, testified before the U.S. Congress in the April 2019 hearing that for "insulin products . . . we negotiate with brand manufacturers to obtain significant discounts off list prices on behalf of our customers."[74]

- The PBM-funded trade association PCMA's website acknowledges, "the insulin market is consolidated, hindering competition and limiting alternatives, leading to higher list prices on new and existing brand insulins," but then misleadingly claims that "PBMs work hard to drive down costs using formulary management and rebates."[75]

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[70] https://www.bizjournals.com/stlouis/news/2016/08/31/express-scripts-launchesprogram-to-control.html (last visited Jan. 15, 2023).

[71] Angela Mueller, *Express Scripts Launches Program to Control Diabetes Costs*, St. Louis Bus. J. (Aug. 31, 2016), https://drugstorenews.com/pharmacy/express-scriptsimplements-latest-diabetes-care-value-program (last visited Jan. 15, 2023).

[72] Dave Muoio, *Insulin Prices: Are PBMs and Insurers Doing Their Part?*, Population Health Learning Network (Dec. 2016), https://www.hmpgloballearningnetwork.com/site/frmc/ article/insulin-prices-are-pbms-and-insurers-doing-their-part (last visited Jan. 15, 2023).

[73] *Priced Out of a Lifesaving Drug*, *supra* note 35.

[74] *Id*.

[75] PCMA, *PCMA on National Diabetes Month: PBMs Lowering Insulin Costs, Providing Support to Patients* (Nov. 16, 2020), https://www.pcmanet.org/pcma-on-nationaldiabetes-month-pbms-lowering-insulin-costs-providing-support-to-patients/ (last visited Aug. 23, 2023); Visante, *Insulins: Managing Costs with Increasing Manufacturer Prices* (2020), https://www. pcmanet.org/ wpcontent/uploads/2020/08/PCMA_Visante-Insulins-Prices-and-Costs-.pdf.

420. The PBM Defendants not only falsely represent that they negotiate with the Manufacturer Defendants to lower the price of the at-issue diabetes medications for *payors*, but also for diabetic *patients* as well. Representative examples include:

- Express Scripts' code of conduct, effective beginning in 2015, states: "At Express Scripts we're dedicated to keeping our promises to *patients and clients* . . . This commitment defines our culture, and all our collective efforts are focused on our mission to make the use of prescription drugs safer and more affordable."[76] (emphasis added)

- Amy Bricker, former President of Express Scripts and PCMA board member, testified before Congress in April 2019: "At Express Scripts we negotiate lower drug prices with drug companies on behalf of our clients, *generating savings that are returned to patients* in the form of lower premiums and reduced out-of-pocket costs."[77] (emphasis added)

- Ms. Bricker of Express Scripts also testified that "Express Scripts remains committed to . . . *patients* with diabetes and creating affordable access to their medications."[78] (emphasis added)

- OptumRx CEO John Prince testified to the Senate: "We *reduce the costs of prescription drugs* [and] we are leading the way to ensure that *those discounts directly benefit consumers*. . . . OptumRx's pharmacy care services business is *achieving better health outcomes for patients, lowering costs* for the system, and *improving the healthcare experience for consumers*. . . . OptumRx negotiates better prices with drug manufacturers *for our customers and for consumers*.[79] (emphasis added)

- In its 2017 Drug Report, CVS Caremark stated that the goal of its pharmacy benefit plans is to ensure "that the cost of a drug is aligned with the value it delivers in terms of *patient* outcomes . . . in 2018, we are doing even more to help keep drugs affordable with our new Savings *Patients* Money initiative." (emphasis added)[80]

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[76] Express Scripts, *Code of Conduct*, https://www.expressscripts.com/aboutus/codeconduct/ExpressScriptsCodeOfConduct.pdf (last visited Jan. 10, 2023).

[77] *Priced Out of a Lifesaving Drug*, *supra* note 35.

[78] *Id.*

[79] Grassley & Wyden, *supra* note 2—*Hearing Transcript* at 174, https://www.finance.senate.gov/imo/media/doc/435631.pdf (last visited Aug. 23, 2023).

[80] CVS Health, *2017 Drug Trend Report* (Apr. 5, 2018), https://payorsolutions.cvshealth.com/insights/2017-drug-trend-report (last visited Aug. 23, 2023).

- The PCMA website touts PBMs as "the only entity in the prescription drug supply and payment chain dedicated to reducing drug costs" and (contradicting the PBM representatives' Congressional testimony), that "when new manufacturers enter the market at a lower list price, PBMs use the competition to drive costs down."[81]

421. Not only have PBM Defendants intentionally misrepresented that they use their market power to save payors money, but they have specifically and falsely disavowed that their conduct drives prices higher. Representative examples include:

- On an Express Scripts' earnings call in February 2017, CEO Tim Wentworth stated: "Drugmakers set prices, and we exist to bring those prices down."[82]

- Larry Merlo, head of CVS Caremark sounded a similar refrain in February 2017: "Any suggestion that PBMs are causing prices to rise is simply erroneous."[83]

- In 2017, Express Scripts' Wentworth went on CBS News to argue that PBMs play no role in rising drug prices, stating that PBMs work to "negotiate with drug companies to get the prices down."[84]

- During the April 2019 Congressional hearings, when asked if PBM-negotiated rebates and discounts were causing the insulin price to increase, OptumRx's Chief Medical Officer Sumit Dutta answered: "we can't see a correlation when rebates raise list prices."[85]

- In 2019, when testifying under oath before Congress on the rising price of insulins, Amy Bricker—former President of Express Scripts and PCMA board member—testified: "I have no idea why the prices [for insulin] are so high none of it is the fault of rebates."[86]

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[81] PCMA, *PBMs Reduce Insulin Costs: PBMs are working to improve the lives of patients living with diabetes and their families*, https://www.pcmanet.org/insulin-managingcosts-with-increasing-manufacturer-prices/ (last visited Jan. 10, 2023).

[82] Samantha Liss, *Express Scripts CEO Addresses Drug Pricing 'Misinformation'*, St. Louis Post-Dispatch (Feb. 17, 2017), https://www.stltoday.com/business/local/expressscripts-ceo-addresses-drug-pricing-misinformation/article_8c65cf2a-96ef-5575-8b5c-95601ac51840.html (last visited Jan. 11, 2023).

[83] Lynn R. Webster, *Who Is To Blame For Skyrocketing Drug Prices?*, The Hill (July 27, 2017, 11:40 AM), https://thehill.com/blogs/pundits-blog/healthcare/344115-who-is-toblame-for-skyrocketing-drug-prices (last visited Jan. 11, 2023).

[84] CBS News, *Express Scripts CEO Tim Wentworth Defends Role of PBMs in Drug Prices* (Feb 7, 2017), https://www.cbsnews.com/news/express-scripts-tim-wentworth-pbmrising-drug-prices-mylan-epipen-heather-bresh/ (last visited Jan. 11, 2023).

[85] *Priced Out of a Lifesaving Drug*, *supra* note 35.

[86] *Id.*

422. All of Defendants' public statements regarding insulin pricing have been consistent with the misrepresentations above and those detailed below. None have contradicted those misrepresentations or revealed the Insulin Pricing Scheme.

423. The PBM Defendants understand that payors like Plaintiff rely on the PBMs to achieve the lowest prices for the at-issue drugs and to construct formularies designed to improve access to medications. Plaintiff did so rely.

424. Throughout the relevant period, the PBM Defendants also falsely claimed they are transparent about the Manufacturer Payments and that the amounts they remit (or not) to payors. In fact, the PBM Defendants' disclosures of their ties to the Manufacturer Defendants were vague, equivocal, and misleading. Their manner of defining "rebates" in payor contracts was illusory and subject to indeterminate conditions and exceptions. The PBM Defendants thereby facilitated and obtained secret Manufacturer Payments far above and beyond the amount of "rebates" remitted to payors.

425. The PBMs' internal processes and accounting were and are abstruse and opaque, allowing them to overtly mislead the public and payors like Plaintiff.

426. In 2011, for example, OptumRx's President stated: "We want our clients to fully understand our pricing structure . . . [e]very day we strive to show our commitment to our clients, and one element of that commitment is to be open and honest about our pricing structure."[87]

[87] UnitedHealth Group, *Prescription Solutions by OptumRx Receives 4th Consecutive TIPPS Certification for Pharmacy Benefits Transparency Standards* (Sept. 13, 2011), https://web.archive.org/web/20210805182422/https://www.unitedhealthgroup.com/newsroom/2011/0913tipps.html (last visited Jan. 11, 2023). *See also, e.g.*, published version of press release at https://www.businesswire.com/news/home/20110913006224/en/Prescription-Solutions-by-OptumRx-Receives-4th-Consecutive-TIPPSSM-Certification-for-Pharmacy-Benefits-Transparency-Standards (last visited Aug. 23, 2023).

427. In a 2017 CBS News interview, Express Scripts' CEO represented, among other things, that Express Scripts was "absolutely transparent" about the Manufacturer Payments they receive and that payors "know exactly how the dollars flow" with respect to these Manufacturer Payments.[88]

428. When testifying before the Senate Finance Committee, CVS Executive Vice President Derica Rice stated: "[A]s it pertains to transparency overall, we at CVS Caremark are very supportive. We provide full visibility to our clients of all our contracts and the discounts that we negotiate on their behalf. . . . And transparency—today we report and fully disclose not only to our clients, but to CMS [Medicare]."[89]

429. At the same hearing, Steve Miller of Cigna (Express Scripts) testified: "we are a really strong proponent for transparency for those who pay for health care. So the patient should know exactly what they are going to pay. Our plan sponsors should know exactly what is in their contract."[90]

430. John Prince of OptumRx chimed in: "Senator, if our discounts were publicly available, it would hurt our ability to negotiate effectively. Our discounts are transparent to our clients."[91]

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[88] CBS News, *supra* note 79.

[89] Grassley & Wyden, *supra* note 2—*Hearing Transcript* at 28, 32, https://www.finance.senate.gov/imo/media/doc/ 435631.pdf (last visited Jan. 11, 2023).

[90] *Id.* at 32.

[91] *Id.*

431. When testifying before Congress in April 2019, Amy Bricker, then a Senior Vice President of Defendant Express Scripts, claimed transparency with payors and echoed Mr. Prince's need for confidentiality around discounts:[92]

> Ms. Bricker. The rebate system is 100 percent transparent to the plan sponsors and the customers that we service. To the people that hire us, employers of America, the government, health plans, what we negotiate for them is transparent to them. . . The reason I'm able to get the discounts that I can from the manufacturer is because it's confidential [to the public].
>
> ***
>
> Mr. Sarbanes. Yeah, because it's a secret. What about if we made it completely transparent? Who would be for that?
>
> ***
>
> Ms. Bricker. Absolutely not . . . [i]t will hurt the consumer. . . . prices will be held high.

432. As recently as May 2022, JC Scott—President of the PBM trade group PCMA—testified as follows before the Senate Commerce Committee:

> PBMs are proud of the work they do to reduce prescription drug costs, expand affordable access to medications, and improve patient outcomes. PBMs negotiate with drug companies to lower prescription drug costs PBMs advocate for patients in the fight to keep prescription drugs accessible and affordable.

433. Mirroring the PCMA website (¶¶ 429, 430, *supra*), Mr. Scott also testified, "The PBM industry is the only stakeholder in the chain dedicated to seeking lower costs."

434. During the relevant period—as seen above—PBM Defendants represented to Plaintiff that they constructed formularies and negotiated with the Manufacturer Defendants for the benefit of payors and patients to maximize drug cost savings while promoting the health of diabetics.

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[92] *Priced Out of a Lifesaving Drug, supra* note 35.

435. Throughout the relevant period, the PBMs made the foregoing and similar misrepresentations consistently and directly to Tennessee payors, including Hamblen County, through bid proposals, member communications, invoices, formulary change notifications, and through extensive direct-to-consumer pull through efforts engaged in with the Manufacturers.

436. All of these representations are false. The Manufacturer and PBM Defendants in fact coordinated to publish the false prices and to construct the PBM formularies, causing the price of the at-issue drugs to skyrocket. For example:

a. In 2018, the US spent $28 billion (USD) on insulin compared with $484 million in Canada. The average American insulin user spent $3,490 on insulin in 2018 compared with $725 among Canadians.

b. Diabetics who receive their medications from federal programs that do not utilize PBMs also pay significantly less. For example, in December 2020, the United States House of Representatives Committee on Oversight and Reform issued a Drug Pricing Investigation Report finding that federal health care programs that negotiate directly with the Manufacturers (such as the Department of Veterans Affairs), and are thus outside the PBM Defendants' scheme, paid $16.7 billion less from 2011 through 2017 for the at-issue drugs than the Medicare Part D program, which relies on the PBM Defendants to set their at-issue drug prices (and are thus victims of the PBMs' concerted efforts to drive up the list prices).

437. Defendants knew their representations were false when they made them and coordinated to affirmatively withhold the truth from payors, including Plaintiff.

438. Defendants concealed the falsity of their representations by closely guarding their pricing negotiations, structures, agreements, sales figures, and the flow of money and other consideration between them.

439. The Defendants have never revealed the full amount of any drug-specific Manufacturer Payments exchanged between them.

440. The PBM Defendants do not disclose the terms of their agreements with the Manufacturers or the Manufacturer Payments they receive. Nor do they disclose the details related

to their agreements (formal or otherwise) with pharmacies. All of these revenue streams are beyond the scope of the payors' contractual audit rights.

441. Further, although PBMs negotiate drug-specific rebates with Manufacturers,[93] the PBM rebate payments to payor clients and summaries of such payments are in the aggregate, rather than on a drug-by-drug basis. It is impossible for payors like Plaintiff to tease out drug-specific rebates, much less the other undisclosed Manufacturer Payments. This allowed the PBM Defendants to hide the large Manufacturer Payments that they receive for the at-issue diabetes medications.

442. The PBM Defendants have gone so far as to sue governmental entities to block the release of details on their pricing agreements with the Manufacturers and pharmacies.

443. Even when audited by payors, the PBM Defendants routinely refuse to disclose their agreements with the Manufacturers and pharmacies, relying on overly broad confidential agreements, claims of trade secrets, and erecting other unnecessary roadblocks and restrictions.

444. Beneficiaries of the Plaintiff's health plans have no choice but to pay prices flowing from Defendants' inflated list prices because Beneficiaries need these medications to survive and the Manufacturer Defendants make virtually all diabetes medications available in the United States. The list prices generated by the Defendants' coordinated efforts directly impact out-of-pocket costs at the point of sale.

445. In sum, the entire insulin pricing structure created by the Defendants—from the false prices to the Manufacturers' misrepresentations related to the reason behind the price, to the inclusion of the false prices in payor contracts, to the non-transparent Manufacturer Payments, to

[93] Grassley & Wyden, *supra* note 2 at 40.

the misuse of formularies, to the PBMs' representations that they work to lower prices and promote the health of diabetics—is unconscionable, deceptive, and immensely lucrative.

446. Plaintiff did not know, because the Defendants affirmatively concealed, that (1) the Manufacturers and PBMs coordinated to create the PBM formularies in exchange for money and other consideration; (2) the list prices were falsely inflated; (3) the list prices were manipulated to satisfy PBM profit demands; (4) the list prices and net costs (purchase prices) paid by Plaintiff bore no relationship to the fair market value of the drugs themselves or the services rendered by the PBMs in coordinating their pricing; or (5) the entire insulin pricing structure Defendants created was false.

J. The Insulin Pricing Scheme Has Damaged Plaintiff

447. Plaintiff Hamblen County provides health and pharmacy benefits to its Beneficiaries, including employees, retirees, and their dependents, who have numbered in the thousands throughout the relevant period.

448. One benefit Plaintiff provides the Beneficiaries of its healthcare plan is paying for their pharmaceutical needs.

449. Plaintiff entered into an agreement with CVS Caremark, whereby CVS Caremark agreed to provide Plaintiff prescription drug benefits and other at-issue services.

450. Plaintiff and Medco entered into an agreement whereby Medco agreed to provide Plaintiff prescription drug benefits and other at-issue services.

451. Plaintiff has renewed and had an active agreement in place with either Express Scripts or Medco or CVS Caremark.

452. Express Scripts acquired Medco in 2012.

453. Plaintiff requested proposals from the PBM Defendants for the at issue services.

454. In response to Plaintiff's requests, all PBM Defendants submitted proposals.

455. Plaintiff was unaware of the Insulin Pricing Scheme. Plaintiff relied on Defendants' public statements and material omissions.

456. Plaintiff contracted with Defendant Express Scripts, Inc. and CVS Caremark for PBM services.

457. Defendants' Insulin Pricing Scheme has cost Plaintiff millions of dollars in overcharges.

458. Indeed, since 2003 Hamblen County has spent exorbitant amounts of money on the at-issue diabetes medications.

459. CVS Caremark's and Express Scripts' respective relationships with Plaintiff were inherently unbalanced and their contracts adhesive. Both Defendants had superior bargaining power and superior knowledge of their relationships with the Manufacturer Defendants, including those that ultimately dictate the drug costs Plaintiff incurred. Although Defendants were supplying a vital service of a quasi-public nature, they both exploited their superior positions to mislead Plaintiff and thwart its expectations, all at great expense to Hamblen County.

460. The Defendants' misrepresentations, omissions, and misconduct—including and as manifested in the Insulin Pricing Scheme—directly and proximately caused economic damage to Plaintiff as a payor/purchaser of Defendants' at-issue diabetes medications.

461. A substantial proportion of the money Plaintiff spent on diabetes medications is attributable to Defendants' inflated prices, which did not arise from competitive market forces but, instead, exist solely by virtue of the Insulin Pricing Scheme.

462. Because of Defendants' success in concealing the Insulin Pricing Scheme through act and omission, no payor, including Plaintiff, knew (or should have known) during the relevant

period that the prices for the at-issue diabetes medications were (and are) artificially inflated due to the Insulin Pricing Scheme.

463. As a result, despite receiving some rebates and incurring drug costs based on discounts off list prices, Plaintiff has unknowingly overpaid for the Manufacturer Defendants' diabetes medications, which would have cost far less but for the Insulin Pricing Scheme.

464. In short, the Insulin Pricing Scheme has directly and proximately caused Plaintiff to substantially overpay for diabetes medications.

465. Because Defendants continue to generate exorbitant, unfair, and deceptive prices for the at-issue drugs through the Insulin Pricing Scheme, the harm to Plaintiff is ongoing.

K. Defendants' Recent Efforts in Response to Rising Insulin Prices

466. In reaction to mounting political and public outcry, Defendants have taken action both on Capitol Hill and in the public relations space.

467. First, in response to public criticism, Defendants have increased their spending to spread their influence in Washington D.C.

468. For example, in recent years Novo Nordisk's political action committee ("PAC") has doubled its spending on federal campaign donations and lobbying efforts. In 2017 alone, Novo Nordisk spent $3.2 million lobbying Congress and federal agencies, its biggest ever investment in directly influencing U.S. policymakers. Eli Lilly and Sanofi also have contributed millions of dollars through their PACs in recent years.

469. Second, Defendants have recently begun publicizing programs ostensibly aimed at lowering the cost of insulins.

470. These affordability measures fail to address the structural issues that caused the price hikes. Rather, these are public-relations measures that do not solve the problem.

471. For example, in March 2019, Defendant Eli Lilly announced that it would produce an authorized generic version of Humalog, "Insulin Lispro," and promised that it would "work quickly with supply chain partners to make [the authorized generic] available in pharmacies as quickly as possible."

472. However, in the months after Eli Lilly's announcement, reports raised questions about the availability of "Insulin Lispro" in local pharmacies.

473. Following this the staff of the Offices of U.S. Senators Elizabeth Warren and Richard Blumenthal prepared a report examining the availability of this drug. The investigative report, *Inaccessible Insulin: The Broken Promise of Eli Lilly's Authorized Generic*, concluded that Eli Lilly's lower-priced, authorized generic insulin is widely unavailable in pharmacies across the country, and that the company has not taken meaningful steps to increase insulin accessibility and affordability.[94]

474. Eli Lilly did lower the price of Lispro by 40% effective January 1, 2022; but it is not included in any of the PBM Defendants' formularies as of January 2023.

475. In 2019, Novo Nordisk partnered with Walmart to offer ReliOn brand insulins for a discounted price at Walmart. However, experts have warned that the Walmart/Novo Nordisk insulins are not substitutes for most diabetics' regular insulins and should only be used in an emergency or when traveling. In particular, for many diabetics, especially Type 1 diabetics, these insulins can be dangerous. In any event, ReliOn is not included in any of the PBM Defendants' formularies as of January 2023.

[94] Sen. Elizabeth Warren & Sen. Richard Blumenthal, *Inaccessible Insulin: The Broken Promise of Eli Lilly's Authorized Generic*, (Dec. 2019), https://www.warren.senate.gov/imo/media/doc/Inaccessible%20Insulin%20report.pdf (last visited Aug. 23, 2023).

476. Thus, Defendants' "lower priced" insulin campaigns have not addressed the problem, and the PBMs continue to exclude drugs with lower list prices despite their assurances of cost-savings for payors and Beneficiaries. Plaintiff continues to suffer harm caused by the Insulin Pricing Scheme.

477. Likewise, FDA in 2020 approved the biosimilar Insulin Glargine-yfgn (branded as Semglee), which is manufactured and sold by newcomers to the market—Viatris and Biocon Biologics.[95] Insulin Glargine-yfgn (Semglee) is interchangeable with Defendant Sanofi's Lantus product and, according Viatris, its list price is three times cheaper than Lantus. It is not included in any of the PBM Defendants' formularies as of January 2023.

[95] As explained in n.3, insulin now is regulated as a biologic rather than a drug. Biosimilars are analogous to generic drugs—approved versions of original products that are virtually identical to, and interchangeable with, the original product.

CLAIMS FOR RELIEF

First Cause of Action (Count I)
Violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962(c)
(against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark)

478. Plaintiff Hamblen County re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

479. Plaintiff brings this count against Express Scripts, CVS Caremark, and the Manufacturer Defendants (Eli Lilly, Novo Nordisk and Sanofi) for violations of 18 U.S.C. § 1962(c).

480. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark are (1) culpable "persons" who (2) willfully and knowingly (3) committed and conspired to commit two or more acts of mail and wire fraud (4) through a "pattern" of racketeering activity that (5) involves an "association in fact" enterprise, (6) the results of which had an effect on interstate commerce.

A. Defendants Are Culpable "Persons" Under RICO.

481. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark, separately, are "persons" as that term is defined in 18 U.S.C. § 1961(3) because each is capable of holding a legal or beneficial interest in property.

482. Each one of Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark are separate entities and "persons" that are distinct from the RICO enterprises alleged below.

B. The Manufacturer-PBM RICO Enterprise

483. For the purposes of this claim, the RICO enterprises are six separate associations-in-fact consisting of one of each of CVS Caremark and Express Scripts and one of each of the Manufacturer Defendants, including those entities' directors, employees, and agents: the Eli Lilly-CVS Caremark Enterprise; the Eli Lilly-Express Scripts Enterprise; the Novo Nordisk-CVS Caremark Enterprise; the Novo Nordisk-Express Scripts Enterprise; the Sanofi-CVS Caremark Enterprise; and the Sanofi-Express Scripts Enterprise.

484. These association-in-fact enterprises are collectively referred to herein as the "Manufacturer-PBM Enterprises."

485. Each Manufacturer-PBM Enterprise is a separate, ongoing, and continuing business organization consisting of corporations and individuals associated for the common purpose of manufacturing, selling, and facilitating the purchase of the Manufacturer Defendants' products, including the at-issue drugs. For example:

(a) The Eli Lilly-CVS Caremark Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Eli Lilly medications including Prozac, Cymbalta, and Zyprexa, as well as the at-issue Eli Lilly insulin and insulin-analog medications (Trulicity, Humulin N, Humulin R, Humalog, and Basaglar), which are Eli Lilly's primary source of revenue.

(b) The Eli Lilly-Express Scripts Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Eli Lilly medications including Prozac, Cymbalta, and Zyprexa, as well as the at-issue Eli Lilly insulin and insulin-analog medications (Trulicity, Humulin N, Humulin R, Humalog, and Basaglar), which are Eli Lilly's primary source of revenue.

(c) The Novo Nordisk-CVS Caremark Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Novo Nordisk medications for the treatment of obesity, hemophilia, and hormone imbalance, as well as the at-issue Novo Nordisk insulin and insulin analog medications (Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic), which account for more than three-quarters of Novo Nordisk's revenue.

(d) The Novo Nordisk-Express Scripts Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Novo Nordisk medications for the treatment of obesity, hemophilia, and hormone imbalance, as well as the at-issue Novo Nordisk insulin and insulin-analog medications (Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic), which account for more than three-quarters of Novo Nordisk's revenue.

(e) The Sanofi-CVS Caremark Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Sanofi medications including Ambien, Plavix, and Dupixent, as well as the at-issue Sanofi insulin and insulin-analog medications (Lantus, Toujeo, Apidra, and Soliqua).

(f) The Sanofi-Express Scripts Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Sanofi medications including Ambien, Plavix, and Dupixent, as well as the at-issue Sanofi insulin and insulin-analog medications (Lantus, Toujeo, Apidra, and Soliqua).

486. Each Manufacturer-PBM Enterprise engaged in the shared purpose of exchanging false list prices and secret Manufacturer Payments for preferred formulary positions for the at-issue drugs in order to control the market for diabetes medications and profit off diabetics and payors, including the Plaintiff.

487. The members of each enterprise are bound by contractual relationships, financial ties, and the ongoing coordination of activities.

488. There is also a common communication network by which Eli Lilly and CVS Caremark, Eli Lilly and Express Scripts, Novo Nordisk and CVS Caremark, Novo Nordisk and Express Scripts, Sanofi and CVS Caremark, and Sanofi and Express Scripts share information and meet on a regular basis. These communications include, but are not limited to, communications relating to the use of false list prices for the at-issue diabetes medications and the regular flow of Manufacturer Payments from each Manufacturer Defendant to CVS Caremark and Express Scripts in exchange for formulary placement.

489. Each Manufacturer-PBM Enterprise functions as a continuing but separate unit separate and apart from the pattern of racketeering activity in which it engages. Each

Manufacturer-PBM Enterprise, for example, engages in the manufacture, distribution and sale of medications and other products other than the at-issue insulin and insulin- analog medications. Additionally, each Manufacturer engages in conduct other than mail and wire fraud in furtherance of the Insulin Pricing Scheme.

490. At all relevant times, each of the Manufacturer-PBM Enterprises was operated and conducted for unlawful purposes by each Manufacturer Defendant and Express Scripts and CVS Caremark, namely, carrying out the Insulin Pricing Scheme.

491. Each Manufacturer-PBM Enterprise derived secret profits from these activities that were greater than those any one of the Manufacturer Defendants or either Express Scripts or CVS Caremark could obtain absent their misrepresentations regarding their non-transparent pricing schemes.

492. To accomplish this common purpose, each Manufacturer Defendant periodically and systematically inflated the prices of the at-issue drugs and then secretly paid a significant, yet undisclosed, portion of this inflated price back to Express Scripts and CVS Caremark in the form of Manufacturer Payments.

493. Each Manufacturer-PBM Enterprise did so willfully and with knowledge that Plaintiff paid for the at-issue drugs at prices directly based on the false list prices.

494. Each Manufacturer-PBM Enterprise's inflation of the list prices and secret Manufacturer Payments was a quid pro quo exchange for preferred formulary placement.

495. Each Manufacturer-PBM Enterprise concealed from Plaintiff that these false prices and secret Manufacturer Payments resulted in each Manufacturer gaining formulary access without requiring significant price reductions and resulted in higher profits for Express Scripts and CVS

Caremark, whose earnings increase the more inflated the price is and the more payment it receives from each Manufacturer Defendant.

496. Each Manufacturer-PBM Enterprise also shares a common purpose of perpetuating the use of the false list prices for the at-issue drugs as the basis for the price that payors, including the Plaintiff, and diabetics pay for diabetes medications.

497. The Manufacturer Defendants would not be able to offer large pricing spreads to Express Scripts and CVS Caremark in exchange for favorable formulary positions without the use of the false list prices as the basis for the price paid by diabetics and payors, including the Plaintiff, for the at-issue drugs.

498. Express Scripts and CVS Caremark share this common purpose because nearly all profit and revenue generated from the at-issue drugs is tied to the false inflated prices generated by the Insulin Pricing Scheme. Without diabetics and payors, including the Plaintiff, paying for diabetes medications based on the inflated list prices, their profits from the Insulin Pricing Scheme would decrease.

499. As a result, CVS Caremark and Express Scripts have, with the knowing and willful participation and assistance of each Manufacturer Defendant, engaged in hidden profit-making schemes falling into four general categories: (1) garnering undisclosed Manufacturer Payments from each Manufacturer Defendant that Express Scripts and CVS Caremark retains to a large extent; (2) generating substantial profits from pharmacies because of the falsely inflated prices; (3) generating profits on the diabetes medications sold through Express Scripts and CVS Caremark's own mail-order and retail pharmacies; and (4) keeping secret discounts each Manufacturer Defendant provides in association with Express Scripts and CVS Caremark's mail-order and retail operations.

500. At all relevant times, Express Scripts and CVS Caremark and each Manufacturer Defendant has been aware of their respective Manufacturer-PBM Enterprise's conduct, has been a knowing and willing participant in and coordinator of that conduct and has reaped profits from that conduct.

501. Neither Express Scripts, CVS Caremark, nor any of the Manufacturer Defendants alone could have accomplished the purposes of the Manufacturer-PBM Enterprises without the other entities.

C. The Enterprises Misrepresent and Fail to Disclose Material Facts in Furtherance of the Insulin Pricing Scheme.

502. Each Manufacturer-PBM Enterprise knowingly made material misrepresentations to the public and the Plaintiff in furtherance of Insulin Pricing Scheme, including publishing artificially inflated prices for insulin on published indices and representing that:

a. the false list prices for the at-issue diabetes medications were reasonably related to the actual prices realized by Defendants and were a reasonable and fair basis on which to base the price Plaintiff paid for these drugs;

b. each Manufacturer priced its at-issue drugs according to each drug's value to the healthcare system and the need to fund innovation;

c. the Manufacturer Payments paid back to Express Scripts and CVS Caremark for each at-issue drug were for Plaintiff's benefit;

d. all "rebates" and discounts negotiated by CVS Caremark and Express Scripts with the Manufacturer Defendants were passed through to the Plaintiff;

e. the "rebates" negotiated by the members of each enterprise saved Plaintiff money;

f. each Manufacturer Defendant and Express Scripts and CVS Caremark were transparent with Plaintiff regarding the Manufacturer Payments and the PBMs did not retain any funds associated with prescription drug rebates or any the margin between guaranteed reimbursement rates and the actual amount paid to the pharmacies; and

g. Express Scripts and CVS Caremark constructed formularies in a manner that lowered the price of the at-issue drugs and promoted the health and safety of diabetics.

503. Each false list price published by the Manufacturer Defendants constituted a material misrepresentation to Plaintiff and the public, in that each purported to be a fair market price for the medication at issue, and each omitted to disclose the fraudulent spread between the list price and the net price of the medication or the basis therefor.

504. Examples of other specific affirmative representations by each RICO Defendant in furtherance of each enterprise's Insulin Pricing Scheme are set forth in this complaint.

505. At all times relevant to this Complaint, each Manufacturer-PBM Enterprise knew the above-described representations to be false.

506. At all times relevant to this Complaint, each Manufacturer-PBM Enterprise intentionally made these representations for the purpose of inducing Plaintiff into paying artificially inflated prices for diabetes medications.

507. Plaintiff relied on the material misrepresentations and omissions made by each Manufacturer-PBM Enterprise in paying prices for the at-issue diabetes medications based upon the false prices generated by Insulin Pricing Scheme.

508. Additionally, each PBM-Manufacturer Enterprise relied on the list prices negotiated and published by the other PBM-Manufacturer enterprises in setting their own list prices and determining the value of the kickbacks paid to the PBMs. Plaintiff was injured by the inflated prices that arose as a result.

509. Express Scripts and CVS Caremark convinced Plaintiff to pay prices for the at-issue drugs based upon the false list prices by utilizing the misrepresentations listed above to

convince Plaintiff that they had secured lower prices when, in fact, they did the opposite, all while concealing the Insulin Pricing Scheme.

510. Without these misrepresentations and each RICO Defendant's failure to disclose the Insulin Pricing Scheme, each Manufacturer-PBM Enterprise could not have achieved its common purpose, as Plaintiff would not have been willing to pay these false list prices.

D. Defendants' Use of the U.S. Mails and Interstate Wire Facilities

511. Each of the Manufacturer-PBM Enterprises engaged in and affected interstate commerce because each engaged in the following activities across state boundaries: the sale, purchase and/or administration of diabetes medications; the setting and publishing of the prices of these drugs; and/or the transmission of pricing information of diabetes medications; and/or the transmission and/or receipt of sales and marketing literature; and/or the transmission of diabetes medications through mail order and retail pharmacies; and/or the transmission and/or receipt of invoices, statements, and payments related to the use or administration of diabetes medications; and/or the negotiations and transmissions of contracts related to the pricing of and payment for diabetes medications.

512. Each Manufacturer-PBM Enterprise participated in the administration of diabetes medications to millions of individuals located throughout the United States, including in Hamblen County and elsewhere in Tennessee.

513. Each Manufacturer Defendant's and Express Scripts' and CVS Caremark's illegal conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information and products and funds through the U.S. mails and interstate wire facilities.

514. The nature and pervasiveness of the Insulin Pricing Scheme, which included each Manufacturer Defendant's and Express Scripts' and CVS Caremark's corporate headquarters operations, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities with each other and with pharmacies, physicians, payors, and diabetics in Hamblen County and throughout Tennessee.

515. Each Manufacturer-PBM Enterprise's use of the U.S. mails and interstate wire facilities to perpetrate the Insulin Pricing Scheme involved thousands of communications including:

a. Marketing materials about the published prices for diabetes medications, which each Manufacturer Defendant sent to Express Scripts and CVS Caremark located across the country, including in Hamblen County and throughout Tennessee;

b. Written and oral representations of the false list prices of diabetes medications that each Manufacturer Defendant and Express Scripts and CVS Caremark made at least annually and, in many cases, several times during a single year to the public;

c. Thousands of written and oral communications discussing, negotiating, and confirming the placement of each Manufacturer Defendant's diabetes medications on Express Scripts and CVS Caremark's formularies;

d. Written and oral representations made by each Manufacturer Defendant regarding information or incentives paid back to each Express Scripts and CVS Caremark for each diabetes medications sold and/or to conceal these Incentives or the Insulin Pricing Scheme;

e. Written communications made by each Manufacturer Defendant, including checks, relating to Manufacturer Payments paid to Express Scripts and CVS Caremark to persuade them to advocate the at-issue diabetes medications;

f. Written and oral communications with U.S. government agencies that misrepresented what the published prices were or that were intended to deter investigations into the true nature of the published prices or to forestall changes to reimbursement based on something other than published prices;

g. Written and oral communications with payors, including the Plaintiff, regarding the price of diabetes medications;

h. Written and oral communications to the Plaintiff, including marketing and solicitation material sent by Express Scripts and CVS Caremark regarding the

existence, amount, or purpose of payments made by each Manufacturer Defendant to Express Scripts and CVS Caremark for the diabetes medications described herein and the purpose of Express Scripts and CVS Caremark's formularies;

i. Transmission of published prices to third parties and payors, including the Plaintiff; and

j. Receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities—the wrongful proceeds of the Insulin Pricing Scheme.

516. Although Plaintiff pleads the dates of certain communications in allegations incorporated into this Count, it cannot allege the precise dates of others without access to books and records within each RICO Defendant's exclusive custody and control. Indeed, an essential part of the successful operation of the Insulin Pricing Scheme depended upon secrecy, and each Manufacturer Defendant and Express Scripts and CVS Caremark took deliberate steps to conceal its wrongdoing.

E. Conduct of the Manufacturer-PBM Enterprises' Affairs

517. Each Manufacturer Defendant and Express Scripts and CVS Caremark participates in the operation and management of Manufacturer-PBM Enterprises with which it is associated and, in violation of Section 1962(c) of RICO, and conducts or participates in the conduct of the affairs of those association-in-fact RICO enterprises, directly or indirectly. Such participation is carried out in the following ways:

a. Each Manufacturer Defendant directly controls the secret Manufacturer Payments it provides to Express Scripts and CVS Caremark for its diabetes medications.

b. Express Scripts and CVS Caremark directly manage and control their respective drug formularies and the placement of the at-issue diabetes medications on those formularies.

c. Express Scripts and CVS Caremark intentionally select higher-priced diabetes medications for formulary placement and exclude lower priced ones in order to generate larger profits and coordinate with the Manufacturer Defendants to increase the availability and use of higher-priced medications because they are more profitable for both groups of Defendants.

d. Each Manufacturer Defendant directly controls the publication of the false list prices generated by the Insulin Pricing Scheme.

e. Each Manufacturer Defendant directly controls the creation and distribution of marketing, sales and other materials used to inform Express Scripts and CVS Caremark of the profit potential from its diabetes medications.

f. Express Scripts and CVS Caremark directly control the creation and distribution of marketing, sales, and other materials used to inform payors and the public of the benefits and cost-saving potential of Express Scripts and CVS Caremark formularies and negotiations with the Manufacturers.

g. Express Scripts and CVS Caremark direct and control each enterprise's direct relationships with payors such as the Plaintiff by negotiating the terms of and executing the contracts that govern those relationships.

h. Express Scripts and CVS Caremark direct and control each enterprise's Insulin Pricing Scheme by hiding, obfuscating, and laundering Manufacturer Payments through their affiliated entities in order to retain a large and undisclosed proportion of the Manufacturer Payments to the detriment of payors, including Plaintiff.

i. Express Scripts and CVS Caremark distribute through the U.S. mail and interstate wire facilities promotional and other materials which claim that the Manufacturer Payments paid from each Manufacturer Defendant to Express Scripts and CVS Caremark save Plaintiff and other payors money on the at-issue drugs.

j. Each Manufacturer Defendant represented to the Plaintiff—by publishing and promoting false list prices without stating that these published prices differed substantially from the prices realized by each Manufacturer Defendant and Express Scripts and CVS Caremark—that the published prices of diabetes medications reflected or approximated the actual price realized by Defendants and resulted from transparent and competitive fair market forces.

F. Defendants' Pattern of Racketeering Activity

518. Each Manufacturer Defendant and Express Scripts and CVS Caremark has conducted and participated in the affairs of their respective Manufacturer-PBM Enterprises through a pattern of racketeering activity, including acts that are unlawful under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud.

519. Each Manufacturer Defendant's and Express Scripts' and CVS Caremark's pattern of racketeering involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of the Insulin Pricing Scheme. Each of these mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), in which each Manufacturer Defendant and Express Scripts and CVS Caremark intended to defraud Plaintiff.

520. By intentionally and falsely inflating the list prices, by misrepresenting the purpose behind both the Manufacturer Payments (made from each Manufacturer Defendant to Express Scripts and CVS Caremark) and Express Scripts' and CVS Caremark's formulary construction, and by subsequently failing to disclose such practices to Plaintiff, each Manufacturer Defendant and Express Scripts and CVS Caremark engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

521. Each Manufacturer Defendant's and Express Scripts' and CVS Caremark's racketeering activities amounted to a common course of conduct, with similar patterns and purposes, intended to deceive Plaintiff.

522. Each separate use of the U.S. mails and/or interstate wire facilities employed by each Manufacturer Defendant and Express Scripts and CVS Caremark was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiff.

523. Each Manufacturer Defendant and Express Scripts and CVS Caremark engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of

the respective Manufacturer-PBM Enterprises with which each of them is and was associated in fact.

G. The RICO Defendants' Motive

524. Each Manufacturer Defendant's and Express Scripts' and CVS Caremark's motives in creating and operating the Insulin Pricing Scheme and conducting the affairs of the Manufacturer-PBM Enterprises described herein was to control the market for diabetes medications and falsely obtain sales of, and profits from, diabetes medications.

525. The Insulin Pricing Scheme was designed to, and did, encourage others, including payors like Plaintiff, to advocate the use of each Manufacturer Defendant's respective products and to pay for those diabetes medications based on a falsely inflated price. Each Manufacturer Defendant used the Insulin Pricing Scheme to obtain formulary placement to sell more of its drugs without having to cut into its profits. Express Scripts and CVS Caremark used the Insulin Pricing Scheme to falsely inflate the price payors such as the Plaintiff paid for diabetes medications in order to profit off the Insulin Pricing Scheme, as discussed above.

H. The Manufacturer-PBM Enterprises' Insulin Pricing Scheme Injured Plaintiff.

526. Each Manufacturer-PBM Enterprise's violations of federal law and pattern of racketeering activity have directly and proximately caused the Plaintiff to be injured in its business or property.

527. The prices the Plaintiff pays for the at-issue drugs are directly tied to the false list prices generated by the Insulin Pricing Scheme.

528. No other intermediary in the supply chain has control over or is responsible for the list prices on which nearly all Plaintiff's payments are based other than the Manufacturer-PBM Defendant Enterprises.

529. Defendants collectively set the prices that the Plaintiff paid for the at-issue diabetes medications.

530. During the relevant period, Express Scripts and CVS Caremark provided PBM services to the Plaintiff and benefited therefrom.

531. During the relevant period, the Plaintiff paid Express Scripts and CVS Caremark for the at-issue drugs.

532. Each Manufacturer-PBM Enterprise controlled and participated in the Insulin Pricing Scheme that was directly responsible for the false list prices upon which the price Plaintiff paid was based.

533. Thus, Plaintiff was damaged by reason of the Insulin Pricing Scheme. But for the misrepresentations and false prices created by the Insulin Pricing Scheme that each Manufacturer-PBM Enterprise employed, Plaintiff would have paid less for diabetes Medications.

534. As a direct result of the Insulin Pricing Scheme the Plaintiff was further damaged by incurring increased healthcare costs and by losing tax revenue due to decreased workforce productivity.

535. The Plaintiff's damages are separate and distinct from any other victim that was harmed by the Manufacturer-PBM Defendant Enterprises' Insulin Pricing Scheme.

536. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(c) of RICO, Defendants are jointly and severally liable to the Plaintiff for three times the damages that were sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

537. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(a) of RICO, the Plaintiff seeks injunctive relief against each Manufacturer and Express

Scripts and CVS Caremark for their fraudulent reporting of their prices and their continuing acts to affirmatively misrepresent and/or conceal and suppress material facts concerning their false and inflated prices for diabetes medications, plus the costs of bringing this suit, including reasonable attorneys' fees.

538. Absent an injunction, the effects of this fraudulent, unfair, and unconscionable conduct will continue. Plaintiff continues to purchase the at-issue diabetes medications. Plaintiff will continue to pay based on the Defendants' false list prices. This continuing fraudulent, unfair, and unconscionable conduct is a serious matter that calls for injunctive relief as a remedy. Plaintiff seeks injunctive relief, including an injunction against each Manufacturer and Express Scripts and CVS Caremark, to prevent them from affirmatively misrepresenting and/or concealing and suppressing material facts concerning their conduct in furtherance of the Insulin Pricing Scheme.

Second Cause of Action (Count II)
Violations of RICO, 18 U.S.C. § 1962(d)
By Conspiring to Violate 18 U.S.C. § 1962(c)
(against all Defendants)

539. Plaintiff re-alleges and incorporates herein by reference the allegations set forth in the preceding paragraphs.

540. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

541. Defendants have violated § 1962(d) by agreeing and conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in the Insulin Pricing Scheme.

542. As set forth in detail above, Defendants each knowingly agreed to facilitate the Insulin Pricing Scheme and each has engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy. Specifically, Defendants agreed to and did

inflate the prices of the at-issue drugs in lockstep to achieve an unlawful purpose; Defendants agreed to and did make false or misleading statements or material omissions regarding the reasons for these price increases, the purpose of the Manufacturer Payments exchanged between Defendants and the PBMs' formulary construction; and PBMs agreed to and did, in concert, request and receive larger Manufacturer Payments and higher prices in exchange for formulary placement.

543. The nature of the above-described Defendant co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

544. Defendants have engaged and continue to engage in the commission of overt acts, including the following unlawful racketeering predicate acts:

a. Multiple instances of mail fraud in violations of 18 U.S.C. § 1341;

b. Multiple instances of wire fraud in violations of 18 U.S.C. § 1343; and

c. Multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

545. Defendants' conspiracy to violate the above federal laws and the effects thereof detailed above are continuing and will continue. Plaintiff has been injured in its property by reason of these violations: Plaintiff has paid more for the at-issue drugs than it would have but for Defendants' conspiracy to violate 18 U.S.C. § 1962(c).

546. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are jointly and severally liable to Plaintiff for three times the damages this District has sustained, plus the cost of this suit, including reasonable attorneys' fees.

Third Cause of Action (Count III)
Unlawful Restraint of Trade
Tenn. Code Ann. §§ 47-25-101, *et seq*.
(against all Defendants)

547. Plaintiff Hamblen County re-alleges and incorporates herein by reference each of the allegations from the preceding paragraphs.

548. As detailed in the foregoing paragraphs, Defendants entered into, established, and maintained a continuing contract, agreement, arrangement, or combination in unreasonable restraint of trade.

549. The purpose and effect of the arrangement was to effect the Insulin Pricing Scheme.

550. The contract, agreement, arrangement, or combination had a direct, substantial, and reasonably foreseeable effect upon commerce within the United States and within Tennessee by: (a) increasing prices paid by Plaintiff for the at-issue diabetes medications; (b) depriving Plaintiff of savings that they would otherwise have received in the absence of the conspiracy; and (c) depriving Plaintiff of free, open, and unrestricted competition in the purchase of the at-issue drugs sold by Defendants.

551. As a result of Defendants' unlawful conduct, Plaintiff has been injured by paying inflated prices for the at-issue diabetes medications.

552. By engaging in the conduct described above, Defendants formed a contract, agreement, arrangement, or combination in restraint of trade in violation of Tenn. Code Ann. §§ 47-25-101, *et seq*.

Fourth Cause of Action (Count IV)
Violation of Tennessee Consumer Protection Act
Tenn. Code Ann. §§ 47-18-101, *et seq*.
(against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark)

553. Plaintiff Hamblen County re-alleges and incorporates herein by reference each of the allegations from the preceding paragraphs.

554. The Tennessee Consumer Protection Act of 1977 makes unlawful "[u]nfair or deceptive acts or practices affecting the conduct of any trade or commerce[.]."[96]

555. Plaintiff is a "person" within the meaning of Tenn. Code Ann. § 47-18-103(18).

556. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark are each a "person" within the meaning of Tenn. Code Ann. § 47-18-103(18).

557. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark's conduct, collectively and as individuals, as described in this Complaint, constitutes deceptive acts in violation of the Tennessee Consumer Protection Act.

558. Because these Defendants' willful and knowing conduct caused injury to Plaintiff, Plaintiff seeks to recover actual damages; discretionary treble damages; punitive damages; reasonable attorneys' fees and costs; an order enjoining Defendants' unlawful conduct; and any other just and proper relief available under.

559. By engaging in the Insulin Pricing Scheme, as described herein, Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark have committed acts of unfair and deceptive trade practices in the conduct of trade or commerce within Tennessee and Hamblen County causing harm to Plaintiff as a reimbursor for, and purchaser and payor of, the at-issue drugs.

[96] Tenn. Code Ann. § 47-18-104(a).

560. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark have engaged in the following materially misleading conduct, which constitutes deceptive trade practice in violations of the Tennessee Consumer Protection Act:

- Making false and misleading misrepresentations of fact that the prices for the at-issue diabetes medications were legal, competitive, and fair market value prices. In particular:
    - A characteristic of every commodity in Tennessee's economy is its price, which is represented by every seller to every buyer that the product being sold is being sold at a legal, competitive, and fair market value.
    - At no point did these Defendants reveal that the prices associated with the lifesaving diabetic treatments at issue herein were not legal, competitive, or at fair market value.
    - At no point did these Defendants disclose that the prices associated with the at-issue drugs were generated by the Insulin Pricing Scheme.
    - At least once per year for each year during the relevant period, these Defendants reported and published false prices for each at-issue drug and in doing so represented that the reported prices were the actual, legal and fair prices for these drugs and resulted from competitive market forces.
    - In addition, by granting the at-issue drugs preferred formulary position—formulary positions that the PBMs represent are reserved for reasonably priced drugs and that are meant to promote the health of diabetics—the PBM Defendants knowingly and purposefully utilized the false prices that were generated by the Insulin Pricing Scheme.
    - By granting the at-issue diabetes medications preferred formulary positions, the PBM Defendants ensured that prices generated by the Insulin Pricing Scheme would harm Plaintiff.
    - The PBM Defendants also misrepresented their formularies promoted the cost-savings to Plaintiff.
    - Defendants' representations are false, and Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark knew they were false. Defendants knew that the prices they reported and utilized are artificially inflated for the purpose of maximizing profits through the Insulin Pricing Scheme.
    - These Defendants also knew that the PBMs' formulary construction fueled the precipitous price increases that damaged Plaintiff's financial well-being.

- Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark affirmatively withheld this truth from Plaintiff Hamblen County, even though these Defendants knew that the Plaintiff's intention was to pay the lowest possible price for diabetes medications and expectation was to pay a legal, competitive price that resulted from transparent market forces.

- Making false and misleading misrepresentations of fact related to the Manufacturer Payments and the negotiations that occurred between the PBM and Manufacturer Defendants.

- The PBM Defendants knowingly made false and misleading statements concerning the reasons for, existence of, and amount of price reductions by misrepresenting that the Manufacturer Payments lower the overall price of diabetes medications and promote the health of diabetics.

- These representations were false, and Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark knew they were false. The PBM Defendants knew that the Manufacturer Payments were not reducing the overall price of diabetes medications but rather are an integral part of the Insulin Pricing Scheme and are responsible for the inflated prices.

561. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark continue to make these misrepresentations and publish prices generated by the Insulin Pricing scheme, and Plaintiff continues to purchase diabetes medications at inflated prices.

562. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark acted knowingly and in a willful, wanton or reckless disregard for the safety of others in committing the violation of the Tennessee Consumer Protection Act described herein.

563. Each at-issue purchase Plaintiff made for diabetes medications at the prices generated by the Insulin Pricing Scheme constitutes a separate violation of the Tennessee Consumer Protection Act.

564. The acts and practices alleged herein are ongoing, repeated, and affect the public interest.

565. The acts and practices alleged herein substantially impact the community of diabetics, their families, healthcare providers, and the public, and have caused substantial actual harm, including to Plaintiff and its beneficiaries.

566. These Defendants' acts and practices in violation of the Tennessee Consumer Protection Act caused Plaintiff to suffer injuries alleged herein, including but not limited to paying excessive and inflated prices for diabetes medications as described herein.

567. As a direct and proximate result of these Defendants' conduct in committing the above and foregoing violations of the Tennessee Consumer Protection Act, these Defendants are directly and jointly and severally liable to Plaintiff for all restitution, damages, punitive damages, treble damages, penalties and disgorgement for which recovery is sought herein, including but not limited to the Plaintiff paying excessive and inflated prices for diabetes medications described herein every time it paid for an at-issue drug.

568. Additionally, Plaintiff did not receive the benefit of its bargain, or otherwise paid a price premium, for the at-issue diabetes medications because it paid an artificially inflated price due to these Defendants' illegal practices.

Fifth Cause of Action (Count V)
Breach of Contract
(against Defendants Express Scripts and CVS Caremark)

569. Plaintiff Hamblen County re-alleges and incorporates herein by reference each of the allegations from the preceding paragraphs.

570. In Tennessee, all contracts—including those between the PBM Defendants and Plaintiff—imply a covenant of good faith and fair dealing in the course of performance (the "Covenant").[97]

[97] *See, e.g.*, *Wallace v. Nat'l Bank of Commerce*, 938 S.W.2d 684, 686 (Tenn. 1996).

571. The Covenant protects "the parties' reasonable expectations as well as their right to receive the benefits of their agreement"[98] and is breached when "a party to the contract exercises discretion authorized in a contract in an unreasonable way."[99]

572. By engaging in the conduct alleged in this Complaint, specifically by arranging with Insulin Manufacturers to hide portions of their rebates by, *inter alia*, relabeling a portion of the rebates as "administrative fees" such that they do not have to be "passed through" to Plaintiff, the PBM Defendants deprived Plaintiff of its rights to receive the benefits of their agreement.

573. PBM Defendants made such arrangements willfully, with the dishonest purpose of enriching themselves at the expense of payors such as Plaintiff. Furthermore, they took efforts to conceal the terms of these arrangements so that payors such as Plaintiff could not discover that they were not receiving the fruits of their contract.

574. As a direct and proximate result of PBM Defendants' breach of the covenant of good faith and fair dealing, Plaintiff did not receive the benefit of its bargain and paid a price-premium for the at-issue diabetes medications because it paid an artificially inflated price due to these Defendants' illegal practices.

Sixth Cause of Action (Count VI)
Unjust Enrichment
(against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark)

575. Plaintiff Hamblen County re-alleges and incorporates herein by reference each of the allegations from the preceding paragraphs.

[98] *Dick Broad. Co. v. Oak Ridge FM, Inc.*, 395 S.W.3d 653, 666 (Tenn. 2013).

[99] *Universal Props. v. Regions Bank*, No. 3:11-cv-538, 2012 U.S. Dist. LEXIS 135256, at *23 (E.D. Tenn. Sep. 21, 2012)).

576. This cause of action is alleged in the alternative to any claim Plaintiff may have for legal relief.

577. Plaintiff conferred a benefit upon Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark. These Defendants deceived Plaintiff Hamblen County and have received a financial windfall from the Insulin Pricing Scheme at Plaintiff's expense.

578. These Defendants wrongfully secured and retained unjust benefits from Plaintiff in the form of amounts paid for diabetes medications and fees and payments collected based on the prices generated by the Insulin Pricing Scheme. They did not adequately compensate Plaintiff therefor.

579. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark were aware of the benefit, voluntarily accepted it, and retained and appreciated the benefit, to which it was not entitled, at Plaintiff's expense.

580. It is inequitable and unfair for these Defendants to retain these benefits.

581. The benefit these Defendants have wrongfully retained is in an amount not less than the difference between the reasonable or fair market value of the at-issue drugs for which Plaintiff paid and the actual value of the at-issue drugs these Defendants delivered.

582. Accordingly, Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark should not be permitted to retain the proceeds from the benefits conferred upon them by Plaintiff, which seeks disgorgement of these Defendants' unjustly acquired profits and other monetary benefits resulting from their unlawful conduct and seeks restitution and/or recission, in an equitable and efficient fashion to be determined by the Court.

583. As a direct and proximate cause of these Defendants' unjust enrichment at the expense of Plaintiff as referenced above, Plaintiff has suffered and continues to suffer ascertainable losses and damages as specified herein in an amount to be determined at trial.

MOTION FOR INJUNCTION

584. Plaintiff Hamblen County re-alleges and incorporates paragraphs 1–477.

585. By Defendants' violations of the Tennessee Consumer Protection Act, RICO, and common law, Plaintiff has suffered, and will continue to suffer, immediate and irreparable injury, loss, and damage, as discussed herein.

586. The ongoing and threatened injury to Plaintiff and its beneficiaries outweighs the harm that an injunction might cause Defendants.

587. As a direct and proximate result of the conduct of the Defendants in committing the above and foregoing acts, Plaintiff moves the Court for injunctive relief against the Defendants pursuant Tenn. Code Ann. § 47-18-109(b) and 18 U.S.C. § 1964(a), thereby enjoining Defendants from committing future violations of the Tennessee Consumer Protection Act and RICO.

588. Granting an injunction is consistent with the public interest because it will protect the health and economic interests of Plaintiff, as well as the integrity of the Tennessee marketplace.

PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiff Hamblen County prays for entry of judgment against the Defendants for all the relief requested herein and to which the Plaintiff may otherwise be entitled, specifically, but without limitation, to-wit:

A. That the Court determine that Defendants have violated the Tennessee Consumer Protection Act, have violated RICO, have breached their contract with Defendants, and have been unjustly enriched;

B. Judgment in favor of Plaintiff and against the Defendants for damages in excess of the minimum jurisdictional requirements of this Honorable Court, in a specific amount to be proven at trial;

C. That Plaintiff be granted the following specific relief:

1. In accordance with Tenn. Code Ann. § 47-18-109(b) and 18 U.S.C. § 1964(a), that Defendants, their affiliates, successors, transferees, assignees, and the officers, directors, partners, agents, and employees thereof, and all other persons acting or claiming to act on their behalf or in concert with them, be enjoined and restrained from in any manner continuing, maintaining or renewing the conduct, contract, conspiracy or combination alleged herein in violation of the and RICO, or from entering into any other contract, conspiracy or combination having a similar purpose or effect, and from adopting or following any practice, plan, program or device having a similar purpose or effect;

2. That Plaintiff:

i. be awarded restitution, damages, disgorgement, penalties and/or all other legal and equitable monetary remedies available under the state laws set forth in this Complaint and the general equitable powers of this Court in an amount according to proof;

ii. be awarded punitive damages because Defendants knowingly, willfully, wantonly and intentionally harmed the health, wellbeing and financial interests Plaintiff and its Beneficiaries;

iii. be awarded pre- and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of the initial complaint in this action;

iv. recover its costs of suit, including its reasonable attorney's fees, as provided by law and pursuant to the Tennessee Consumer Protection Act and 18 U.S.C. § 1964(c); and

v. be awarded such other, further and different relief as the case may require and the Court may deem just and proper under the circumstances.

JURY DEMAND

Plaintiff Hamblen County demands trial by jury on all issues so triable.

Dated: April 5, 2024

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Counsel for Plaintiff

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

GREENE COUNTY, TENNESSEE,

Plaintiff,

v.

ELI LILLY AND COMPANY; NOVO NORDISK INC.; SANOFI-AVENTIS U.S. LLC; CVS HEALTH CORPORATION; CVS PHARMACY, INC.; CAREMARKPCS HEALTH, LLC; CAREMARK, LLC; CAREMARK RX, LLC; EVERNORTH HEALTH, INC. (F/K/A EXPRESS SCRIPTS HOLDING COMPANY); EXPRESS SCRIPTS, INC.; EXPRESS SCRIPTS ADMINISTRATORS, LLC; MEDCO HEALTH SOLUTIONS, INC.; ESI MAIL PHARMACY SERVICES, INC.; EXPRESS SCRIPTS PHARMACY, INC.; UNITEDHEALTH GROUP, INC.; OPTUM, INC.; OPTUMRX INC.; OPTUMRX HOLDINGS I LLC; OPTUMINSIGHT, INC.,

Defendants.

Civil Action No. _____

COMPLAINT

JURY TRIAL DEMANDED

Complaint and Demand for Jury Trial

TABLE OF CONTENTS

INTRODUCTION 1

PARTIES 10

A. Plaintiff 10

B. Manufacturer Defendants 11

C. PBM Defendants 15

JURISDICTION AND VENUE 38

ADDITIONAL FACTUAL ALLEGATIONS 39

A. Diabetes and Insulin Therapy 39

- The Diabetes Epidemic 39
- Insulin: A Century-Old Drug 40
- The Current Insulin Landscape 42
- Insulin Adjuncts: Type 2 Medications 42

B. The Dramatic Rise in the Price of Diabetes Medications in the U.S. 45

- The Defendant-Manufacturers Have Increased Prices in Lockstep 48

C. Pharmaceutical Payment and Supply Chain 52

D. The PBMs' Role in the Pharmaceutical Payment Chain 53

- The Rise of the PBMs in the Pharmaceutical Supply Chain 55
- The Insular Nature of the Pharmaceutical Industry 57

E. The Insulin Pricing Scheme 61

F. Defendants Play Down the Insulin Pricing Scheme and Its Harms 65

G. Defendant Profit from the Insulin Pricing Scheme 72

- The PBMs Pocket a Substantial Share of Manufacturer Payments 73
- The Insulin Pricing Scheme Allows the PBMs to Profit Off Pharmacies 80

- The Insulin Pricing Scheme Increases PBM Mail-Order Profits 84

H. Plaintiff Purchases the At-Issue Drugs Directly from Defendants 85

I. Defendants Deceived Plaintiff 87

J. The Insulin Pricing Scheme Has Damaged Plaintiff 100

K. Defendants' Recent Efforts in Response to Rising Insulin Prices 102

CLAIMS FOR RELIEF 105

FIRST CLAIM FOR RELIEF (Violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962(c)) (against Defendants Eli Lilly, Novo Nordisk, Sanofi, CVS Caremark, and Express Scripts) 105

A. Defendants Are Culpable "Persons" Under RICO. 105

B. The Manufacturer-PBM RICO Enterprises 106

C. The Enterprises Misrepresent and Fail to Disclose Material Facts in Furtherance of the Insulin Pricing Scheme. 110

D. Defendants' Use of the U.S. Mails and Interstate Wire Facilities 112

E. Conduct of the Manufacturer-PBM Enterprises' Affairs 114

F. Defendants' Pattern of Racketeering Activity 115

G. The RICO Defendants' Motive 117

H. The Manufacturer-PBM Enterprises' Insulin Pricing Scheme Injured Plaintiff.....117

SECOND CLAIM FOR RELIEF (Violations of RICO, 18 U.S.C. § 1962(d) By Conspiring to Violate 18 U.S.C. § 1962(c))(against all Defendants).....119

THIRD CLAIM FOR RELIEF (Unlawful Restraint of Trade, Tenn. Code Ann. §§ 47-25-101, *et seq*) (against all Defendants) 121

FOURTH CLAIM FOR RELIEF (Violation of Tennessee Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101, *et seq*) (against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx) 122

FIFTH CLAIM FOR RELIEF (Breach of Contract) (against Defendants Express Scripts, CVS Caremark, and OptumRx).....127

SIXTH CLAIM FOR RELIEF (Unjust Enrichment) (against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx)……...128

MOTION FOR INJUNCTION 130

PRAYER FOR RELIEF 130

JURY DEMAND 132

Plaintiff, Greene County, Tennessee ("Plaintiff," the "County" or "Greene County"), by and through undersigned counsel, brings this lawsuit against the above-named Defendants and alleges as follows:

INTRODUCTION

1. The cost of diabetes medications has risen more than tenfold over the past 20 years. Over the same period of time, the average cost of consumer goods and services has risen just 1.75-fold. The skyrocketing prices of diabetes medications are not tethered the rising cost of goods, production costs, investment in research and development, or competitive market forces. Instead, Defendants engineered these price increases via an opaque, conspiratorial kickback scheme (referred to herein as the "Insulin Pricing Scheme"), which has exponentially increased their profits at the expense of payors like Plaintiff and its plan members. The Insulin Pricing Scheme is a multibillion-dollar industry.

2. Diabetes is widespread. The total estimated cost of diabetes in the U.S. in 2017, according to the American Diabetes Association, was $327 billion. One in four healthcare dollars is spent caring for people with diabetes.

3. As of 2020, more than 13% of adults in Tennessee have been diagnosed with diabetes.[1] An additional 9.9% of the Tennessee adult population are prediabetic, with blood glucose levels higher than normal but not yet high enough to be diagnosed as diabetic.[2] In Greene, approximately 8.9%, of adult residents are living with diabetes.[3] In Tennessee alone, diabetes costs

[1] Tennessee Diabetes Action Legislative Report, Feb. 2021, https://www.capitol.tn.gov/Archives/senate/112GA/committees/health-welfare/2021/Diabetes%20Legislative%20Report_FinalDraft.%2001-29-2021%208%2045%20pm.pdf.

[2] *Id.*

[3] United States Diabetes Surveillance System, https://gis.cdc.gov/grasp/diabetes/diabetesatlas-analysis.html# (last visited January 26, 2024).

an estimated $5.2 billion per year in direct medical costs attributed to diabetes.[4] An additional $2.1 billion is spent on indirect costs from attributed to diabetes.[5]

4. Diabetics in Tennessee generally rely on daily insulin treatments, oral medications, or a combination of both to treat and control diabetes. Defendants Eli Lilly, Novo Nordisk, and Sanofi (collectively, the "Manufacturer Defendants" or the "Manufacturers") manufacture the vast majority of insulins and other diabetic medications available in the United States. In 2020, as in the years preceding, the Manufacturer Defendants controlled 92% by volume, and 96% by revenue, of the global market for diabetes drugs.

5. Defendants CVS Caremark, Express Scripts, and OptumRx (collectively, the "PBM Defendants" or the "PBMs") are pharmacy benefit managers that work with the Manufacturer Defendants to dictate the availability and price of the at-issue drugs for most of the U.S. market.[6] The PBM Defendants are, at once, (1) the three largest pharmacy benefit managers in the United States (controlling more than 80% of the PBM market); (2) the largest pharmacies in the United States (comprising three of the top five dispensing pharmacies in the U.S.); and (3) housed within the same corporate families as three of the largest insurance companies in the United States—Aetna (CVS Health), Cigna (Express Scripts), and UnitedHealthcare (OptumRx).

6. These corporate conglomerate Defendants sit at 4th (CVS Health), 5th (UnitedHealth Group), and 12th (Cigna) on the Fortune 500 list as of year-end 2022.

[4] Tennessee Diabetes Profile, https://www.cdc.gov/diabetes/programs/stateandlocal/state-diabetes-profiles/tennessee.html (last visited January 26, 2024).

[5] *Id.*

[6] In the context of this Complaint, the "at-issue drugs" or "at-issue medications" are: Apidra, Basaglar, Humalog, Humulin N, Humulin R, Humulin R 500, Humulin 70/30, Lantus, Levemir, Novolin N, Novolin R, Novolin 70/30, Novolog, Ozempic, Soliqua, Toujeo, Tresiba, Trulicity, and Victoza.

Figure 1: Manufacturers, PBMs & PBM-Affiliated Insurers

Manufacturers	PBMs	PBM-Affiliated Insurer
Eli Lilly		
Novo Nordisk		
Sanofi		
	CVS	Aetna
	Express Scripts	Cigna
	Optum	UnitedHealthcare

7. For transactions in which the PBM Defendants control the insurer, the PBM, and the pharmacy (e.g., Aetna–Caremark–CVS Pharmacy), these middlemen capture as much as half of the money spent on each insulin prescription (up from 25% in 2014), even though they contribute nothing to the development, manufacture, innovation, or production of the drugs.

8. As part of this work, the PBM Defendants establish national formulary offerings (i.e., approved drug lists), which, among other things, set the baseline for which diabetes medications are covered and which are not covered by nearly every payor in the United States, including in Tennessee and, more specifically, Greene County.

9. The Manufacturers and PBMs understand that the PBMs' national formularies drive drug utilization. The more accessible a drug is on the PBMs' national formularies, the more that drug will be purchased throughout the United States. Conversely, exclusion of a drug from one or more of the PBMs' formularies can render the drug virtually inaccessible for millions of covered persons.

10. Given the PBMs' market power and the crucial role their standard formularies play in the pharmaceutical pricing chain, both Defendant groups understand that the PBM Defendants wield enormous control over drug prices and purchasing behavior.

11. The unfair and deceptive conspiracy at the root of this complaint—the Insulin Pricing Scheme—was borne from this mutual understanding.

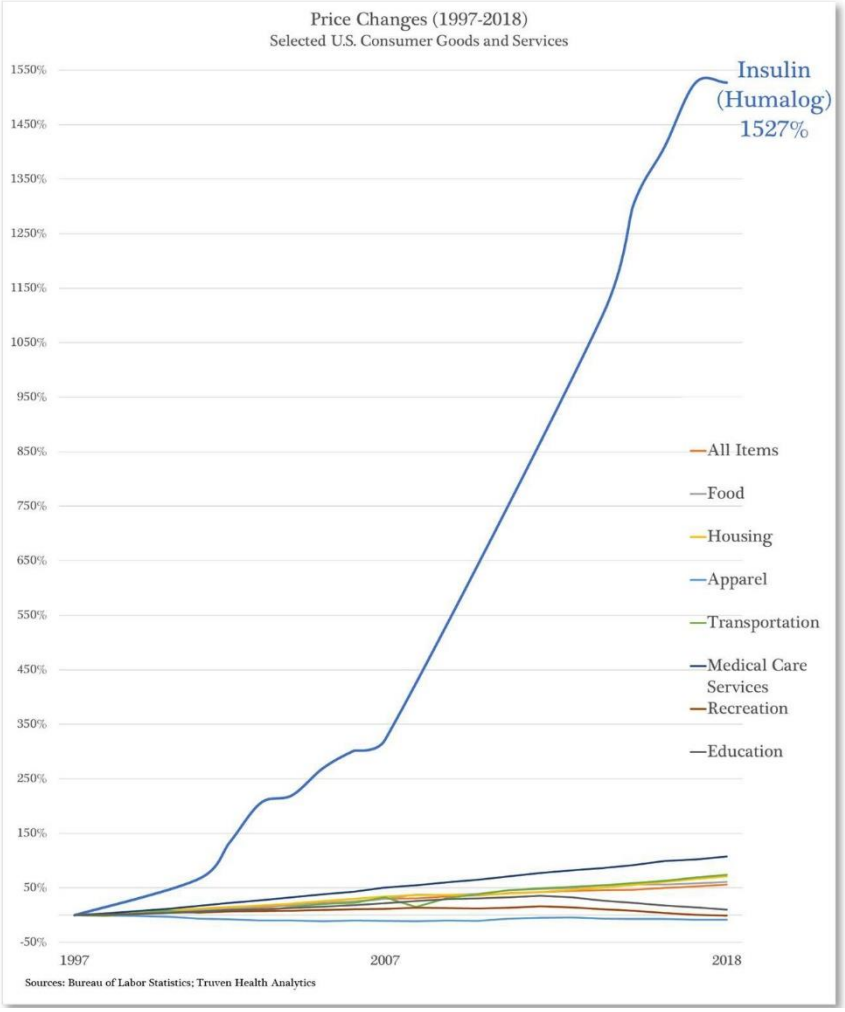
12. The Manufacturers set the initial list (wholesale) price for their respective insulin medications. Over the last 20 years, list prices have sharply increased in lockstep, even though the cost to produce these drugs decreased during that period.

13. Insulins, which today cost Manufacturers as little as $2 to produce, and which were originally priced at $20 the 1990s, now range in price from $300 to $700.

14. The Manufacturer Defendants have in tandem increased the prices of their insulins up to 1,000%, taking the same increase down to the decimal point within a few days of one another and, according to a U.S. Senate Finance Committee investigation, "sometimes mirroring" one another in "days or even hours."[7] Figure 2 shows the rate at which Defendant Eli Lilly raised the list price of its analog insulin, Humalog, compared to the rate of inflation for other consumer goods and services during the period from 1997- 2018.

[7] Charles E. Grassley & Ron Wyden, *Staff Report on Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug, Sen. Fin. Comm.*, at 6, 54, 55 (Jan. 2021), https://www.finance.senate.gov/imo/media/doc/GrassleyWyden%20Insulin%20Report%20 FINAL%201). Pdf (hereinafter "Grassley & Wyden" or "January 2021 Senate Insulin Report").

Figure 2: Price Increase of Insulin vs. Selected Consumer Goods, 1997-2018



15. Today's exorbitant prices do not accord with insulin's origins. The discoverers sold the original patent for $1 to ensure that the medication would remain affordable. But today, insulin is the poster child for skyrocketing pharmaceutical prices.

16. Nothing about these medications has changed over the past 100 years; today's $350 insulin is the same product Defendants once sold for $20.

How the Insulin Pricing Scheme Works

17. In the simplest terms, there are three important participants in the insulin medication chain.

a. **Greene County.** During the relevant period, Plaintiff Greene County operated a health plan for its employees and their dependents. The plan includes pharmacy benefits, meaning Plaintiff purchased the at-issue drugs for its beneficiaries. Operators of self-funded plans, like Plaintiff, may be referred to as payors or plan sponsors (or PBM "clients").

b. **PBMs.** Payors routinely engage pharmacy benefit managers to manage their prescription benefits, which includes negotiating prices with drug manufacturers and (ostensibly) helping payors manage drug spending. Each pharmacy benefit manager maintains a formulary—a list of covered medications. A pharmacy benefit manager's power to include or exclude a drug from its formulary theoretically should incentivize manufacturers to lower their list price. Pharmacy benefit managers also contract with pharmacies to reimburse them for medications purchased by the plan's beneficiaries. Pharmacy benefit managers are compensated by retaining a portion of what should—again in theory—be shared savings on the cost of medications.

c. **Manufacturers.** Manufacturers produce the at-issue insulin medications.[8] Each sets a list price for each of its products. The terms "list price" often is used interchangeably with the Wholesale Acquisition Cost (WAC) (defined by federal law as the undiscounted list price for a drug or biological to wholesalers or direct purchasers). The manufacturers self-report

[8] There are three types of insulin medications. First are *biologics*, which are manufactured insulins derived from living organisms. Second are *biosimilars*, which are "highly similar" copies of biologics. They are similar in concept to "generic" drugs; but in seeking approval they use biologics (rather than drugs) as comparators. Third, the confusingly-named *authorized generics* are not true generics—they are an approved brand-name drug marketed without the brand name on the label. FDA approved the original insulins as drug products rather than biologics, so although there was a regulatory pathway to introduce biosimilars generally (copies of biologics), companies could not introduce insulin biosimilars because their comparators were "drugs" rather than "biologics." In 2020, FDA moved insulin to the biologic regulatory pathway, thus opening the door to approval of biosimilars through an abbreviated approval process.

list prices to publishing compendiums such as First DataBank, Medi-Span, or Redbook, who then publish those prices.[9]

18. Given the PBMs' purchasing power and their control over formularies that govern the availability of drugs, their involvement should theoretically drive down list prices. Instead, to gain access to the PBMs' formularies, the Manufacturers artificially inflate their list prices and then pay a significant, but undisclosed, portion of the inflated price back to the PBMs (the "Manufacturer Payments").[10] The Manufacturer Payments bear a variety of dubious labels—rebates, discounts, credits, inflation/price protection fees, administrative fees, etc. By whatever name, the inflated list prices and resulting Manufacturer Payments are a quid pro quo for inclusion and favorable placement on the PBMs' formularies.[11]

19. Contracts between PBM Defendants and payors like Plaintiff tie the definition of "rebates" to patient drug utilization. But the contracts between PBMs and Manufacturers define "rebates" and other Manufacturer Payments differently—e.g., calling rebates for formulary placement "administrative fees." Defendants thus profit from the "rebates" and other Manufacturer Payments, and the payments are beyond a payor's contractual audit right to verify the accuracy of "rebate" payments they receive.

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[9] The related term Average Wholesale Price (AWP) is the published price for a drug sold by wholesalers to retailers.

[10] In this Complaint, "Manufacturer Payments" is defined as all payments or financial benefits of any kind conferred by the Manufacturer Defendants to PBM Defendants (or a subsidiary, affiliated entity, or group purchasing organization or rebate aggregator acting on a PBM's behalf), either directly via contract or indirectly via Manufacturer-controlled intermediaries. Manufacturer Payments includes rebates, administrative fees, inflation fees, pharmacy supplemental discounts, volume discounts, price or margin guarantees, and any other form of consideration exchanged.

[11] Favorable or preferred placement may, for example, involve placing a branded product in a lower cost-sharing tier or relaxing utilization controls (such as prior authorization requirements or quantity limits). Favorable placement of a relatively more expensive drug encourages use of that drug and leads to higher out-of-pocket costs for payors and copayors.

20. The PBMs' staggering revenues vastly exceed the fair market value of the services they provide and, specifically, the amount of Manufacturer Payments the PBMs receive in connection with the at-issue drugs vastly exceeds the fair market value of the services they provide with respect to those drugs.

21. The Manufacturers' list prices are not the result of free-market competition for payors' business. The Manufacturers' list prices are so untethered from the net prices that the Manufacturers ultimately realize that the Manufacturers know the list price constitutes a false price. It does not reflect the Manufacturers' actual costs to produce the at-issue drugs or the fair market value of the drugs.[12]

22. The PBMs grant formulary status based upon the highest inflated price—a price that the PBMs know is false—and based upon which diabetes medications will generate the largest profits for themselves.

23. The Insulin Pricing Scheme creates a "best of both worlds" scenario for Defendants. The Manufacturer Defendants buy formulary access and increase their revenues while the PBM Defendants receive significant secret Manufacturer Payments.

24. The PBM Defendants profit off the Insulin Pricing Scheme in numerous ways, including by: (1) retaining a significant, but undisclosed, share of the Manufacturer Payments, either directly or through rebate aggregators, (2) using the price produced by the Insulin Pricing Scheme to generate unwarranted profits from pharmacies, and (3) relying on those same artificial

[12] "Net price" refers to the price the manufacturer ultimately realizes, i.e., the list price less rebates, discounts, etc. (net sales divided by volume). At times, Defendants' representatives use "net price" to refer to the amount payors or plan members pay for medications. In this Complaint, "net price" refers to the former—the amount that the Defendant Manufacturers realize for the at-issue drugs, which is roughly the List Price less Manufacturer Payments.

list prices to drive up the PBMs' margins and pharmacy related fees, including those relating to their mail-order pharmacies.

25. As detailed below, although the PBM Defendants represent both publicly and directly to their client payors that they use their market power to drive down prices for diabetes medications, these representations are false and deceptive. Instead, the PBMs intentionally incentivize the Manufacturers to inflate list prices, and the PBMs' "negotiations" intentionally drive up the price of the at-issue drugs and are directly responsible for the skyrocketing price of diabetes medications, which confers unearned benefits upon the PBMs and Manufacturers alike.

26. Because the purchase price of every at-issue diabetes medication flows from the false list price generated by Defendants' unfair and deceptive scheme, every payor in the United States that purchases these life-sustaining drugs, including Plaintiff, has been directly harmed by the Insulin Pricing Scheme.

27. Even if temporary reductions in Plaintiff's costs for the at-issue drugs occurred from time to time, those costs remained higher than the prices that would have resulted from a transparent exchange in an open and competitive market.

28. As a payor for and purchaser of the at-issue drugs, and, as a direct result of the Insulin Pricing Scheme, Greene County has spent exorbitant amounts of capital on the at-issue diabetes medications.

29. A substantial portion of this exorbitant amount is attributable to Defendants' artificially inflated prices that did not arise from transparent or competitive market forces; rather, these inflated costs can be attributed to undisclosed dealings between the Manufacturer Defendants and the PBM Defendants as further described herein.

30. This action alleges that Defendants violated the Racketeer Influenced and Corrupt Organizations Act, Tennessee Consumer Protection Act, and Tennessee common law by engaging in the Insulin Pricing Scheme. The Insulin Pricing Scheme directly and foreseeably caused and continues to cause harm to Plaintiff.

31. This action seeks injunctive relief, restitution, disgorgement, actual damages, treble damages, punitive damages, and attorneys' fees and costs to address and abate the harm caused by the Insulin Pricing Scheme.

32. The relevant period for damages alleged in this Complaint is from 2003 through the present.

PARTIES

A. Plaintiff

33. Plaintiff Greene County is a body corporate and politic under the laws of the State of Tennessee.

34. Plaintiff, as a government entity, provides vital services to its population of over 70,000 residents including public safety, emergency management, and health services.

35. Any increase in spending has a detrimental effect on Plaintiff's overall budget and, in turn, negatively impacts its ability to provide necessary services to the community.

36. The Insulin Pricing Scheme has had such an effect.

37. Additionally, as a government employer, Plaintiff provides health benefits to its employees, retirees, and their dependents ("Beneficiaries"). These benefits include paying for Beneficiaries' pharmaceutical drugs, including the at-issue diabetes medications. Plaintiff also purchases the at-issue diabetes medications for use in county-run facilities.

38. Plaintiff maintains a self-insured health plan for its Beneficiaries.

39. Exclusive of the costs associated with providing diabetes medications at county-run facilities, such as correctional facilities, Plaintiff spends thousands of dollars per year on the costs of providing diabetes medications for its health-plan members. Accordingly, during the relevant period, and to the detriment of its Beneficiaries and taxpayers, Plaintiff has paid millions of dollars more for insulin than it otherwise would have paid absent Defendants' conduct.

40. Plaintiff seeks to recover for the losses it has suffered due to Defendants' illegal Insulin Pricing Scheme.

B. Manufacturer Defendants

41. **Defendant Eli Lilly and Company ("Eli Lilly")** is an Indiana corporation with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

42. Eli Lilly is registered to do business in the State of Tennessee. Eli Lilly may be served through its registered agent: National Registered Agents, Inc., 300 Montvue Road, Knoxville, Tennessee 37919-5546.

43. In Tennessee and nationally, Eli Lilly manufactures, promotes, and distributes several at-issue diabetes medications: Humulin N, Humulin R, Humalog, Trulicity, and Basaglar.

44. Eli Lilly's global revenues in 2019 were $4.13 billion from Trulicity, $2.82 billion from Humalog, $1.29 billion from Humulin and $1.11 billion from Basaglar.

45. Eli Lilly's global revenues in 2018 were $3.2 billion from Trulicity, $2.99 billion from Humalog, $1.33 billion from Humulin and $801 million from Basaglar.

46. Eli Lilly transacts business in Tennessee and in Greene County, targeting these markets for its products, including the at-issue diabetes medications.

47. Eli Lilly employs sales representatives throughout Tennessee to promote and sell Humulin N, Humulin R, Humalog, Trulicity, and Basaglar.

48. Eli Lilly also directs advertising and informational materials to Tennessee and Greene County physicians and potential users of Eli Lilly's products.

49. At all times relevant hereto, in furtherance of the Insulin Pricing Scheme, Eli Lilly published its prices for the at-issue diabetes medications throughout Tennessee with the express knowledge that payment and reimbursement by Plaintiff would be based on those false list prices.

50. During the relevant time period, Plaintiff purchased Eli Lilly's at-issue drugs at a price based on false list prices generated by the Insulin Pricing Scheme through its employee health plans and for use in county-run facilities.

51. All of the Eli Lilly diabetes medications related to the at-issue transactions were paid for and/or reimbursed in Tennessee based on the specific false and inflated prices Eli Lilly caused to be published in Tennessee in furtherance of the Insulin Pricing Scheme.

52. **Defendant Sanofi-Aventis U.S. LLC ("Sanofi")** is a Delaware limited liability company with its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

53. Sanofi may be served through its registered agent: Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808.

54. Sanofi manufactures, promotes, and distributes pharmaceutical drug both in Tennessee and nationally, including several at-issue diabetes medications: Lantus, Toujeo, Soliqua, and Apidra.

55. Sanofi's global revenues in 2019 were $3.50 billion from Lantus and $1.03 billion from Toujeo, $400 million from Apidra and $144 million from Soliqua.

56. Sanofi's global revenues in 2018 were $3.9 billion from Lantus, $923 million from Toujeo, $389 million from Apidra and $86 million from Soliqua.

57. Sanofi does business in Tennessee and in Greene County, targeting these markets for its products, including the at-issue diabetes medications.

58. Sanofi employs sales representatives throughout Tennessee and in this District to promote and sell Lantus, Toujeo, Soliqua, and Apidra.

59. Sanofi also directs advertising and informational materials to Tennessee physicians and potential users of Sanofi's products for the specific purpose of selling the at-issue drugs in Tennessee and Greene County and profiting from the Insulin Pricing Scheme.

60. At all times relevant hereto, in furtherance of the Insulin Pricing Scheme, Sanofi published its prices of its at-issue diabetes medications throughout Tennessee for the purpose of payment and reimbursement by payors, including Plaintiff.

61. During the relevant time period, Plaintiff Greene County purchased Sanofi's at-issue drugs at prices based on false list prices generated by the Insulin Pricing Scheme through its employee health plans and for use in county-run facilities.

62. All of the Sanofi diabetes medications related to the at-issue transactions were paid for and/or reimbursed in Tennessee and Greene County based on the specific false and inflated prices Sanofi caused to be published in Tennessee in furtherance of the Insulin Pricing Scheme.

63. **Defendant Novo Nordisk Inc. ("Novo Nordisk")** is a Delaware corporation with its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

64. Novo Nordisk is registered to do business in the State of Tennessee. Novo Nordisk may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

65. Novo Nordisk manufactures, promotes, and distributes pharmaceutical drugs both in Tennessee and nationally, including at-issue diabetic medications: Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic.

66. Nordisk's global revenues in 2019 were $2.89 billion from Novolog, $973 million from Levemir, $968 million from Tresiba, $2.29 billion from Victoza and $1.17 billion from Ozempic.[13]

67. Novo Nordisk's global revenues in 2018 were $4.19 billion from Novolog, $1.66 billion from Levemir, $1.19 billion from Tresiba, $3.61 billion from Victoza and $185 million from Ozempic.

68. Novo Nordisk transacts business in Tennessee and in Greene County, targeting these markets for its products, including the at-issue diabetes medications.

69. Novo Nordisk employs sales representatives throughout Tennessee and Greene County to promote and sell Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic.

70. Novo Nordisk also directs advertising and informational materials to Tennessee and Greene County physicians and potential users of Novo Nordisk's products.

71. At all times relevant hereto, in furtherance of the Insulin Pricing Scheme, Novo Nordisk published its prices of its at-issue diabetes medications throughout Tennessee for the purpose of payment and reimbursement by Plaintiff.

72. During the relevant time period, Plaintiff purchased Novo Nordisk's at-issue diabetes medications at prices based on false list prices generated by the Insulin Pricing Scheme through its employee health plans and for use in county-run facilities.

[13] Novo Nordisk, Annual Report (Form 20-F) (Dec. 31, 2019).

73. All Novo Nordisk diabetes medications related to the at-issue transactions were paid for and/or reimbursed in Tennessee based on the specific false and inflated prices Novo Nordisk caused to be published in Tennessee in furtherance of the Insulin Pricing Scheme.

74. Collectively, Defendants Eli Lilly, Novo Nordisk, and Sanofi are referred to as the "Manufacturer Defendants" or the "Manufacturers."

C. PBM Defendants

75. **Defendant CVS Health Corporation ("CVS Health")** is a Delaware corporation with its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895. CVS Health transacts business and has locations throughout the United States and Tennessee.

76. CVS Health may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

77. CVS Health—through its executives and employees, including its CEO, Chief Medical Officer, Executive Vice Presidents, Senior Executives in Trade Finance, Senior Vice Presidents, and Chief Communication Officers—is directly involved in creating and implementing the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs involved in the Insulin Pricing Scheme.

78. CVS Health's conduct had a direct effect in Tennessee and damaged Plaintiff Greene County as a payor and purchaser.

79. On a regular basis, CVS Health executives and employees communicate with and direct its subsidiaries related to the at-issue PBM services and formulary activities.

80. In each annual report for at least the last decade, CVS Health (or its predecessor) has repeatedly and explicitly stated that CVS Health:

- designs pharmacy benefit plans that minimize the costs to the client while prioritizing the welfare and safety of the clients' members;

- negotiates with pharmaceutical companies to obtain discounted acquisition costs for many of the products on CVS Health's drug lists, and these negotiated discounts enable CVS Health to offer reduced costs to clients; and

- utilizes an independent panel of doctors, pharmacists, and other medical experts, referred to as its Pharmacy and Therapeutics Committee, to select drugs that meet the highest standards of safety and efficacy for inclusion on its drug lists.

81. CVS Health publicly represents that it constructs programs that lower the cost of the at-issue diabetes medications. For example, in 2016, CVS Health announced a new program to "reduce overall spending in diabetes" that is available in all states, including Tennessee, stating:

> *CVS Health* introduced a new program available to help the company's pharmacy benefit management (PBM) clients to improve the health outcomes of their members, *lower pharmacy costs [for diabetes medications]* through aggressive trend management and decrease medical costs . . . [and that] participating clients could save between $3000 to $5000 per year for each member who successfully improves control of their diabetes" (emphasis supplied).[14]

82. In 2017, CVS Health stated that "*CVS Health* pharmacy benefit management (PBM) strategies reduced trend for commercial clients to 1.9 percent per member per year the lowest in five years. Despite manufacturer price increases of near 10 percent, *CVS Health* kept drug price growth at a minimal 0.2 percent."

83. In November 2018, CVS Health acquired Aetna for $69 billion and became the first combination of a major health insurer, PBM, and mail-order and retail pharmacy chain. As a result, CVS Health controls the health plan/insurer, the PBM, and the pharmacies utilized by approximately 40 million Aetna members in the United States, including in Tennessee. CVS Health controls the entire drug pricing chain for these 40 million Americans.

[14] CVS HEALTH, *CVS Health Introduces New "Transform Diabetes Care" Program to Improve Health Outcomes and Lower Overall Health Care Costs* (Dec. 13, 2016), https://cvshealth.com/newsroom/press-releases/cvs-health-introduces-newtransform-diabetes-care-program-improve-health.

84. CVS Health is the immediate or indirect parent of many pharmacy subsidiaries that own and operate hundreds of pharmacies throughout Tennessee that dispensed and received payment for the at-issue diabetes medications throughout the relevant time period.

85. **Defendant CVS Pharmacy, Inc. ("CVS Pharmacy")** is a Rhode Island corporation whose principal place of business is at the same location as CVS Health. CVS Pharmacy is a wholly owned subsidiary of CVS Health.

86. CVS Pharmacy is the immediate or indirect parent of many pharmacy subsidiaries that own and operate hundreds of pharmacies throughout Tennessee and is directly involved in these pharmacies dispensing and payment policies related to the at issue diabetes medications.

87. CVS Pharmacy is also the immediate and direct parent of Defendant Caremark Rx, LLC.

88. CVS Pharmacy is registered to do business in Tennessee and has been since at least 1997.

89. CVS Pharmacy is registered to do business in the State of Tennessee. CVS Pharmacy may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

90. During the relevant time period, CVS Pharmacy provided retail pharmacy services in Tennessee that gave rise to the Insulin Pricing Scheme, which damaged Plaintiff.

91. **Defendant Caremark Rx, LLC** is a Delaware limited liability company and an immediate or indirect parent of many subsidiaries, including pharmacy benefit management and mail-order subsidiaries that engaged in the activities in Tennessee that gave rise to this Complaint.

92. Caremark Rx, LLC is a wholly owned subsidiary of Defendant CVS Pharmacy and its principal place of business is at the same location as CVS Pharmacy and CVS Health.

93. Caremark Rx, LLC is registered to do business in Tennessee and has been since at least 2007. Caremark Rx, LLC may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

94. During the relevant time period, Caremark Rx, LLC provided PBM and mail order pharmacy services in Tennessee that gave rise to the Insulin Pricing Scheme and damaged payors in Tennessee, including Plaintiff.

95. **Defendant Caremark, LLC** is a California limited liability company whose principal place of business is at the same location as CVS Health. Caremark, LLC is a wholly owned subsidiary of Caremark Rx, LLC.

96. Caremark, LLC is registered to do business in Tennessee and has been since at least 2007. Caremark, LLC may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

97. During the relevant time period, Caremark, LLC provided PBM and mail order pharmacy services in Tennessee and Greene County that gave rise to the Insulin Pricing Scheme, which damaged Plaintiff.

98. **Defendant CaremarkPCS Health, LLC** is a Delaware limited liability company whose principal place of business is at the same location as CVS Health. CVS Health is the direct or indirect parent company of CaremarkPCS Health LLC.

99. CaremarkPCS Health, LLC, doing business as CVS Caremark, provides pharmacy benefit management services.

100. CaremarkPCS Health, LLC is registered to do business in Tennessee and has been since at least 2009. CaremarkPCS Health, LLC may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

101. During the relevant time period, CaremarkPCS Health, LLC provided PBM services in the State of Tennessee, which gave rise to the Insulin Pricing Scheme and damaged Plaintiff Greene.

102. Defendants CaremarkPCS Health, LLC and Caremark, LLC are agents and/or alter egos of Caremark Rx, LLC, CVS Pharmacy, and CVS Health.

103. As a result of numerous interlocking directorships and shared executives, Caremark Rx, LLC, CVS Pharmacy, and CVS Health are directly involved in the conduct of and control CaremarkPCS Health, LLC and Caremark, LLC's operations, management, and business decisions related to the at-issue formulary construction; Manufacturer Payments; and mail-order and retail pharmacy services—to the ultimate detriment of Plaintiff. For example:

a. During the relevant time period, these parent and subsidiaries have had common officers and directors, including:

- Thomas S. Moffatt, Vice President and Secretary of Caremark Rx, LLC, CaremarkPCS Health LLC, and Caremark, LLC, is also a Vice President, Assistant Secretary, and Senior Legal Counsel at CVS Health and the Vice President, Secretary and Senior Legal Counsel of CVS Pharmacy;

- Melanie K. Luker, Assistant Secretary of Caremark Rx, LLC, CaremarkPCS Health, LLC, and Caremark, LLC, is also a Manager of Corporate Services at CVS Health;

- Carol A. Denale, Senior Vice President and Treasurer of Caremark Rx, LLC, is also Senior Vice President, Treasurer and Chief Risk Officer at CVS Health Corporation;

- John M. Conroy has been Vice President of Finance at CVS Health since 2011, and was also President and Treasurer of Caremark, LLC and CaremarkPCS Health LLC in 2019; and

- Sheelagh Beaulieu has been the Senior Director of Income Tax at CVS Health while also acting as the Assistant Treasurer at CaremarkPCS Health LLC and Caremark LLC.

b. CVS Health owns all the stock of CVS Pharmacy, which, in turn, owns all the stock of Caremark Rx, LLC, which, in turn, owns all the stock of Caremark LLC. CVS Health also directly or indirectly owns all the stock of CaremarkPCS Health LLC.

c. CVS Health, as a corporate family, does not operate as separate entities. The public filings, documents, and statements of CVS Health present its subsidiaries, including CVS Pharmacy, CaremarkPCS Health, LLC, Caremark, LLC and Caremark Rx, LLC as divisions or departments of one unified "diversified health services company" that "works together across our disciplines" to "create unmatched human connections to transform the health care experience." The day-to-day operations of this corporate family reflect these public statements. These entities are a single business enterprise and should be treated as such as to all legal obligations discussed in this Complaint.[15]

d. All executives of CaremarkPCS Health, LLC, Caremark, LLC, Caremark Rx, LLC, and CVS Pharmacy ultimately report to the executives at CVS Health, including the President and CEO of CVS Health.

e. As stated above, CVS Health's CEO, Chief Medical Officer, Executive Vice Presidents, Senior Executives in Trade Finance, Senior Vice Presidents, and Chief Communication Officers are directly involved in the policies and business decisions of CaremarkPCS Health, LLC and Caremark, LLC that gave rise to Plaintiff Greene County's claims in this Complaint.

[15] CVS Caremark/CVS Health, Annual Report (Form 10-K) (Dec. 31, 2009-2019); CVS Health, *Our Purpose*, https://cvshealth.com/about-cvs-health/our-purpose (last visited Sept. 9, 2022); CVS Health, *Quality of Care*, https://cvshealth.com/health-withheart/improving-health-care/quality-of-care (last visited Sept. 9, 2022).

104. Collectively, Defendants CVS Health, CVS Pharmacy, Caremark Rx, LLC, Caremark, LLC and CaremarkPCS Health, LLC, including all predecessor and successor entities, are referred to as "CVS Caremark."

105. CVS Caremark is named as a Defendant in its capacities as a PBM and pharmacy.

106. In its capacity as a PBM, CVS Caremark coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the price of the at-issue diabetes medications, as well as for the placement of these Manufacturers' diabetes medications on CVS Caremark's formularies.

107. CVS Caremark has the largest PBM market share based on total prescription claims managed, representing approximately 40% of the national market. CVS Caremark's pharmacy services segment generated $141.5 billion in total revenues last year.

108. At all times relevant hereto, CVS Caremark offered pharmacy benefit services nationwide and to Tennessee payors, and derived substantial revenue therefrom, and, in doing so, made the at-issue misrepresentations (discussed below) and utilized the false prices generated by the Insulin Pricing Scheme to unlawfully profit off of payors like Plaintiff.

109. At all times relevant hereto, CVS Caremark offered pharmacy benefit management services nationwide and maintained standard formularies that are used nationwide, including in Tennessee. During the relevant time period, those formularies included diabetes medications, including all of those at issue in this Complaint.

110. CVS Caremark purchases drugs directly from manufacturers and through drug wholesalers for dispensing through its mail-order pharmacy.

111. During the relevant time period, CVS Caremark provided PBM services to Plaintiff and, in doing so, CVS Caremark set the price that Plaintiff paid for the at-issue drugs based on the

false list prices generated by the Insulin Pricing Scheme. Plaintiff paid CVS Caremark for the at-issue drugs.

112. In its capacity as a retail pharmacy, CVS Caremark further and knowingly profited from the false list prices produced by the Insulin Pricing Scheme by pocketing the spread between acquisition cost for the drugs at issue (an amount well below the list price generated by the Insulin Pricing Scheme), and the amounts it received from payors (which amounts were based on the false list prices and, in many cases, were set by CVS Caremark in its capacity as a PBM).

113. During the relevant time period, CVS Caremark provided mail-order and retail pharmacy services to Plaintiff and, in doing so, Plaintiff paid CVS Caremark for the at-issue drugs at prices based on the false list prices generated by the Insulin Pricing Scheme.

114. At all times relevant hereto, CVS Caremark dispensed the at-issue medications nationwide and directly to Plaintiff through its mail-order and retail pharmacies and derived substantial revenue from these activities in Tennessee.

115. At all times relevant hereto, CVS Caremark had express agreements with Defendants Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid by the Manufacturer Defendants to CVS Caremark, as well as agreements related to the Manufacturers' at-issue drugs sold through CVS Caremark's mail-order pharmacies.

116. **Defendant Evernorth Health, Inc. ("Evernorth")**, formerly known as Express Scripts Holding Company, is a Delaware corporation with its principal place of business at 1 Express Way, St. Louis, Missouri 63121.[16]

[16] Until 2021, Evernorth Health, Inc. conducted business under the name Express Scripts Holding Company. For the purposes of this Complaint "Evernorth" refers to Evernorth Health, Inc and Express Scripts Holding Company.

117. Evernorth may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

118. Evernorth, through its executives and employees, including its CEO and Vice Presidents, is directly involved in shaping the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs, related to the Insulin Pricing Scheme.

119. Evernorth's conduct had a direct effect in Tennessee and with respect to Plaintiff Greene County.

120. On a regular basis, Evernorth executives and employees communicate with and direct Evernorth's subsidiaries related to the at-issue PBM services and formulary activities.

121. Evernorth is the immediate or indirect parent of pharmacy and PBM subsidiaries that operate throughout Tennessee, which engaged in the activities that gave rise to this Complaint.

122. In December 2018, Evernorth merged with Cigna in a $67 billion deal to consolidate their businesses as a major health insurer, PBM, and mail-order pharmacy. As a result, the Evernorth corporate family controls the health plan/insurer, the PBM, and the mail-order pharmacies utilized by approximately 15 million Cigna members in the United States, including in Tennessee. Evernorth controls the entire drug pricing chain for these 15 million Americans.

123. In each annual report for at least the last decade, Evernorth has repeatedly and explicitly:

- Acknowledged that it is directly involved in the company's PBM services, stating "[Evernorth is] the largest stand-alone PBM company in the United States."

- Stated that Evernorth: "provid[es] products and solutions that focus on improving patient outcomes and assist in controlling costs; evaluat[es] drugs for efficacy, value and price to assist clients in selecting a cost-effective formulary; [and] offer[s] cost-effective home delivery pharmacy and specialty services that result in cost savings for plan sponsors and better care for members."

124. **Defendant Express Scripts, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. Express Scripts, Inc.'s principal place of business is the same location as Evernorth.

125. Express Scripts, Inc. is registered to do business in Tennessee and has been since at least 2017. Express Scripts, Inc. may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 39719-5546.

126. Express Scripts, Inc. is the immediate or indirect parent of pharmacy and PBM subsidiaries that operate throughout Tennessee that engaged in the conduct that gave rise to this Complaint.

127. During the relevant time period, Express Scripts Inc. was directly involved in the PBM and mail-order pharmacy services that gave rise to the Insulin Pricing Scheme and damaged Plaintiff.

128. Indeed, Express Scripts, Inc. provided pharmacy benefit services to Plaintiff, based on Plaintiff's reliance upon Express Scripts, Inc.'s response to Plaintiff's Request for Proposals.

129. **Defendant Express Scripts Administrators, LLC**, doing business as Express Scripts and formerly known as Medco Health, LLC, is a Delaware limited liability company and is a wholly owned subsidiary of Evernorth. Express Scripts Administrators, LLC's principal place of business is at the same location as Evernorth.

130. Express Scripts Administrators, LLC is registered to do business in Tennessee and may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

131. During the relevant time period, Express Scripts Administrators, LLC provided the PBM services in Tennessee discussed in this Complaint that gave rise to the Insulin Pricing Scheme that damaged Plaintiff.

132. **Defendant Medco Health Solutions, Inc. ("Medco")** is a Delaware Corporation with its principal place of business located at 100 Parsons Pond Road, Franklin Lakes, New Jersey.

133. Medco is registered to do business in Tennessee and may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

134. In 2012, Express Scripts acquired Medco for $29 billion.

135. Prior to the merger, Express Scripts and Medco were two of the largest PBMs in the United States and in Tennessee.

136. Prior to the merger, Medco provided the at-issue PBM and mail-order services, which gave rise to the Insulin Pricing Scheme and damaged Plaintiff, within Tennessee.

137. Following the merger, all of Medco's PBM and mail-order pharmacy functions were combined into Express Scripts. The combined company (Medco and Express Scripts) continued under the name Express Scripts with all of Medco's payor customers becoming Express Scripts' customers. The combined company covered over 155 million lives at the time of the merger.

138. At the time of the merger, on December 6, 2011, in his testimony before the Senate Judiciary Committee, David B. Snow, the then-CEO of Medco, publicly represented that "the merger of Medco and Express Scripts will result in immediate savings to our clients and, ultimately, to consumers. This is because our combined entity will achieve even greater [Manufacturer Payments] from drug manufacturers and other suppliers."

139. The then-CEO of Express Scripts, George Paz, during a Congressional subcommittee hearing in September 2011, echoed these sentiments: "A combined Express Scripts and Medco will be well-positioned to protect American families from the rising cost of prescription medicines."

140. **Defendant ESI Mail Pharmacy Service, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. ESI Mail Pharmacy Service, Inc.'s principal place of business is the same location as Evernorth.

141. ESI Mail Pharmacy Service, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

142. During the relevant time period, ESI Mail Pharmacy Services provided the mail-order pharmacy services in Tennessee discussed in this Complaint, which gave rise to the Insulin Pricing Scheme and damaged Plaintiff.

143. **Defendant Express Scripts Pharmacy, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. Express Scripts Pharmacy, Inc.'s principal place of business is at the same location as Evernorth.

144. Express Scripts Pharmacy, Inc. is registered to do business in Tennessee and has been since 2021. Express Scripts Pharmacy, Inc. may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

145. During the relevant time period, Express Scripts Pharmacy, Inc. provided the mail-order pharmacy services in Tennessee discussed in this Complaint, which gave rise to the Insulin Pricing Scheme and damaged Plaintiff.

146. As a result of numerous interlocking directorships and shared executives, Evernorth and Express Scripts, Inc. control Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., and Express Scripts Pharmacy, Inc's operations, management, and business decisions related to the at-issue formulary construction, negotiations, and mail-order pharmacy services to the ultimate detriment of Plaintiff. For example:

a. During the relevant time period, these parent and subsidiaries have had common officers and directors:

- Officers and/or directors shared between Express Scripts, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; David Queller, President; Jill Stadelman, Managing Counsel; and Scott Lambert, Treasury Manager Director;
- Executives shared between Express Scripts Administrators, LLC and Evernorth include Bradley Phillips, Chief Financial Officer; and Priscilla Duncan, Associate Senior Counsel;
- Officers and/or directors shared between ESI Mail Pharmacy Service, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; Priscilla Duncan, Associate Senior Counsel; and Joanne Hart, Treasury Director; and
- Officers and/or directors shared between Express Scripts Pharmacy, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; Jill Stadelman, Managing Counsel; Scott Lambert, Treasury Manager Director; and Joanne Hart, Treasury Director.

b. Evernorth directly or indirectly owns all the stock of Express Scripts Administrators, LLC, Medco Health Solutions, Inc., ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc. and Express Scripts, Inc.

c. The Evernorth corporate family does not operate as separate entities. The public filings, documents, and statements of Evernorth present its subsidiaries, including Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc. and Express Scripts, Inc., as divisions or departments of a single company that "unites businesses that have as many as 30+ years of experience . . . to

take health services further with integrated data and analytics that help us deliver better care to more people." The day-to-day operations of this corporate family reflect these public statements. All of these entities comprise a single business enterprise and should be treated as such as to all legal obligations detailed in this Complaint. All of the executives of Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc., and Express Scripts, Inc. ultimately report to the executives, including the CEO, of Evernorth.

d. As stated above, Evernorth's CEO and other executives and officers are directly involved in the policies and business decisions of Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., Express Scripts Pharmacy, Inc., and Express Scripts, Inc. that gave rise to Plaintiff's claims in this Complaint.

147. Collectively, Defendants Evernorth Health, Inc., Express Scripts, Inc., Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., and Express Scripts Pharmacy, Inc., including all predecessor and successor entities, are referred to as "Express Scripts."

148. Express Scripts is named as a Defendant in its capacities as a PBM and mail order pharmacy.

149. In its capacity as a PBM, Express Scripts coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the price of the at-issue diabetes medications, as well as for the placement of these Manufacturers' diabetes medications on Express Script's formularies.

150. Prior to merging with Cigna in 2019, Express Scripts was the largest independent PBM in the United States. During the relevant period of this Complaint, Express Scripts controlled

30% of the PBM market in the United States. Express Scripts has only grown larger since the Cigna merger.

151. In 2017, annual revenue for Express Scripts was over $100 billion.

152. As of December 31, 2018, more than 68,000 retail pharmacies, representing over 98% of all retail pharmacies in the nation, participated in one or more of Express Scripts' networks.

153. Express Scripts transacts business throughout the United States and Tennessee.

154. At all times relevant hereto, Express Scripts derived substantial revenue providing pharmacy benefits in Tennessee.

155. At all times relevant hereto, and contrary to their express representations, Express Scripts knowingly insisted that its payor clients use the false list prices produced by the Insulin Pricing Scheme as the basis for reimbursement of the at-issue drugs.

156. At all times relevant hereto, Express Scripts concealed its critical role in the generation of those false list prices.

157. At all times relevant hereto, Express Scripts maintained standard formularies that are used nationwide, including in Tennessee. During the relevant time period, those formularies included drugs produced by the Manufacturer Defendants, including the at-issue diabetes medications.

158. During the relevant time period, Express Scripts provided PBM services to Plaintiff and, in doing so, Express Scripts set the price that Plaintiff paid for the at-issue drugs, at prices based on the false list prices generated by the Insulin Pricing Scheme, and Plaintiff paid Express Scripts for the at-issue drugs.

159. In its capacity as a mail-order pharmacy, Express Scripts received payments from Tennessee payors for, and set the out-of-pocket price paid for, the at-issue drugs based on the falsely inflated prices generated by the Insulin Pricing Scheme and, as a result, damaged Plaintiff.

160. At all times relevant hereto, Express Scripts offered pharmacy benefit management services nationwide and maintained standard formularies that are used nationwide, including in Tennessee. During the relevant time period, those formularies included diabetes medications, including all of those at issue in this Complaint.

161. Express Scripts purchases drugs directly from manufacturers for dispensing through its mail-order pharmacy.

162. At all times relevant hereto, Express Scripts dispensed the at-issue medications nationwide and directly to Plaintiff through its mail-order pharmacies and derived substantial revenue from these activities in Tennessee.

163. During the relevant time period, in addition to its critical role in the Insulin Pricing Scheme, which detrimentally affected all payors and purchasers of the at-issue drugs, Express Scripts also provided PBM services directly to Plaintiff Greene County.

164. During the years when some of the largest at-issue price increases occurred, Express Scripts worked directly with OptumRx to negotiate Manufacturer Payments on behalf of OptumRx and its clients in exchange for preferred formulary placement.

165. For example, in a February 2014 email released by the U.S. Senate in conjunction with its January 2021 report titled “Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug” (“January 2021 Senate Insulin Report”), Eli Lilly describes a “Russian nested

doll situation" in which Express Scripts was negotiating rebates on behalf of OptumRx related to the at-issue drugs for Cigna (who later would become part of Express Scripts).[17]

166. At all times relevant hereto, Express Scripts had express agreements with Defendants Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid by the Manufacturer Defendants to Express Scripts, as well as agreements related to the Manufacturers' at-issue drugs sold through Express Scripts' mail-order pharmacies.

167. **Defendant UnitedHealth Group, Inc**. is a corporation organized under the laws of Delaware with its principal place of business at 9900 Bren Road East, Minnetonka, Minnesota, 55343.

168. UnitedHealth Group, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

169. UnitedHealth Group, Inc. is a diversified managed healthcare company. In 2015, UnitedHealth Group reported revenue in excess of $257 billion, and the company is currently ranked sixth on the Fortune 500 list. UnitedHealth Group, Inc. offers a spectrum of products and services including health insurance plans through its wholly owned subsidiaries and prescription drugs through its PBM, OptumRx.

170. Over one-third of the overall revenues of UnitedHealth Group come from OptumRx.

[17] CHARLES E. GRASSLEY & RON WYDEN, STAFF REPORT ON INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG, S. FIN. COMM., https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf; Letter from Joseph B. Kelley, Eli Lilly Vice President, Global Gov. Affairs, to Charles E. Grassley & Ron Wyden, S. Fin. Comm. (Mar. 8, 2019), https://www.finance.senate.gov/imo/media/doc/Eli%20Lilly_Redacted%20v1.pdf

171. UnitedHealth Group, through its executives and employees, is directly involved in the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs and related to the Insulin Pricing Scheme. For example, UnitedHealth Group executives structure, analyze, and direct the company's overarching policies, including with respect to PBM and mail-order services, as a means of maximizing profitability across the corporate family.

172. UnitedHealth Group's Sustainability Report states that "OptumRx works directly with pharmaceutical manufacturers to secure discounts that lower the overall cost of medications and create tailored formularies – or drug lists – to ensure people get the right medications. [*UnitedHealth Group*] then negotiate[s] with pharmacies to lower costs at the point of sale . . . [*UnitedHealth Group*] also operate[s] [mail-order pharmacies] . . .. [*UnitedHealth Group*] work[s] directly with drug wholesalers and distributors to ensure consistency of the brand and generic drug supply, and a reliance on that drug supply."

173. In addition to being a PBM and a mail-order pharmacy, UnitedHealth Group owns and controls a major health insurance company, UnitedHealthcare. As a result, UnitedHealth Group controls the health plan/insurer, the PBM, and the mail-order pharmacies utilized by approximately 26 million UnitedHealthcare members in the United States, including those in Tennessee. UnitedHealth Group controls the entire drug pricing chain for these 26 million Americans.

174. UnitedHealth Group's conduct had a direct effect in Tennessee and damaged Plaintiff.

175. UnitedHealth Group states in its Annual Reports that UnitedHealth Group "utilizes Optum's capabilities to help coordinate patient care, improve affordability of medical care, analyze

cost trends, manage pharmacy benefits, work with care providers more effectively and create a simpler consumer experience."

176. **Defendant Optum, Inc.** is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. Optum, Inc. is a health services company managing subsidiaries that administer pharmacy benefits, including Defendant OptumRx, Inc.

177. Optum, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

178. Optum, Inc. is directly involved, through its executives and employees, in the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs and related to the Insulin Pricing Scheme, which had a direct effect in Tennessee and damaged Plaintiff.

179. For example, according to Optum Inc.'s press releases, Optum, Inc. is "UnitedHealth Group's information and technology-enabled health services business platform serving the broad healthcare marketplace, including care providers, plan sponsors, payors, life sciences companies and consumers."[18] In this role Optum, Inc. is directly responsible for the "business units – OptumInsight, OptumHealth and OptumRx"[19] and the CEOs of all these companies report directly to Optum, Inc. regarding their policies, including those that inform the at-issue formulary construction and mail order activities.

180. **Defendant OptumRx, Inc.** is a California corporation with its principal place of business at 2300 Main Street, Irvine, California, 92614.

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[18] UNITEDHEALTH GROUP, https://www.unitedhealthgroup.com/ (last visited on Sept. 9, 2022); *UnitedHealth Group Announces "Optum" Master Brand for Its Health Services Businesses*, FIERCE HEALTHCARE (Apr. 11, 2011, 9:21 AM), https://www.fiercehealthcare.com/healthcare/unitedhealth-group-announces-optummaster-brand-for-its-health-services-businesses.

[19] *Id.*; UNITEDHEALTH GROUP, *UnitedHealth Group Announces "Optum" Master Brand for Its Health Services Businesses* (Apr. 11, 2011), https://www.unitedhealthgroup.com/newsroom/2011/0411optum.html.

181. OptumRx, Inc. operates as a subsidiary of OptumRx Holdings I, LLC, which, in turn, operates as a subsidiary of Defendant Optum, Inc.

182. OptumRx, Inc. is registered to do business in Tennessee and has been since at least 2008. OptumRx, Inc. may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

183. During the relevant time period, OptumRx, Inc. provided the PBM and mail order pharmacy services to Plaintiff and in Tennessee that gave rise to the Insulin Pricing Scheme, which damaged Plaintiff.

184. **Defendant OptumInsight, Inc**. is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota.

185. OptumInsight, Inc. is registered to do business in Tennessee and has been since at least 1997. OptumInsight, Inc. may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

186. OptumInsight, Inc. is an integral part of the Insulin Pricing Scheme and, during the relevant time period coordinated directly with the Manufacturer Defendants in furtherance of the conspiracy. OptumInsight analyzed data and other information from the Manufacturer Defendants to advise the other Defendants with regard to the profitability of the Insulin Pricing Scheme to the benefit of all Defendants.

187. As a result of numerous interlocking directorships and shared executives, UnitedHealth Group, OptumRx Holdings I, LLC, and Optum, Inc are directly involved in the conduct of and control OptumInsight and Optum Rx's operations, management, and business decisions related to the at-issue formulary construction, negotiations, and mail order pharmacy services to the ultimate detriment of Plaintiff. For example:

a. These parent and subsidiaries have common officers and directors, including:

- Sir Andrew Witty is president of UnitedHealth Group and CEO of Optum, Inc.;
- Dan Schumacher is president of Optum, Inc and is also named to the Office of the Chief Executive at UnitedHealth Group, Inc.;
- Terry Clark is a senior vice president and chief marketing officer at UnitedHealth Group and also oversees the branding, marketing and advertising for UnitedHealth Group and Optum, Inc.;
- Tom Roos serves as chief accounting officer for UnitedHealth Group and Optum, Inc.;
- Heather Lang is Deputy General Counsel, Subsidiary Governance at UnitedHealth Group, Inc. and also Assistant Secretary at OptumRx, Inc.;
- Peter Gill is Vice President at UnitedHealth Group, Inc. and also Treasurer at OptumRx, Inc.;
- John Santelli leads Optum Technology, the leading technology division of Optum, Inc serving the broad customer base of Optum and UnitedHealthcare and also serves as UnitedHealth Group's chief information officer; and
- Eric Murphy is the Chief Growth and Commercial Officer for Optum, Inc. and has also led OptumInsight, Inc.

b. UnitedHealth Group directly or indirectly owns all the stock of Optum, Inc., OptumRx, Inc., and OptumInsight, Inc.;

c. The UnitedHealth Group corporate family does not operate as separate entities. The public filings, documents, and statements of UnitedHealth Group present its subsidiaries, including Optum, Inc., OptumRx, Inc., and OptumInsight as divisions or departments of a single company that is "a diversified family of businesses" and that "leverages core competencies" to "help[] people live healthier lives and help[] make the health system work better for everyone." The day-to-day operations of this corporate family reflect these public statements. These entities are a single business

enterprise and should be treated as such as to all legal obligations detailed in this Complaint.[20]

d. All the executives of Optum, Inc., OptumRx, Inc., and OptumInsight ultimately report to the executives, including the CEO, of UnitedHealth Group.

e. As stated above, UnitedHealth Group's executives and officers are directly involved in the policies and business decisions of Optum, Inc., OptumRx, Inc., and OptumInsight that gave rise to Plaintiff's claims in this Complaint.

188. Collectively, Defendants UnitedHealth Group, Inc., OptumRx, Inc., OptumInsight, Inc. and Optum, Inc., including all predecessor and successor entities, are referred to as "OptumRx."

189. OptumRx is named as a Defendant in its capacities as a PBM and mail-order pharmacy.

190. OptumRx is a pharmacy benefit manager and, as such, coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the price of the at-issue diabetes medications, as well as for the placement of these Manufacturers' diabetes medications on OptumRx's drug formularies.

191. OptumRx provides pharmacy care services to more than 65 million people in the nation through a network of more than 67,000 retail pharmacies and multiple delivery facilities.[21]

192. In 2018, OptumRx managed more than $91 billion in pharmaceutical spending, representing 23% of the PBM market in the United States. OptumRx's 2018 revenue was $69 billion.

[20] UnitedHealth Group, Quarterly Report (Form 10-Q) (Mar. 31, 2017).
[21] UnitedHealth Group, Annual Report (Form 10-K) (Dec. 31, 2018).

193. In 2019, OptumRx managed more than $96 billion in pharmaceutical spending, with a revenue of $74 billion.[22]

194. At all times relevant hereto, OptumRx derived substantial revenue providing pharmacy benefits in Tennessee.

195. At all times relevant hereto, OptumRx offered pharmacy benefit management services nationwide and maintained standard formularies that are used nationwide, including in Tennessee. During the relevant time period, those formularies included diabetes medications, including all of those at issue in this Complaint.

196. At all times relevant hereto, and contrary to their express representations, OptumRx knowingly insisted that its payor clients use the false list prices produced by the Insulin Pricing Scheme as the basis for reimbursement of the at-issue drugs.

197. At all times relevant hereto, OptumRx concealed its critical role in the generation of those false list prices.

198. In its capacity as a mail-order pharmacy, OptumRx received payments from payors for, and set the out-of-pocket price paid for, the at-issue drugs based on the falsely inflated prices produced by the Insulin Pricing Scheme and, as a result, damaged Plaintiff.

199. At all times relevant hereto, OptumRx dispensed the at-issue medications nationwide and directly to Plaintiff and Plaintiff's Beneficiaries in Tennessee through its mail-order pharmacies and derived substantial revenue from these activities in Tennessee.

200. OptumRx purchases the Manufacturer Defendants' drugs, including the at issue diabetes medications, for dispensing through its mail-order pharmacies.

[22] UnitedHealth Group, Annual Report (Form 10-K) (Dec. 31, 2019).

201. At all times relevant hereto, OptumRx had express agreements with Defendants Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid by the Manufacturer Defendants to OptumRx, as well as agreements related to the Manufacturers' at-issue drugs sold through OptumRx's mail-order pharmacies.

202. Collectively, CVS Caremark, Optum Rx, and Express Scripts are referred to as the "PBM Defendants" or the "PBMs."

JURISDICTION AND VENUE

203. This action is directly filed in *In Re: Insulin Pricing Litigation*, MDL No. 3080, which was established on August 3, 2023, pursuant to the United States Judicial Panel on Multidistrict Litigation transfer order, and in accordance with this Court's August 2023 "Instructions for Opening a Case Relevant to MDL 3080". This Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1331 and pursuant to 18 U.S.C. § 1964(c) because this action alleges violations of the Racketeer influenced and Corrupt Organizations Act, 18 U.S.C. § 1962, which raises a federal question. This Court has supplemental jurisdiction over the state law claims in this action pursuant to 28 U.S.C. § 1367.

204. There is also federal subject matter jurisdiction over this action because complete diversity exists among the parties, 28 U.S.C. § 1332. The parties are citizens of different states, and the amount in controversy, exclusive of interests or costs, exceeds the sum or value of $75,000.

205. This Court also has personal jurisdiction over all Defendants under 18 U.S.C. § 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the Court in a single trial.

206. Venue is proper pursuant to 18 U.S.C. § 1965 because Defendants Sanofi, Novo Nordisk and Medco reside, are found, have an agent, or transact their affairs in this District, and the ends of justice require that any Defendant residing elsewhere be brought before this Court.

207. Venue is also proper in this District pursuant to 28 U.S.C. § 1391(b) and (c) because all Defendants transact business in, are found in, and/or have agents in this District, and because some of the actions giving rise to the Complaint took place within this District.

ADDITIONAL FACTUAL ALLEGATIONS

A. Diabetes and Insulin Therapy

The Diabetes Epidemic

208. Diabetes occurs when a person's blood glucose is too high. In people without diabetes, the pancreas secretes the hormone insulin, which controls the rate at which food is converted to blood glucose. When insulin is lacking or when cells stop responding to insulin, however, blood sugar stays in the bloodstream. Over time, this can cause serious health problems, including heart disease, blindness, and kidney disease.

209. There are two basic types of diabetes: Type 1 and Type 2. Roughly 90-95% of diabetics are Type 2, which develops when a person does not produce enough insulin or has become resistant to the insulin they produce. While Type 2 patients can initially be treated with tablets, in the long term most patients switch to insulin injections.

210. Diabetes has been on the rise for decades. In 1958, only 1.6 million Americans had diabetes. By the turn of the century, that number had grown to over ten million. Fourteen years later, the number had tripled. Today, more than 37 million Americans—approximately 11% of the country—live with the disease.

211. The prevalence of diabetes in Tennessee has increased as well. Over 760,000 Tennessee adults now live with diabetes and hundreds of thousands more have prediabetes.[23]

Insulin: A Century-Old Drug

212. Despite its potentially deadly impact, diabetes is highly treatable. Patients able to follow a prescribed treatment plan consistently may avoid the health complications associated with the disease. Unlike many high-burden diseases, treatment for diabetes has been available for almost a century.

213. In 1922, Frederick Banting and Charles Best, while working at the University of Toronto, pioneered a technique for removing insulin from an animal pancreas that could then be used to treat diabetes. After discovery, Banting and Best obtained a patent and then sold it to the University of Toronto for $1 (equivalent of $14 today), explaining "[w]hen the details of the method of preparation are published anyone would be free to prepare the extract, but no one could secure a profitable monopoly."[24]

214. After purchasing the patent, the University of Toronto contracted with Defendants Eli Lilly and Novo Nordisk to scale their production. Under this arrangement, Eli Lilly and Novo Nordisk were allowed to apply for patents on variations to the manufacturing process.

215. Although early iterations of insulin were immediately perceived as lifesaving, there have been numerous incremental improvements since its discovery.

216. The earliest insulin was derived from animals and, until the 1980s, was the only diabetes treatment.

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[23] https://www.cdc.gov/diabetes/programs/stateandlocal/state-diabetes-profiles/tennessee.html; Tennessee Diabetes Action Legislative Report, Feb. 2021, https://www.capitol.tn.gov/Archives/senate/112GA/committees/health-welfare/2021/Diabetes%20Legislative%20Report_FinalDraft.%2001-29-2021%208%2045%20pm.pdf.

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[24] Jessica DiGiacinto & Valencia Higuera, *Everything You Need to Know About Insulin*, HEALTHLINE (Oct. 5, 2021), http://www.healthline.com/health/type-2-diabetes/insulin; M. BLISS, THE DISCOVERY OF INSULIN (2013).

217. While effective, animal-derived insulin created the risk of allergic reaction. This risk was lessened in 1982 when synthetic insulin, known as human insulin, was developed by Defendant Eli Lilly. Eli Lilly marketed this insulin as Humulin. The development of human insulin benefited heavily from government and non-profit funding through the National Institute of Health and the American Cancer Society.

218. Over a decade later, Eli Lilly released the first analog insulin.

219. Analog insulin is laboratory-grown and genetically altered insulin. Analogs are slight variations on human insulin that make the injected treatment act more like the insulin naturally produced and regulated by the body.

220. Defendant Eli Lilly developed the first analog insulin, Humalog, in 1996.

221. Other rapid-acting analogs are Defendant Novo Nordisk's Novolog and Defendant Sanofi's Apidra, which have similar profiles. Diabetics use these rapid-acting insulins in combination with longer-acting insulins, such as Sanofi's Lantus and Novo Nordisk's Levemir.

222. The Manufacturer Defendants introduced these rapid-acting and long-acting analog insulins between 1996 and 2007.

223. In 2015, Sanofi introduced Toujeo, another long-acting insulin similar to Lantus; however, Toujeo is highly concentrated, making injection volume smaller than Lantus.

224. In 2016, Eli Lilly introduced Basaglar, which is a long-acting insulin biologically similar to Sanofi's Lantus.

225. Even though insulin was first extracted 100 years ago, and despite its profitability, only Defendants Eli Lilly, Novo Nordisk, and Sanofi manufacture insulin for the United States market. This did not occur by chance.

226. Many of the at-issue medications are now off-patent.

227. The Manufacturers maintain market domination through patent "evergreening." Drugs usually face generic competition when their 20-year patents expire. While original insulin formulas may technically be available for generic use, the Manufacturers "stack" patents around the original formulas, making new competition more costly and risky. For example, Sanofi has filed more than 70 patents on Lantus—more than 95% were filed after the drug was approved by the FDA—potentially providing more than three additional decades of patent "protection" for the drug. The market therefore remains highly concentrated.

The Current Insulin Landscape

228. While insulin today is generally safer and more convenient to use than when originally developed in 1922, there remain questions about whether the overall efficacy of insulin has significantly improved over the last twenty years.

229. For example, while long-acting analogs may have certain advantages over human insulins, such as affording more flexibility around mealtime planning, it has yet to be shown that analogs lead to better long-term outcomes. Recent work suggests that older human insulins may work just as well for patients with Type 2 diabetes.

230. Moreover, all insulins at issue have either been available in the same form since the late 1990s/early 2000s or are biologically equivalent to insulins available then.

231. As Dr. Kasia Lipska, a Yale researcher, explained in the Journal of the American Medical Association:

> We're not even talking about rising prices for better products here. I want to make it clear that we're talking about rising prices for the same product . . . there's nothing that's changed about Humalog. It's the same insulin that's just gone up in price and now costs ten times more.[25]

[25] Natalie Shure, *The Insulin Racket*, American Prospect (June 24, 2019), https://prospect.org/health/insulin-racket/ (last visited Jan. 14, 2023).

232. Production costs have also decreased in recent years. A September 2018 study calculated that, based on production costs, a reasonable price for a year's supply of human insulin is $48 to $71 per person and $78 to $133 for analog insulins. Another recent study found that the Manufacturers could profit at as little as $2 per vial.

233. United States diabetics spent an average of $5,705 each for insulin in 2016. According to a 2020 RAND report, the 2018 list price per vial across all forms of insulin was just $12 in Canada and less than $7 in Australia. In the U.S., it was $98.70.

234. While R&D costs often contribute significantly to a drug's price, the initial basic insulin research occurred 100 years ago and its costs have long-since been recouped. Other costs, such as developing the recombinant DNA-fermentation process and the creation of insulin analogs, were incurred decades ago.

Insulin Adjuncts: Type 2 Medications

235. The Manufacturer Defendants have released several non-insulin diabetes medications over the past decade. Novo Nordisk released Victoza in 2010, followed by Trulicity (Eli Lilly), Soliqua (Sanofi), and Ozempic (Novo Nordisk).[26] The following is a list of diabetes medications at issue in this lawsuit:

[26] Victoza, Trulicity, and Ozempic are glucagon-like peptide-1 receptor agonists ("GLP-1") and mimic the GLP-1 hormone produced in the body. Soliqua is a combination long-acting insulin and GLP-1 drug. Each of these drugs can be used in conjunction with insulins to control diabetes.

Table 1: Diabetes medications at issue in this case

Insulin Type	Action	Name	Company	FDA Approval	Current/Recent List Price
Human	*Rapid-Acting*	Humulin R	Eli Lilly	1982	$178 (vial)
		Humulin R 500	Eli Lilly	1982	$1784 (vial), $689 (pens)
		Novolin R	Novo Nordisk	1991	$165 (vial), $312 (pens)
	Intermediate	Humulin N	Eli Lilly	1982	$178 (vial), $566 (pens)
		Humulin 70/30	Eli Lilly	1989	$178 (vial), $566 (pens)
		Novolin N	Novo Nordisk	1991	$165 (vial), $312 (pens)
		Novolin 70/30	Novo Nordisk	1991	$165 (vial), $312 (pens)
Analog	*Rapid-Acting*	Humalog	Eli Lilly	1996	$342 (vial), $636 (pens)
		Novolog	Novo Nordisk	2000	$347 (vial), $671 (pens)
		Apidra	Sanofi	2004	$341 (vial), $658 (pens)
	Long-Acting	Lantus	Sanofi	2000	$340 (vial), $510 (pens)
		Levemir	Novo Nordisk	2005	$370 (vial), $555 (pens)
		Basaglar (Kwikpen)	Eli Lilly	2015	$392 (pens)
		Toujeo (Solostar)	Sanofi	2015	$466 (pens), $622 (max pens)
		Tresiba	Novo Nordisk	2015	$407 (vial) $610 (pens – 100u) $732 (pens – 200u)
Type 2 Medications		Trulicity	Eli Lilly	2014	$1013 (pens)
		Victoza	Novo Nordisk	2010	$813 (2 pens) $1220 (3 pens)
		Ozempic	Novo Nordisk	2017	$1022 (pens)
		Soliqua	Sanofi	2016	$928 (pens)

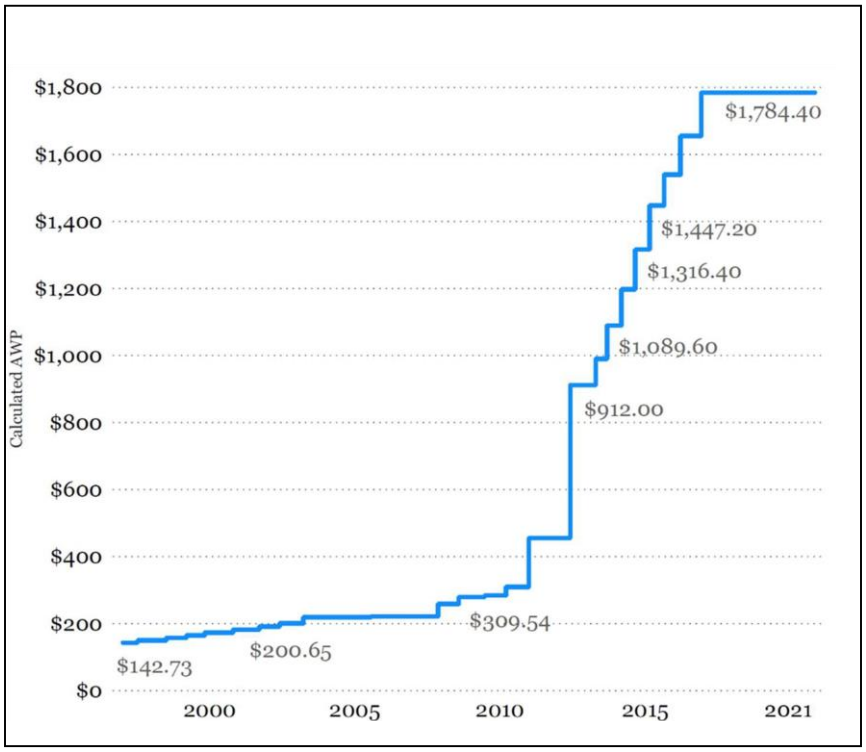
B. The Dramatic Rise in the Price of Diabetes Medications in the U.S.

236. Over the past 25 years, the list price of certain insulins has increased in some cases by more than 1000% (10x).

237. According to the U.S. Bureau of Labor Statistics, $165 worth of consumer goods and services in 1997 dollars would, in 2021, have cost $289 (1.75x).[27]

238. Since 1997, Eli Lilly has raised the list price of a vial of Humulin R (500U/mL) from $165 to $1784 in 2021 (10.8x).

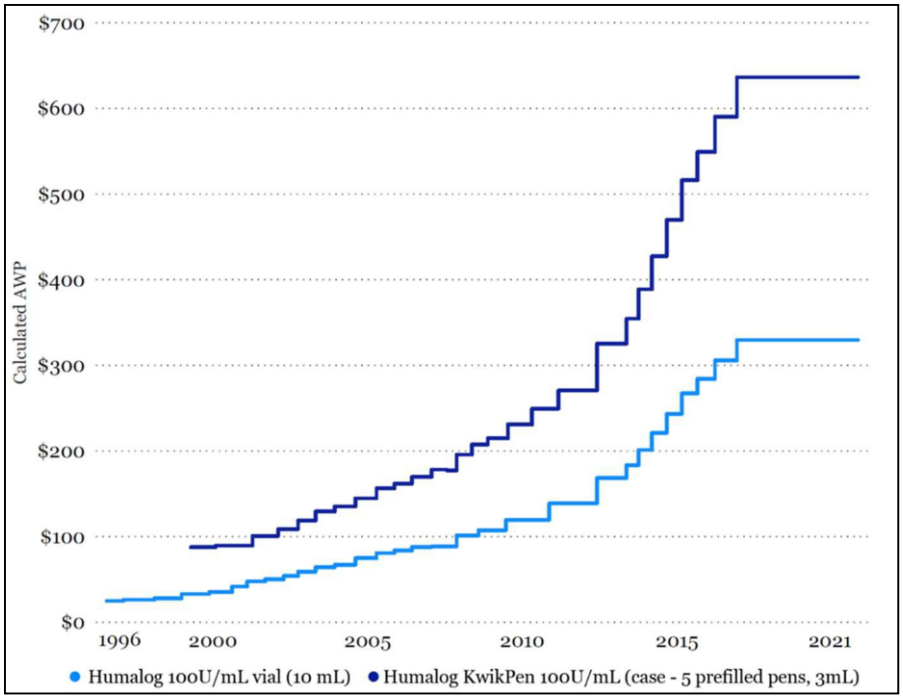
Figure 3: Rising list prices of Humulin R (500U/mL) from 1997-2021



239. Since 1996, Eli Lilly has raised the price for a package of Humalog pens from less than $100 to $663 (6.6x) and from less than $50 per vial to $342 (6.8x). (See Fig. 4.)

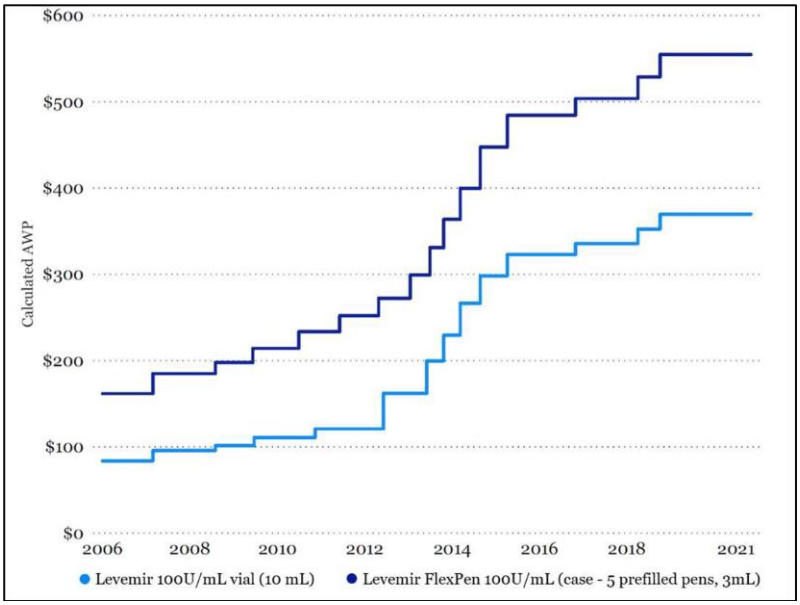
Figure 4: Rising list prices of Humalog vials and pens from 1996-2021

[27] https://www.bls.gov/data/inflation_calculator.htm (last visited Aug. 23, 2023). The Consumer Price Index (CPI) measures "the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services." (https://www.bls.gov/cpi/).



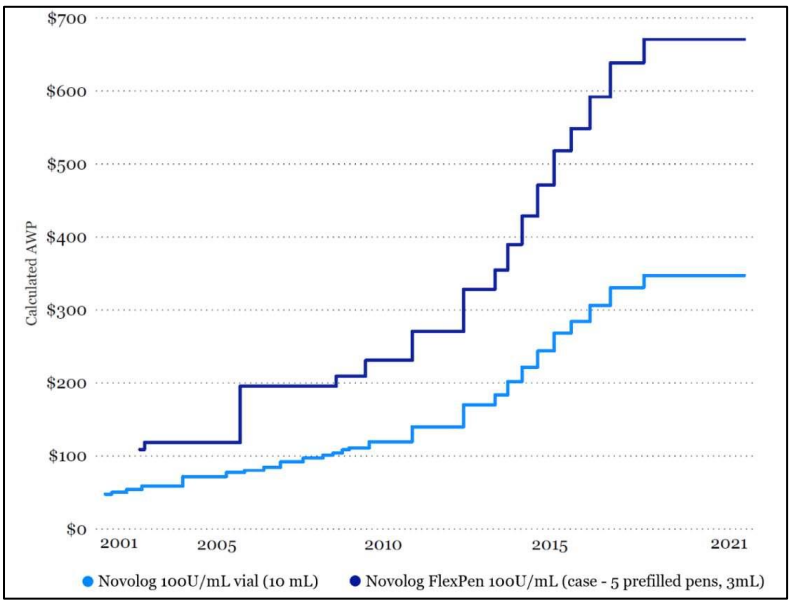
240. From 2006 to 2020, Novo Nordisk has raised Levemir's list price from $162 to $555 (3.4x) for pens and from under $100 to $370 per vial (3.7x).

Figure 5: Rising list prices of Levemir from 2006-2021



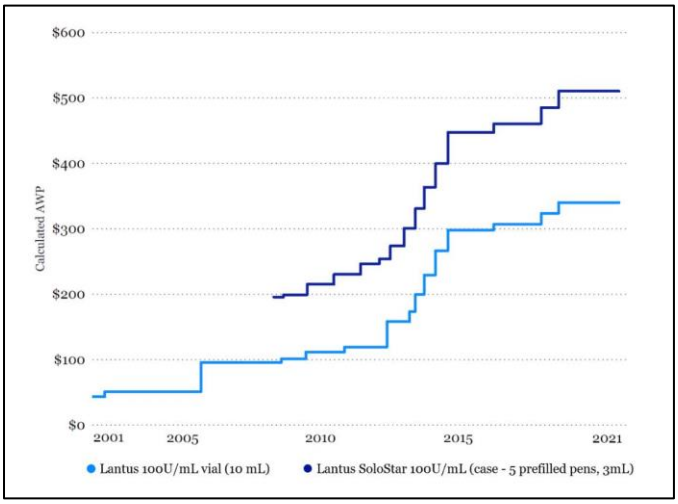
241. From 2002 to 2021, Novo Nordisk raised the list price of Novolog from $108 to $671 (6.2x) for a package of pens and from less than $50 to $347 (6.9x) for a vial.

Figure 6: Rising list prices of Novolog vials and pens from 2002-2021



242. Defendant Sanofi has kept pace. It manufactures a top-selling analog insulin—Lantus—which has been and remains a flagship brand for Sanofi. It has been widely prescribed nationally and within Tennessee, including to Plaintiff's Beneficiaries. Sanofi has raised the list prices for Lantus from less than $200 in 2006 to over $500 in 2020 (2.5x) for a package of pens and from less than $50 to $340 for a vial (6.8x). (See Fig. 7.)

Figure 7: Rising list prices of Lantus vials and pens from 2001-2021



243. The Manufacturer Defendants have similarly ballooned the prices for noninsulin diabetes medications.

244. Driven by these price hikes, payors' and diabetics' spending on these drugs has steadily increased with totals in the tens of billions of dollars. The Defendant-Manufacturers Have Increased Prices in Lockstep

245. The timing of the price increases reveals that the Manufacturer Defendants have not only dramatically increased prices for the at-issue diabetes treatments, but have done so in lockstep.

246. Between 2009 and 2015, for example, Sanofi and Novo Nordisk raised the list prices of their insulins in tandem 13 times, taking the same price increase down to the decimal point within a few days of each other (sometimes within a few hours).[28]

247. This conduct is known as "shadow pricing," which communicates between competitors their intention not to price compete against one another.

[28] Grassley & Wyden, *supra* note 2.

248. In 2016, Novo Nordisk and Sanofi's lockstep increases for the at-issue drugs represented the highest drug price increases in the pharmaceutical industry.

249. Eli Lilly and Novo Nordisk have engaged in the same lockstep behavior with respect to their rapid-acting analog insulins, Humalog and Novolog. Figure 8 demonstrates this collusive behavior with respect to Lantus and Levemir. Figure 9 demonstrates this behavior with respect to Novolog and Humalog.

Figure 8: Rising list prices of long-acting insulins

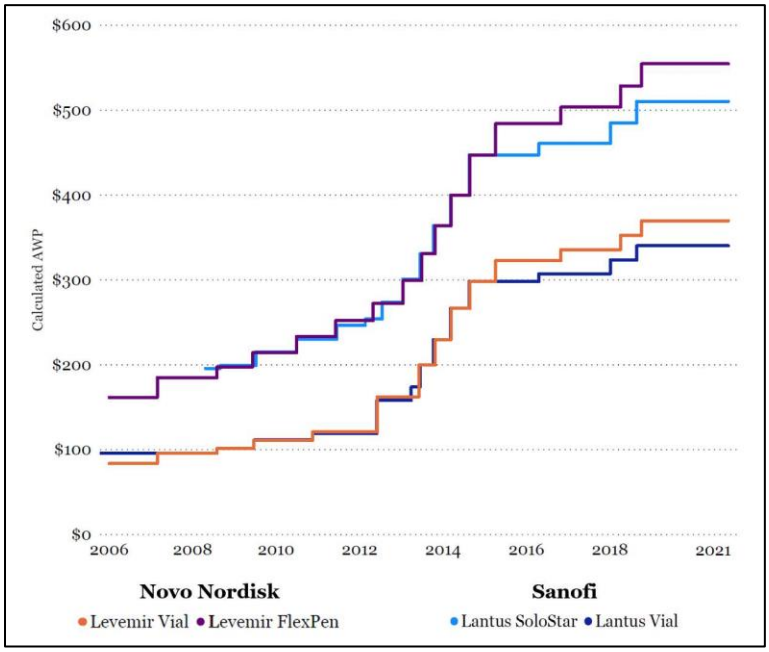
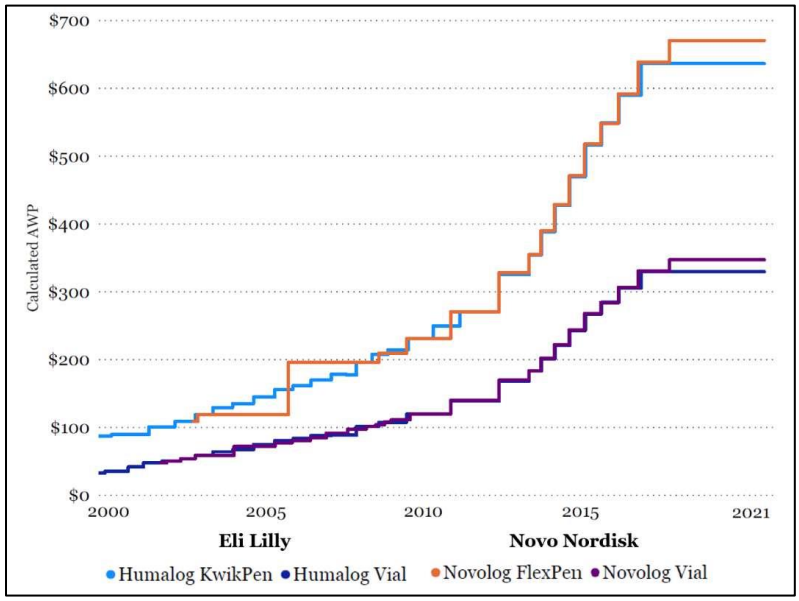
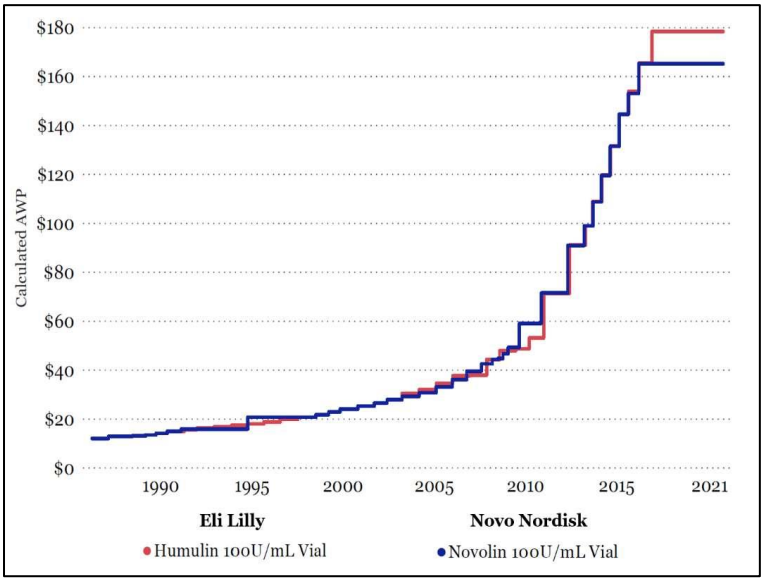


Figure 9: Rising list prices of rapid-acting insulins



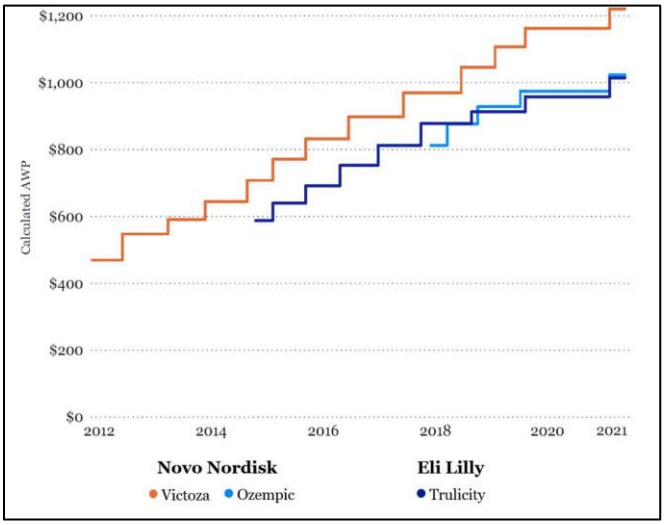
250. Figure 10 below demonstrates this behavior with respect to the human insulins—Eli Lilly's Humulin and Novo Nordisk's Novolin.

Figure 10: Rising list price increases for human insulins



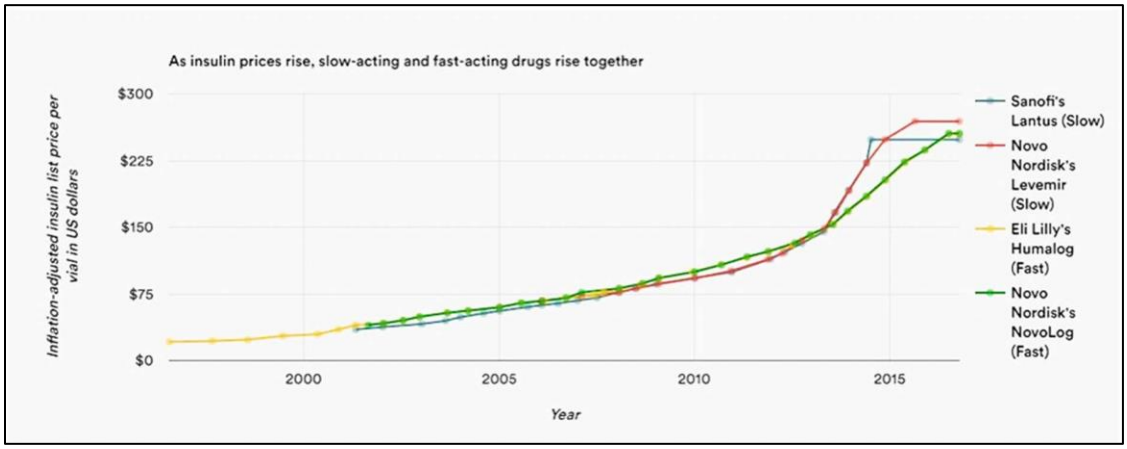
251. Figure 11 below demonstrates Novo Nordisk and Eli Lilly's lockstep price increases for their Type 2 drugs Trulicity, Victoza, and Ozempic.

Figure 11: Rising list prices of Type 2 drugs



252. Figure 12 below shows how, collectively, the Manufacturer Defendants have exponentially raised the prices of insulin products in near-perfect unison.

Figure 12: Lockstep insulin price increases



253. Because of the Manufacturer Defendants' collusive price increases, nearly a century after the discovery of insulin, diabetes medications have become unaffordable for many diabetics.

C. Pharmaceutical Payment and Supply Chain

254. The prescription drug industry is comprised of a deliberately opaque network of entities engaged in multiple distribution and payment structures. These entities include drug manufacturers, wholesalers, pharmacies, health plans/third-party payors, PBMs, and patients.

255. Given the complexities of the different parties involved in the pharmaceutical industry, there are many ways in which pharmaceutical drugs are distributed. Generally speaking, branded prescription drugs, such as the at-issue diabetes medications, are often distributed in one of three ways: (1) from manufacturer to wholesaler (distributor), wholesaler to pharmacy, and pharmacy to patient; (2) from manufacturer to mail-order pharmacy to patient; and (3) from manufacturer to mail-order pharmacy, mail-order pharmacy to self-insured payor, and then self-insured payor to patient.

256. The pharmaceutical industry, however, is unique in that the pricing chain is distinct from the distribution chain. The prices for the drugs distributed in the pharmaceutical chain are different for each participating entity, i.e., different actors pay different prices set by different entities for the same drugs. The unifying factor is that the price that each entity in the pharmaceutical chain pays for a drug is inexorably tied to the price set by the manufacturer. The pricing chain includes self-insured payors paying PBMs directly.

257. There is no transparency in this pricing system. Typically, only a brand drug's list price—also known as its Average Wholesale Price (AWP) or the mathematically related Wholesale Acquisition Cost (WAC)—is available.

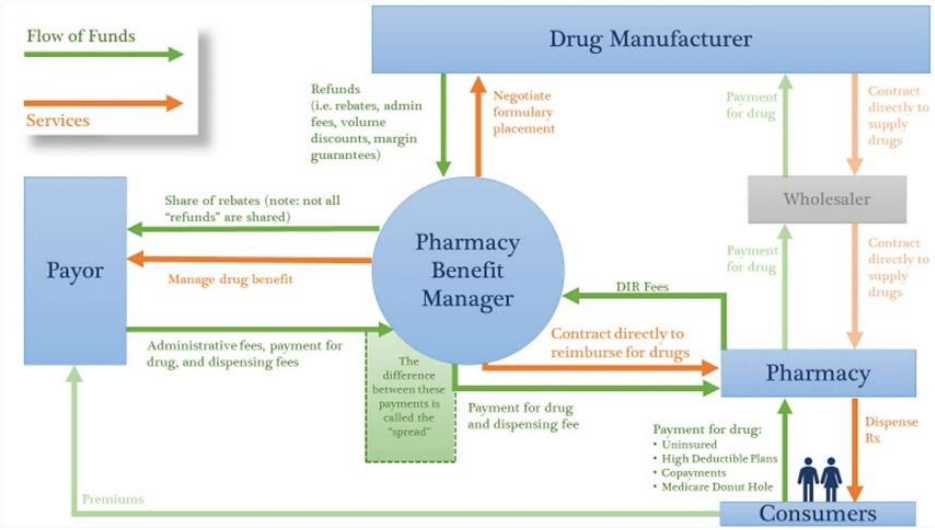
258. Drug manufacturers self-report AWP, or other prices upon which AWP is based, to publishing compendiums such as First DataBank, Redbook, and others who then publish those prices.

259. As a direct result of the PBMs' conduct, AWP persists as the most commonly and continuously used list price in reimbursement and payment calculations and negotiations for both payors and patients.

D. The PBMs' Role in the Pharmaceutical Payment Chain

260. The PBMs are at the center of this convoluted pharmaceutical payment chain, as illustrated in Figure 13 below.

Figure 13: Insulin distribution and payment chain



261. The PBM Defendants develop drug formularies, process claims, create a network of retail pharmacies, set the prices in coordination with the Manufacturers that the payor will pay for prescription drugs, and are paid by the payor to reimburse pharmacies for the drugs utilized by the payor's beneficiaries.

262. The PBMs also contract with a network of retail pharmacies. Pharmacies agree to dispense drugs to patients and pay fees back to the PBMs. The PBMs reimburse pharmacies for the drugs dispensed.

263. The PBM Defendants also own mail-order and specialty pharmacies, which purchase and take possession of prescription drugs, including those at-issue here, and directly supply those drugs to payors like Plaintiff Greene County, their Beneficiaries, and other patients, by mail.

264. Often, the PBM Defendants purchase drugs directly from the Manufacturers and distribute them directly to the patients. The prices that the PBM Defendants pay are significantly less than the purchase prices paid by payors.

265. Even where PBM Defendant mail-order pharmacies purchase drugs from wholesalers, their costs are set by direct contracts with the manufacturers.

266. In addition, and of particular significance here, the PBM Defendants contract with pharmaceutical manufacturers, including the Manufacturer Defendants. The PBMs extract from the Manufacturers rebates, fees, and other consideration that are paid back to the PBMs, including the Manufacturer Payments related to the at-issue drugs.

267. The Manufacturers also interact with the PBMs related to other services outside the scope of the Insulin Pricing Scheme, such as health and educational programs and patient and prescriber outreach with respect to drugs not at issue here.

268. These relationships allow PBMs to exert tremendous influence over what drugs are available throughout the United States, including in Greene County, on what terms, and at what prices.

269. Thus, PBMs are at the center of the flow of pharmaceutical money. Historically and today PBMs:

- negotiate the price that payors pay for prescription drugs (based on prices generated by the Insulin Pricing Scheme);

- separately negotiate a different (and often lower) price that pharmacies in their networks receive for the same drug;
- set the amount in fees that the pharmacy pays back to the PBM for each drug sold (based on prices generated by the Insulin Pricing Scheme);
- set the price paid for each drug sold through their mail-order pharmacies (based on prices generated by the Insulin Pricing Scheme); and
- negotiate the amount that the Manufacturers pay back to the PBM for each drug sold (based on prices generated by the Insulin Pricing Scheme).

270. Yet, for most of these transactions, only the PBMs are privy to the amount that any other entity in this supply chain is paying or receiving for the same drugs. The contracts between the PBMs and Manufacturers are undisclosed to Plaintiff. Payors, including Plaintiff, do not know and cannot learn the terms of those contracts.

271. This lack of transparency affords Defendants the opportunity to extract billions of dollars from this payment and supply chain without detection.

272. In every interaction that the PBMs have within the pharmaceutical pricing chain, they stand to profit from the prices generated by the Insulin Pricing Scheme.

The Rise of the PBMs in the Pharmaceutical Supply Chain

273. At first, in the 1960s, pharmacy benefit managers functioned largely as claims processors. Over time, however, they have taken on increasingly larger roles.

274. One of the roles the pharmacy benefit managers have taken on, as discussed above, was negotiating with drug manufacturers—ostensibly on behalf of payors. In so doing, the PBMs affirmatively represented that they were using their leverage to drive down drug prices.

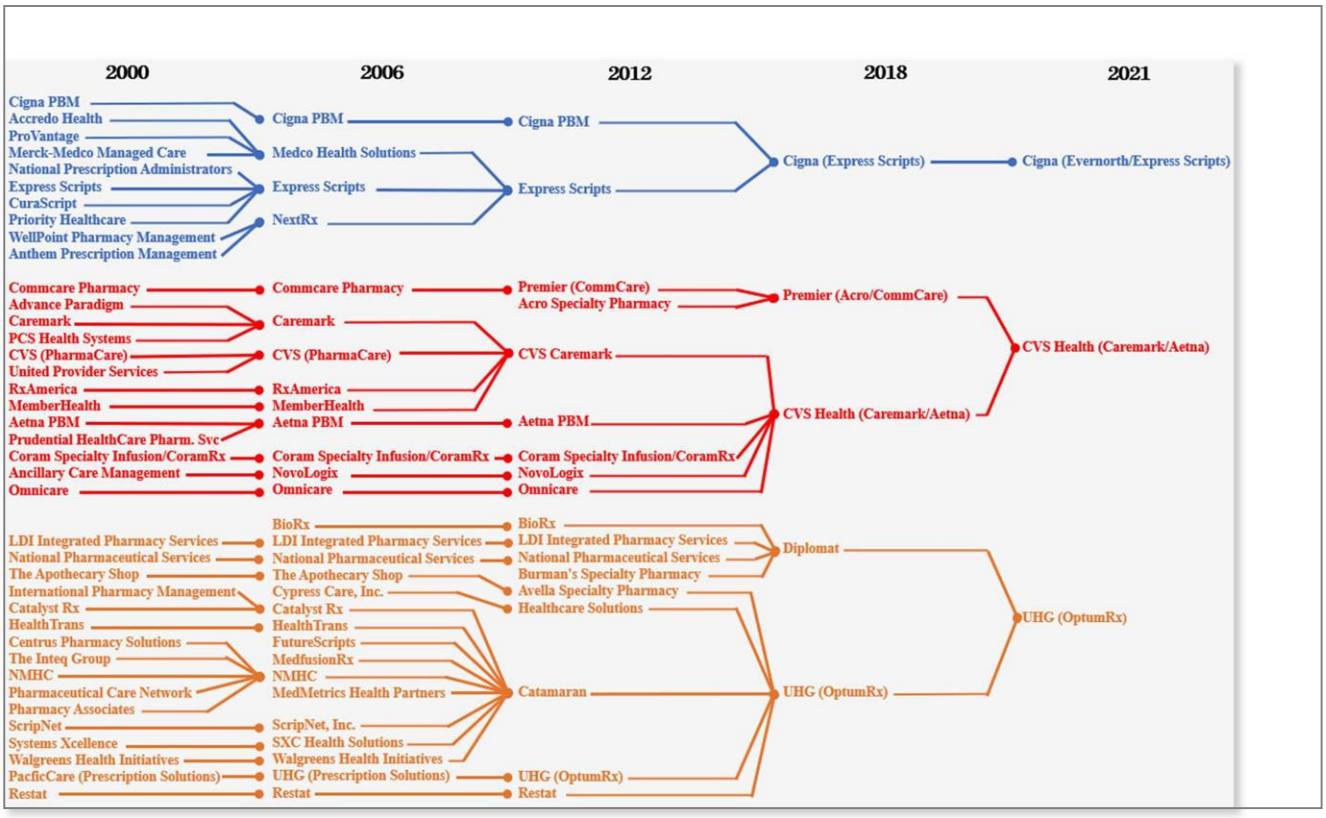
275. In the early 2000s, the PBMs started buying pharmacies, thus creating an additional incentive to collude with manufacturers to keep certain prices high.

276. These perverse incentives still exist today with respect to both retail and mail-order pharmacies housed within the PBMs' corporate families. Further recent consolidation in the industry has given the pharmacy benefit managers disproportionate market power.

277. Nearly forty pharmacy benefit manager entities have combined into what are now the three PBM Defendants. Moreover, each PBM Defendant now is owned by other significant players in the pharmaceutical chain, e.g., Express Scripts merged with Cigna; CVS bought Caremark, which now also owns Aetna; and UnitedHealth Group acquired OptumRx.

278. Figure 14 depicts this consolidation within the pharmacy benefit manager market.

Figure 14: PBM consolidation



279. After merging with or acquiring all of their competitors, and now backed by multibillion-dollar corporations, the PBM Defendants have taken over the market in the past

decade, controlling more than 80% of the market and managing pharmacy benefits for more than 270 million Americans.

280. Together, the PBM Defendants report more than $300 billion in annual revenue.

281. The PBMs use this market consolidation and the resulting purchasing power as leverage when negotiating with other entities in the pharmaceutical pricing chain.

The Insular Nature of the Pharmaceutical Industry

282. The insular nature of the pharmaceutical industry has provided Defendants with ample opportunity to contact and communicate with the other PBM and Manufacturer Defendants and to devise, coordinate, and carry out the Insulin Pricing Scheme.

283. The Manufacturer Defendants are all members of the industry-funded Pharmaceutical Research and Manufacturers of America ("PhRMA") and routinely communicate through PhRMA meetings and platforms in furtherance of the Insulin Pricing Scheme. According to PhRMA's 2019 IRS Form 990, it received $515,420,431 in "membership dues." All members are pharmaceutical companies.[29]

284. David Ricks (CEO of Eli Lilly), Paul Hudson (CEO of Sanofi), and Douglas Langa (President of Novo Nordisk and EVP of North American Operations), serve on the PhRMA board of directors and/or part of the PhRMA executive leadership team.

285. The PBM Defendants also routinely communicate through direct interaction with their competitors and the Manufacturers at trade associations and industry conferences.

[29] PhRMA 2019 Form 990, https://projects.propublica.org/nonprofits/organizations/530241211/202043189349300519/full; PhRMA, About PhRMA, https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/About-PhRMA2.pdf (last visited Aug.23,2023).

286. Each year during the relevant period, the main PBM trade association, the industry-funded Pharmaceutical Care Management Association ("PCMA"), held several yearly conferences, including its Annual Meeting and its Business Forum conferences.[30]

287. The PCMA is governed by PBM executives. The current (July 2023) board of the PCMA includes David Joyner (Executive Vice President and President of Pharmacy Services of PBM Defendant CVS Caremark); Adam Kautzner (President of PBM Defendant Express Scripts); and Heather Cianfrocco (CEO of PBM Defendant OptumRx).

288. In 2022, Former Express Scripts President Amy Bricker was the Chair of the PCMA board of directors and the only Express Scripts employee on the board. But when Ms. Bricker left Express Scripts in late 2022/early 2023, she was removed from the PCMA board. On February 3, 2023, PCMA issued a press release naming Mr. Kautzner to the board and appointing him Chairman of the Board of Directors. Mr. Kautzner was not on the board as of late 2022. Mr. Kauztner was added to the PCMA board and named Chair of the board to ensure that the PCMA board has directors from all three PBM Defendants and to facilitate the Insulin Pricing Scheme.

289. All PBM Defendants are members of the PCMA and, due to their leadership positions, have substantial control over that association.

290. Additionally, the Manufacturer Defendants are affiliate members of the PCMA.

291. Every year, high-level representatives and corporate officers from both the PBM and Manufacturer Defendants attend these conferences to meet in person and engage in discussions, including those in furtherance of the Insulin Pricing Scheme.

[30] The PCMA's industry funding in the form of "membership dues" is set out in its 2019 Form 990, https://projects.propublica.org/nonprofits/organizations/383676760/202042969349301134/full (last visited Aug, 23, 2023).

292. In fact, for at least the last eight years, all Manufacturer Defendants have been "Partners," "Platinum Sponsors," or "Presidential Sponsors" of these PBM conferences.

293. Notably, many of the forums at these conferences are specifically advertised as offering opportunities for private, non-public communications. For example, as Presidential Sponsors of these conferences, Manufacturer Defendants each hosted "private meeting rooms" that offer "excellent opportunities for . . . one-on-one interactions between PBM and pharma executives."[31]

294. Representatives from each Manufacturer Defendant have routinely met privately with representatives from each PBM Defendant during the Annual Meetings and Business Forum conferences that the PCMA holds (and the manufacturers sponsor) each year.

295. In addition, all PCMA members, affiliates and registered attendees of these conferences are invited to join PCMA-Connect, "invitation only LinkedIn group and online networking community."[32]

296. As PCMA members, the PBM and Manufacturer Defendants clearly utilized both PCMA-Connect, as well as the private meetings at the PCMA conferences, to exchange information and to reach agreements in furtherance of the Insulin Pricing Scheme.

297. Key at-issue lockstep price increases occurred shortly after the Defendants had convened at PCMA meetings. For example, on September 26 and 27, 2017, the PCMA held its annual meeting where each of the Manufacturer Defendants hosted private rooms and executives from each Defendant engaged in several meetings throughout the conference. Mere days after the

[31] PCMA, *The PCMA Annual Meeting 2021 Will Take Place at the Broadmoor in Colorado Springs, CO September 20 and 21*, https://www.pcmanet.org/pcmaevent/annual-meeting-2021/ (an event "tailored specifically for senior executives from PBMs and their affiliated business partners" with "private reception rooms" and "interactions between PBM members, drug manufacturers, and other industry partners") (last visited Aug 23, 2023).

[32] PCMA, *PCMA-Connect*, https://www.pcmanet.org/contact/pcma-connect/ (last visited Sept. 9, 2022).

conference, on October 1, 2017, Sanofi increased Lantus's list price by 3% and Toujeo's list by 5.4%. Novo Nordisk also recommended that their company make a 4% list price increase effective on January 1, 2018, to match the Sanofi increase.

298. Likewise, on May 30, 2014, Novo Nordisk raised the list price of Levemir a matter of hours after Sanofi made its list price increase on Lantus. These price hikes occurred just weeks after the 2014 PCMA spring conference in Washington, D.C., attended by representatives from all the PBM Defendants.

299. The PBMs control the PCMA and have exploited it to further their interests and to conceal the Insulin Pricing Scheme. The PCMA has brought numerous lawsuits and lobbying campaigns aimed at blocking drug-pricing transparency efforts, including recently suing the Department of Health and Human Services (HHS) to block the finalized HHS "rebate rule," which would eliminate anti-kickback safe harbors for Manufacturer Payments and instead offer them as direct-to-consumer discounts.

300. Notably, the PCMA's 2019 tax return reports more than a million dollars in revenue for "litigation support." Prior tax returns available at ProPublica reveal millions of dollars in revenue for "litigation support" (and tens of millions in revenue for "industry relations") year after year.[33]

301. Communications among the PBM Defendants are facilitated by the fluidity and frequency with which executives relocate from one PBM Defendant to another. For example:

- Mark Thierer worked as an executive at Caremark Rx (now CVS Caremark) prior to becoming the CEO of OptumRx in 2016 (he also served as Chairman of the Board for PCMA starting in 2012);

- Bill Wolfe was the President of the PBM Catalyst Rx (now OptumRx) prior to becoming the President of Aetna Rx in 2015 (he also served as a PCMA board member from 2015-2017 while with Aetna Rx);

[33] *See, e.g.*, PCMA 2019 Form 990, *supra* note 24, and prior years' returns on ProPublica.

- Derica Rice, former EVP for CVS Health and President of CVS Caremark, previously served as EVP and CFO for Eli Lilly;

- Duane Barnes was the Vice President of Medco (now Express Scripts) before becoming division President of Aetna Rx in 2006 (he also served as a PCMA board member);

- Everett Neville was the division President of Aetna Rx before becoming Senior Vice President of Express Scripts;

- Albert Thigpen was a Senior Vice President at CVS Caremark for 11 years before becoming a Senior Vice President at OptumRx in 2011;

- Harry Travis was the Chief Operating Officer at Medco (now Express Scripts) before becoming a Vice President at Aetna Rx in 2008; he served as SVP Member Services Operations for CVS Caremark from 2020-2022; and

- Bill Kiefer was a Vice President of Express Scripts for 14 years before becoming Senior Vice President of Strategy at OptumRx in 2013.

E. The Insulin Pricing Scheme

302. The market for the at-issue diabetes medications is unique in that it is highly concentrated with no true generics and few biosimilar options. The drugs and biosimilars have similar efficacy and risk profiles.

303. This affords the PBMs great leverage that, in theory, could be used to negotiate with the Manufacturer Defendants to drive down list prices for the at-issue drugs through open competition.

304. But the PBMs do not want the prices for diabetes medications to go down. A 2022 report by the Community Oncology Alliance put it this way:

> Among the different sources of revenue, the most prolific by far is in the form of rebates from pharmaceutical manufacturers that PBMs extract in exchange for placing the manufacturer's product drug on a plan sponsor's formulary or encouraging utilization of the manufacturer's drugs . . . . [T]he growing number and scale of rebates is the primary fuel of today's high drug prices. The truth is that PBMs have a vested interest to have drug prices remain high, and to extract rebates

> off of these higher prices. PBM formularies tend to favor drugs that offer higher rebates over similar drugs with lower net costs and lower rebates.[34]

305. The Manufacturer Defendants understand that PBM Defendants make more money as prices increase. This is confirmed by the January 2021 Senate Insulin Report after review of internal documents produced by the Manufacturers: [B]oth Eli Lilly and Novo Nordisk executives, when considering lower list prices, were sensitive to the fact that PBMs largely make their money on rebates and fees that are based on a percentage of a drug's list price.[35]

306. The documents eventually released by the Senate also show how the Manufacturers' pricing strategy focuses on *the PBMs' profitability*. In an internal August 6, 2015, email, Novo Nordisk executives debated delaying increasing the price of an at-issue drug in order to make the increase more profitable for *CVS Caremark*, stating:

> Should we take 8/18 [for a price increase], as agreed to by our [pricing committee], or do we recommend pushing back due to the recent CVS concerns on how we take price? . . . We know CVS has stated their disappointment with our price increase strategy (ie taking just after the 45th day) and how it essentially results in a lower price protection, admin fee and rebate payment for that quarter/time after our increase . . . it has been costing CVS a good amount of money. [36]

307. The Manufacturer Defendants also understand that because of the PBMs' market dominance, most payors, including Plaintiff Greene County and its Beneficiaries, accept the baseline national formularies offered by the PBMs with respect to the at-issue drugs.

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[34] Community Oncology Alliance & Frier Levitt, *Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers* (Feb. 2022), https://communityoncology.org/wpcontent/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf (last visited Jan. 14, 2023).

[35] Grassley & Wyden, *supra* note 2 at 89.

[36] Letter from Raphael A. Prober, Counsel for Novo Nordisk Inc., to Charles E. Grassley & Ron Wyden, S. Fin. Comm. (Mar. 8, 2019), https://www.finance.senate.gov/imo/media/doc/Novo_ Redacted.pdf (last visited Jan. 15, 2023).

308. The Insulin Pricing Scheme was borne from these understandings. Both sets of Defendants realized that if the Manufacturers artificially inflate their list prices while paying large, undisclosed Manufacturer Payments back to the PBMs, both the PBMs and Manufacturers would generate billions of unearned dollars. The plan worked.

309. Over the past several years the Manufacturers have raised prices in unison and have paid correspondingly larger Manufacturer Payments to the PBMs.

310. In exchange for the Manufacturers artificially inflating their prices and paying the PBMs substantial amounts in Manufacturer Payments, the PBM Defendants grant the Manufacturer Defendants' diabetes medications elevated prices and preferred status on their national formularies. During the relevant period, the rebate amounts (as a proportion of the list price) grew year-over-year while list prices themselves increased.

311. Beyond increased rebate demands, the PBMs also have sought and received larger and larger administrative fee payments and other Manufacturer Payments from the Manufacturers during the relevant period.

312. A recent study by the Pew Charitable Trust estimated that, between 2012 and 2016, the amount of administrative and other fees that the PBMs requested and received from the Manufacturers tripled, reaching more than $16 billion. The study observed that, although rebates were sent to payors during this period, PBMs retained the same volume of rebates in pure dollars, given the overall growth in rebate volume while administrative fees and spread pricing (charging a client payor more for a drug than the PBM pays the pharmacy) further offset reductions in retained rebate volumes.

313. Thus—and contrary to their public representations—the PBM Defendants' negotiations and agreements with the Manufacturer Defendants (and the formularies that result

from these agreements) have caused and continue to cause precipitous price increases for the at-issue drugs.

314. As a result of the Insulin Pricing Scheme, every payor, including Plaintiff, that pays for and/or reimburses for the at-issue drugs has been overcharged.

315. Moreover, the PBMs use this false price to misrepresent the amount of "savings" they generate for diabetics, payors, and the healthcare system. For example, in January 2016, Express Scripts' president Tim Wentworth stated at the 34th annual JP Morgan Healthcare Conference that Express Scripts "saved our clients more than $3 billion through the Express Scripts National Preferred Formulary."[37] Likewise, in April 2019, CVS Caremark President Derica Rice stated: "Over the last three years . . . CVS Caremark has helped our clients save more than $141 billion by blunting drug price inflation, prioritizing the use of effective, lower-cost drugs and reducing the member's out-of-pocket spend."[38]

316. In making these representations, the PBMs fail to disclose that the amount of "savings" generated is calculated based on the false list price, which is not paid by any entity in the pharmaceutical pricing chain and which all Defendants are directly responsible for artificially inflating.

317. The Insulin Pricing Scheme is a coordinated effort among the Manufacturer and PBM Defendants in which each agreed to, and did, participate, and which created enormous profits for all. For example:

a. The Manufacturers and the PBMs are in constant communication and regularly meet and exchange information to construct and refine the PBM formularies that

[37] Surabhi Dangi-Garimella, *PBMs Can Help Bend the Cost Curve: Express Scripts' Tim Wentworth*, AJMC (Jan. 12, 2016), https://www.ajmc.com/view/pbms-can-help-bendthe-cost-curve-express-scripts-tim-wentworth (last visited Jan. 15, 2023).

[38] CVS Health, *CVS Health PBM Solutions Blunted the Impact of Drug Price Inflation, Helped Reduce Member Cost, and Improved Medication Adherence in 2018* (Apr. 11, 2019), https://www.cvshealth.com/news-and-insights/press-releases/cvs-health-pbmsolutions-blunted-the-impact-of-drug-price (last visited Jan. 11, 2023).

form and fuel the scheme. As part of these communications, the Manufacturers are directly involved in determining not only where their own diabetes medications are placed on the PBMs' formularies and with what restrictions, but also in determining the same for competing products;

b. The Manufacturers and the PBMs share confidential and proprietary information with each other in furtherance of the Insulin Pricing Scheme, such as market data gleaned from the PBMs' drug utilization tracking efforts and mail-order pharmacy claims, internal medical efficacy studies, and financial data. Defendants then use this information in coordination to set the false prices for the at-issue medications and to construct their formularies in the manner that is most profitable for both sets of Defendants. The data that is used to further this coordinated scheme is compiled, analyzed, and shared either by departments directly housed within the PBM or by subsidiaries of the PBM, as is the case with OptumRx, which utilizes OptumInsight and Optum Analytics; and

c. The Manufacturers and the PBMs engage in coordinated outreach programs directly to patients, pharmacies, and prescribing physicians to convince them to switch to the diabetes medications that are more profitable for the PBMs and Manufacturers, even drafting and editing letters in tandem to send out to diabetes patients on behalf of the PBMs' clients. For example, the Grassley-Wyden Senate committee recently released an email where Eli Lilly discussed paying Defendant UnitedHealth Group and OptumRx additional rebates for every client that was converted to formularies that exclusively preferred Eli Lilly's at-issue drugs, including Humalog. The email continued: "United's leadership committee made one ask of Lilly – that we are highly engaged in the communication/pull through plan.[39] I of course indicated we fully expect to support this massive patient transition [to Eli Lilly's at-issue drugs favored by United] and provider education with the full breadth of Lilly resources. UHC also proactively thanked Lilly for our responsiveness, solution generation and DBU execution."

318. Rather than using their prodigious bargaining power to lower drug prices as they claim, Defendants instead used their dominant positions to conspire to generate billions of dollars in illicit profits at the expense of payors like Plaintiff.

F. Defendants Play Down the Insulin Pricing Scheme and Its Harms

319. On April 10, 2019, the United States House of Representatives Committee on Energy and Commerce held a hearing on industry practices titled, "Priced Out of a Lifesaving

[39] "Pull through" is an industry term that refers to an integrated process between PBMs and Manufacturers aimed at moving market share and increasing sales for a certain product following the PBM granting that product preferred placement on its formulary.

Drug: Getting Answers on the Rising Cost of Insulin."[40]

320. Representatives from all Defendants testified at the hearing, and each acknowledged before Congress that the price for insulin has increased exponentially in the past 15 years.

321. Further, each Defendant conceded that the price that diabetics pay out-of-pocket for insulin is too high. For example:

- Dr. Sumit Dutta, SVP and Chief Medical Officer of OptumRx since 2015, stated: "A lack of meaningful competition allows the [M]anufacturers to set high [list] prices and continually increase them which is odd for a drug that is nearly 100 years old and which has seen no significant innovation in decades. These price increases have a real impact on consumers in the form of higher out-of-pocket costs."

- Thomas Moriarty, Chief Policy and External Affairs Officer and General Counsel for CVS Health testified: "A real barrier in our country to achieving good health is cost, including the price of insulin products which are too expensive for too many Americans. Over the last several years, [list] prices for insulin have increased nearly 50 percent. And over the last ten years, [list] price of one product, Lantus, rose by 184 percent."

- Mike Mason, Senior Vice President of Eli Lilly when discussing how much diabetics pay out-of-pocket for insulin stated: "it's difficult for me to hear anyone in the diabetes community worry about the cost of insulin. Too many people today don't have affordable access to chronic medications . . ."

- Kathleen Tregoning, Executive Vice President External Affairs at Sanofi, testified: "Patients are rightfully angry about rising out-of-pocket costs and we all have a responsibility to address a system that is clearly failing too many people. . . we recognize the need to address the very real challenges of affordability . . . Since 2012, average out-of-pocket costs for Lantus have risen approximately 60 percent for patients . . ."

- Doug Langa, Executive Vice President of Novo Nordisk, stated: "On the issue of affordability . . . I will tell you that at Novo Nordisk we are accountable for the [list] prices of our medicines. We also know that [list] price matters to many, particularly those in high-deductible health plans and those that are uninsured."

[40] https:// www.congress.gov/event/116th-congress/house-event/109299?s=1&r=3 (last visited Jan. 9, 2023) (hereinafter *Priced Out of a Lifesaving Drug*).

322. None of the testifying Defendants claimed that the significant increase in the price of insulin was related to competitive factors such as increased production costs or improved clinical benefit.

323. Instead, Novo Nordisk's President Doug Langa's written testimony for the April 2019 hearing recognized "misaligned incentives" that have led to higher drug costs, including for insulin: "Chief among these misaligned incentives is the fact that the rebates pharmaceutical companies pay to PBMs are calculated as a percentage of WAC [list] price. That means a pharmaceutical company fighting to remain on formulary is constrained from lowering WAC price, or even keeping the price constant, if a competitor takes an increase. This is because PBMs will then earn less in rebates and potentially choose to place a competitor's higher-priced product on their formulary to the exclusion of others." Likewise, Mr. Langa's responses to questions for the record conceded that "[t]he disadvantage of a system in which administrative fees are paid as a percentage of the list price is that there is increased pressure to keep list prices high. . . ." The hearing transcript records Mr. Langa's further comments in this regard:

> So as you heard from Dr. Cefalu last week of the ADA [American Diabetes Association], there is this perverse incentive and misaligned incentives and this encouragement to keep list prices high. And *we've been participating in that system* because the higher the list price, the higher the rebate . . . There is a significant demand for rebates…. *We're spending almost $18 billion a year in rebates*, discount, and fees, and *we have people with insurance with diabetes that don't get the benefit of that*. (emphasis added)

324. Eli Lilly admitted that it raises list prices as a quid pro quo for formulary positions. At the April 2019 Congressional hearing, Mike Mason, Senior Vice President of Eli Lilly, testified:

> Seventy-five percent of our list price is paid for rebates and discounts . . . . $210 of a vial of Humalog is paid for discounts and rebates. . . . We have to provide rebates [to PBMs] in order to provide and compete for that [formulary position] so that people can use our insulin. In the very next question, Mr. Langa of Novo Nordisk was asked, "[H]ave you ever lowered a list price? His answer: "We have not."

325. Sanofi's Executive Vice President for External Affairs, Kathleen Tregoning, testified:

> The rebates is [sic] how the system has evolved. . . . I think the system became complex and rebates generated through negotiations with PBMs are being used to finance other parts of the healthcare system and not to lower prices to the patient.

Her written response to questions for the record acknowledged that "it is clear that payments based on a percentage of list price result in a higher margin [for PBMs] for the higher list price product than for the lower list price product."

326. The PBM Defendants also conceded at the April 2019 Congressional hearing that they grant preferred, or even exclusive, formulary position because of higher Manufacturer Payments paid by the Manufacturer Defendants.

327. In her responses to questions for the record, Amy Bricker, former SVP of Express Scripts and PCMA board member, confirmed that "manufacturers lowering their list prices" would give patients "greater access to medications;" yet when asked to explain why Express Scripts did not grant an insulin with a lower list price preferred formulary status, answered, "Manufacturers do give higher discounts [i.e., payments] for exclusive [formulary] position . . ." When asked why the PBM would not include both costly and lower-priced insulin medications on its formulary, Ms. Bricker stated plainly, "We'll receive less discount in the event we do that."[41]

328. As Dr. Dutta, SVP of OptumRx, perversely reasoned, the cheaper list-priced alternative Admelog is not given preference on the formulary because "it would cost the payer more money to do that . . . because the list price is not what the payer is paying. They are paying

[41] Buried in Express Scripts' 2017 10-K is the following: "We maintain contractual relationships with numerous pharmaceutical manufacturers, which provide us with, among other things administrative fees for managing rebate programs, including the development and maintenance of formularies that include particular manufacturer's products . . . ." That is, the Manufacturers pay the PBMs to effectively participate in the creation of formularies that payors are required to adopt as a condition for obtaining PBM services. Express Scripts Annual Report (Form 10-K) (FYE Dec. 31, 2017) at 24. It also notes that its business would be "adversely affected" if it were to "lose [its] relationship with one or more key pharmaceutical manufacturers." *Id.*

the net price."[42] In other words, under the pricing scheme, PBMs and manufacturers can make a drug with a lower list price effectively more expensive for payors and then ostensibly save payors from that artificially inflated price by giving preference to drugs that had higher list prices to begin with (yielding higher Manufacturer Payments to the PBMs).

329. While all Defendants acknowledged before Congress their participation in conduct integral to the Insulin Pricing Scheme, none revealed its inner workings or the connection between their coordination and the economic harm that payors, like Plaintiff, and Beneficiaries were unwittingly suffering. Instead, in an effort to obscure the true reason for precipitous price increases, each Defendant group pointed the finger at the other as the more responsible party.

330. The PBM Defendants testified to Congress that the Manufacturer Defendants are solely responsible for their list price increases and that the Manufacturer Payments that the PBMs receive are not correlated to rising insulin prices.

331. This testimony is false. The amounts Manufacturers pay back to the PBMs is *directly correlated* to an increase in list prices. On average, a $1 increase in Manufacturer Payments is associated with a $1.17 increase in list price. Reducing or eliminating Manufacturer Payments would lower prices and reduce out-of-pocket expenditures.

332. Further, in large part because of the increased list prices and related Manufacturer Payments, the PBMs' profit per prescription has grown substantially over the same time period that insulin prices have steadily increased. For example, since 2003, Defendant Express Scripts has seen its profit per prescription increase more than 500% per adjusted prescription.[43]

[42] *Id.* As noted in the hearing, even the "cheaper" alternative Admelog "costs over $200 a bottle."

[43] David Balto, *How PBMs Make the Drug Price Problem Worse*, Hill (Aug. 31, 2016, 5:51 PM), https://thehill.com/blogs/pundits-blog/healthcare/294025-how-pbms-make-thedrug-price-problem-worse (last visited Jan. 15, 2023).

333. Novo Nordisk's President, Doug Langa, submitted written testimony to Congress acknowledging "there is no doubt that the WAC [list price] is a significant component" of "what patients ultimately pay at the pharmacy counter." Yet, the Manufacturers urged upon Congress the fiction that the PBMs were solely to blame for insulin prices because of their demands for rebates in exchange for formulary placement. The Manufacturers claimed their hands were tied and sought to conceal their misconduct by suggesting that they have not profited off rising insulin prices.

334. Given the Manufacturers' claims that rebates were the sole reason for rising prices, each was asked directly during the Congressional hearing to guarantee it would decrease list prices if rebates were restricted or eliminated. The spokespersons for Eli Lilly, Novo Nordisk and Sanofi all said only that they would "consider it."

335. In addition, a 2020 study from the Institute of New Economic Thinking titled, "Profits, Innovation and Financialization in the Insulin Industry," demonstrates that during the time insulin price increases were at their steepest, distributions to the Manufacturers' shareholders in the form of cash dividends and share repurchases totaled $122 billion. In fact, during this period the Manufacturers spent a significantly lower proportion of profits on R&D compared to shareholder payouts. The paper also notes that "[t]he mean price paid by patients for insulin in the United States almost tripled between 2002 and 2013" and that "per-person spending on insulin by patients and insurance plans in the United States doubled between 2012 and 2016, despite only a marginal increase in insulin use."[44]

336. The 2022 Community Oncology Alliance report found:[45]

[44] Rosie Collington, *Profits, Innovation and Financialization in the Insulin Industry*, Inst. for New Econ. Thinking (Apr. 2020), https://www.ineteconomics.org/research/research-papers/ profits-innovation-and-financialization-in-the-insulin-industry (last visited Jan. 15, 2023).

[45] Community Oncology Alliance, *supra* note 29.

> [T]here are several important ways that PBM rebates increase the costs of drugs for both plan sponsors and patients. . . . PBMs employ exceedingly vague and ambiguous contractual terms to recast monies received from manufacturers outside the traditional definition of rebates, which in most cases must be shared with plan sponsors. Rebate administration fees, *bona fide* service fees, and specialty pharmacy discounts/fees are all forms of money received by PBMs and rebate aggregators which may not be shared with (or even disclosed to) the plan sponsor. These charges serve to increase the overall costs of drugs, while providing no benefit whatsoever to plan sponsors. . . . The total drug spend of a plan sponsor, regardless of whether it is a federal or state governmental program or a self-funded employer, will inevitably increase because PBMs are incentivized to favor expensive drugs that yield high rebates. . . .

337. In January 2021, the Senate Finance Committee (Grassley-Wyden) issued a report titled "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug,"[46] which detailed Congress's findings after reviewing more than 100,000 pages of internal company documents from Sanofi, Novo Nordisk, Eli Lilly, CVS Caremark, Express Scripts, OptumRx, and Cigna. The report concluded, among other things:

- The Manufacturer Defendants retain more revenue from insulin than in the 2000s—for example, Eli Lilly has reported a steady increase in Humalog revenue for more than a decade—from $1.5 billion in 2007 to $3 billion in 2018;
- The Manufacturer Defendants have aggressively raised the list price of their Insulin products absent significant advances in the efficacy of the drugs; and
- The Manufacturer Defendants only spend a fraction of their revenue related to the at-issue drugs on research and development—Eli Lilly spent $395 million on R&D costs for Humalog, Humulin, and Basaglar between 2014-2018, during which time the company generated $22.4 billion in revenue on these drugs.

[46] Grassley & Wyden, *supra* note 2 at 5, 7.

338. The truth is that, despite their finger pointing in front of Congress, the Manufacturers and PBMs are *both* responsible for their concerted efforts in creating the Insulin Pricing Scheme.

G. Defendants Profit from the Insulin Pricing Scheme

339. The Insulin Pricing Scheme affords the Manufacturer Defendants the ability to pay the PBM Defendants secret but significant Manufacturer Payments in exchange for formulary placement, which garners the Manufacturer Defendants greater revenues from sales without decreasing their profit margins. During the relevant period, the PBM Defendants granted national formulary position to each at-issue drug in exchange for large Manufacturer Payments and inflated prices.

340. The Manufacturer Defendants also use the inflated price to earn hundreds of millions of dollars in additional tax breaks by basing their deductions for donated insulins on the inflated list price.

341. Because of the increased list prices and related Manufacturer Payments, the PBMs' profit per prescription has grown exponentially during the relevant period as well. A recent study published in the Journal of the American Medical Association concluded that the amount of money that goes to the PBM Defendants for each insulin prescription increased more than 150% from 2014 to 2018. In fact, for transactions where the PBM Defendants control the PBM and the pharmacy (e.g., Caremark-CVS pharmacy) these Defendants were capturing an astonishing 40% of the money spent on each insulin prescription (up from only 25% just four years earlier), despite the fact that they do not contribute to the development, manufacture, innovation or production of the product.[47]

[47] Karen Van Nuys, et al., *Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans From 2014 to 2018*,

342. The PBM Defendants profit from the artificially inflated prices created by the Insulin Pricing Scheme in a number of ways, including by: (1) retaining a significant, yet undisclosed, percentage of the Manufacturers Payments, (2) using the inflated list price to generate profits from pharmacies, and (3) relying on the inflated list price to drive up the PBMs' margins through their own mail-order pharmacies.

The PBMs Pocket a Substantial Share of Manufacturer Payments

343. The first way in which the PBMs profit from the Insulin Pricing Scheme is by keeping a significant portion of the secret Manufacturer Payments.

344. The amount that the Manufacturers pay back to the PBMs has increased over time both in real dollars and as a proportion of the ever-increasing list prices.

345. Historically, contracts between PBMs and payors allowed the PBMs to keep most or all of the rebates they received, rather than forwarding them to the payor.

346. Over time, payors secured contract provisions guaranteeing payment to them of all or some portion of the rebates paid by the Manufacturers to the PBMs. Critically, however, "rebates" are only one aspect of the total Manufacturer Payments, particularly as "rebates" are narrowly defined and qualified by vague exceptions in the PBM contracts with payors.

347. Indeed, as described in the January 2021 Senate Insulin Report, the PBMs and Manufacturers coordinate to determine the contract options made available to payors: "Contracts between PBMs and manufacturers provide a menu of options from which their health plan clients can choose certain terms and conditions."[48] The contracts between the PBMs and Manufacturers also "stipulate terms the plans must follow regarding factors such as formulary placement and

JAMA Network (Nov. 5, 2021), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2785932 (last visited Aug. 23, 2023).

[48] Grassley & Wyden, *supra* note 2 at 40.

competition from other drugs in the therapeutic class."[49] Thus, the Manufacturers ultimately played a role in dictating the terms and conditions of the contracts that payors like Plaintiff entered into with PBMs. Of course, the payors were not involved in the coordination or the negotiation of the contracts between the PBMs and Manufacturers and the PBMs disclosed only the fact that such relationships may exist—the terms of the contracts, the consideration exchanged between the PBMs and Manufacturers, and the means of reaching these determinations all were and remain shrouded in secrecy.

348. The PBM and Manufacturer Defendants thus created a "hide-the-ball" system where payors like Plaintiff are not privy to rebate negotiations or contracts between the Manufacturers and the PBMs. The consideration exchanged between them (and not shared with payors) is labeled and relabeled. As more payors moved to contracts that required PBMs to remit some or all of the manufacturer "rebates" through to the payor, the PBMs rechristened Manufacturer Payments to shield them from scrutiny and from their payment obligations. Payments once called "rebates" now include administrative fees, volume discounts, service fees, inflation fees, or other industry monikers designed to obfuscate the substantial sums being secretly exchanged between the PBMs and the Manufacturers.

349. Just last year, the Senate Commerce, Science and Transportation Committee released testimony from David Balto—a former antitrust attorney with the DOJ and Policy Director for the FTC's Bureau of Competition—from a hearing on fairness and transparency in drug pricing:

> The PBM rebate system turns competition on its head with PBMs seeking higher, not lower prices to maximize rebates and profits. In the past decade, PBM profits have increased to $28 billion annually. . . . PBMs establish tremendous roadblocks to prevent payors from knowing the amount of rebates they secure. Even sophisticated buyers are unable to secure specific drug by drug rebate information.

[49] *Id.* at 44.

> PBMs prevent payors from being able to audit rebate information. As the Council of Economic Advisors observed, the PBM market lacks transparency as "[t]he size of manufacturer rebates and the percentage of the rebate passed on to health plans and patients are secret." Without adequate transparency, plan sponsors cannot determine if the PBMs are fully passing on any savings, or whether their formulary choices really benefit the plan and subscribers.

350. The renamed, undisclosed Manufacturer Payments are substantial. "Administrative fees" are one example. A heavily redacted complaint filed by Defendant Express Scripts in 2017 revealed that Express Scripts retains up to 13 times more in "administrative fees" than it remits to payors in rebates.[50]

351. These so-called administrative fees typically are based on a percentage of the drug price—as opposed to a flat fee—such that even if the actual "administrative" cost associated with processing two drugs is the same, the "administrative fee" would be correspondingly higher for the higher-priced drug, which creates (by design) a perverse incentive to give preference to more expensive drugs. Moreover, the PBM Defendants' contracts with payors, including those with Plaintiff, narrowly define "rebates" by tying them to patient drug utilization, so rebates for formulary placement are characterized as "administrative fees" that are not remitted to payors and are beyond a payor's contractual audit right to verify the accuracy of "rebate" payments under the contracts.

352. The opaque nature of these arrangements between the Manufacturers and PBM Defendants also makes it impossible for a given payor to discover, much less assess or confront, conflicts of interest that may affect it or its members. The January 2021 Senate Insulin Report observed with respect to these arrangements: "Relatively little is publicly known about these financial relationships and the impact they have on insulin costs borne by consumers."[51]

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[50] *Express Scripts, Inc. v. Kaleo, Inc.*, No. 4:17-cv-01520-RLW (E.D. Mo. 2017).
[51] Grassley & Wyden, *supra* note 2 at 4.

353. Unsurprisingly, the PBMs have gone to great lengths to obscure these renamed Manufacturer Payments in order keep them for themselves and to avoid scrutiny from payors and others.

354. For example, with regard to the Manufacturer Payments now known as "inflation fees," the PBMs often create a hidden gap between how much the Manufacturers pay them to increase their prices and the amount in "price protection guarantees" that the PBMs agree to pay back to their client payors.

355. In particular, the Manufacturer Defendants often pay the PBM Defendants "inflation fees" in order to increase the price of their diabetes medications. The thresholds for these payments are typically set at around 6% to 8%—if the Manufacturer Defendants raise their prices by more than the set percentage during a specified time period, they pay the PBM Defendants an additional "inflation fee" (based on a percentage of the list prices).

356. For many of their clients, the PBMs have separate "price protection guarantees" that state that if the overall drug prices for that payor increase by more than a set amount, then the PBMs will remit a portion of the amount to the client.

357. The PBMs set these "price protection guarantees" at a higher rate than the thresholds that trigger the Manufacturers' "inflation fees," usually around 10%-15%.

358. Thus, if the Manufacturers increase their list prices more than the 6% (or 8%) inflation fee rate but less than the 10%-15% client price protection guarantee rate, then the PBMs keep all of these "inflation fee" payments. This is a win-win for the Manufacturers and PBMs—they share and retain the entire benefit of these price increases while the PBM contracts with payors imply that payors are protected from price hikes by their price protection guarantees.

359. The PBMs also hide the renamed Manufacturer Payments with "rebate aggregators." Rebate aggregators, sometimes referred to as rebate group purchasing organizations ("GPOs"), are entities that negotiate for and collect payments from drug manufacturers, including the Manufacturer Defendants, on behalf of a large group of pharmacy benefit managers (including the PBM Defendants) and different entities that contract for pharmaceutical drugs.

360. These rebate aggregators are often affiliated with or owned by the PBM Defendants, such as Ascent Health Services (Express Scripts), Coalition for Advanced Pharmacy Services and Emisar Pharma Services (OptumRx), and Zinc (CVS Caremark).

361. The PBMs carefully guard the revenue streams from their rebate aggregator activities, hiding them in complex contractual relationships and not reporting them separately in their quarterly SEC filings.

362. Certain rebate-aggregator companies are located offshore, for example, in Switzerland (Express Scripts' Ascent Health) and Ireland (Emisar Pharma Services), making oversight even more difficult.

363. As summarized by the recent Community Oncology Alliance report:[52]

> PBMs have increasingly "delegated" the collection of manufacturer rebates to "rebate aggregators," which are often owned by or affiliated with the PBMs, without seeking authorization from plan sponsors and without telling plan sponsors. . . . Even some of the major PBMs (i.e., the "Big Three" PBMs) sometimes find themselves contracting with other PBMs' rebate aggregators for the collection of manufacturer rebates. . . . In both the private sector and with respect to government health care programs, the contracts regarding manufacturer rebates (i.e., contracts between PBMs and rebate aggregators, as well as contracts between PBMs/rebate aggregators and pharmaceutical manufacturers) are not readily available to plan sponsors.

364. For example, a 2017 audit conducted by a local governmental entity on Defendant OptumRx related to its PBM activities from 2013 to 2015 concluded that the auditor was unable

[52] Community Oncology Alliance, *supra* note 29.

to verify the percentage of rebates OptumRx remitted to its client payor because OptumRx would not allow the auditor access to its rebate contracts. The audit report explained:

> Optum[Rx] has stated that it engaged the services of an aggregator to manage its rebate activity. Optum[Rx] shared that under this model, they are paid by their aggregator a certain amount per prescription referred. Then, the aggregator, through another entity, seeks rebates from the drug manufacturers, based upon the referred [Payor Client] prescription utilization, and retains any rebate amounts that may be received. Optum[Rx] states that they have paid [Payor Client] all amounts it has received from its aggregator, and that they do not have access to the contracts between the aggregator (and its contractors) and the manufacturer. However, our understanding is that Optum[Rx] has an affiliate relationship with its aggregator.[53]

365. A footnote in the audit report clarifies that "Optum[Rx] contracted with Coalition for Advanced Pharmacy Services (CAPS), and CAPS in turn contracted with Express Scripts, Inc."

366. In other words, according to this report, OptumRx contracts with its own affiliate aggregator Coalition for Advanced Pharmacy Services, who then contracts with OptumRx's co-conspirator Express Scripts, who then contracts with the Manufacturers for rebates related to OptumRx's client's drug utilization. OptumRx then uses this complex relationship to obscure the amount of Manufacturer Payments that are being generated from its client's utilization.

367. A subsequent audit by the same local entity—covering the period September 2017 to September 2018, concluded:[54]

> Several material weaknesses in Broward's agreement with Optum were identified, many of which are commonplace across pharmacy benefit manager agreements in general. Due to contract weaknesses, comparison of Broward's PBM agreement, including rebate amounts received, to the Consultant's marketplace data is not feasible. Broward could save an estimated $1,480,000 per year in net prescription drug benefit expenses (based upon minimum rebate guarantees) by switching from

[53] Laura Rogers & Stacey Thomas, Broward County Florida, Audit of Pharmacy Benefit Management Services Agreement, No. 18-13 (Dec. 7, 2017), https://www.broward.org/Auditor/Reports/Documents/2017_1212%20Agenda%20Review%20of%20Pharmacy%20Benefit%20Management%20Services%20by%20StoneBridge/2017_1212%20Exh1_OptumRx.pdf (last visited Jan. 15, 2023).

[54] Broward County, Florida, *Analysis of Broward County's Prescription Drug Coverage*, https://www.broward.org/Auditor/Reports/Reports/082019_Exh1_BCRxDrug_19-15.pdf (last visited Aug. 23, 2023).

> its current flawed agreement with Optum, to an agreement with its Coalition, which offers clearly defined terms, increased rebate guarantees and cost saving requirements.

Among other "loopholes" discovered in the contract were a number of "flawed" (i.e., vague and manipulable) definitions—including the definition of Rebates, which "allows the exclusion of monies that should be included—and limitation with respect to "Pass Through Transparency Pricing."

368. The January 2021 Grassley-Wyden Senate Report summarizing findings of their two-year probe into the Insulin Pricing Scheme contained the following observation on these rebate aggregators[55]:

> [T]he recent partnership between Express Scripts and Prime Therapeutics may serve as a vehicle to avoid increasing legislative and regulatory scrutiny related to administrative fees by channeling such fees through a Swiss based group purchasing organization (GPO), Ascent Health. While there are several regulatory and legislative efforts underway to prohibit manufacturers from paying administrative fees to PBMs, there is no such effort to change the GPO safe harbor rules. New arrangements used by PBMs to collect fees should be an area of continued investigative interest for Congress.

369. Federal regulations governing Medicare attempt to capture all possible forms of Direct or Indirect Remuneration (DIR) to PBMs (and plan sponsors), defining DIR as "any form of price concession" received by a plan sponsor or PBM "from any source," including "discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, legal judgment amounts, settlement amounts from lawsuits or other legal action, and other price concessions or similar benefits. DIR also includes price concessions from and additional contingent payments to network pharmacies that cannot reasonably be determined at the point of sale."[56]

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[55] Grassley & Wyden, *supra* note 2 at 83.

[56] CMS, *Final Medicare Part D DIR Reporting Guidance for 2021* at 7, https://www.cms.gov/files/document/final2021dirreportingreqsmemo508v3.pdf (last visited Jan. 15, 2023).

370. The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) considers all of the following as DIR: rebates, grants, reduced price administrative services, PBM-retained rebates, PBM rebate guarantee amounts, all post-point of sale payments by pharmacies that are not included in the negotiating price including dispensing incentive payments, prompt pay discounts, and payment adjustments. On the other hand, "bona fide service fees from pharmaceutical manufacturers" and "remuneration for administrative services with no impact on the sponsor's or PBM's drug cost (e.g., PBM incentive payments)" are not considered DIR, but only to the extent they reflect fair market value for services rendered.[57]

371. Because the PBMs retain and conceal a majority of the secret Manufacturer Payments that they receive, they are able to reap significant profits on the Insulin Pricing Scheme.

372. Even where payor clients receive a portion of the Manufacturer Payments from their PBM, those payors still are significantly overcharged as a direct result of the Insulin Pricing Scheme given the extent to which Defendants have deceptively and egregiously inflated the prices of the at-issue drugs.

The Insulin Pricing Scheme Allows the PBMs to Profit Off Pharmacies

373. A second way the PBM Defendants profit off the Insulin Pricing Scheme is by using the Manufacturers' inflated price to derive profit from the pharmacies with whom they contract, including those in Greene County.

374. Each PBM Defendant decides which pharmacies are included in the PBM's network and how much it will reimburse these pharmacies for each drug dispensed.

375. The PBM Defendants, in coordination with the Manufacturers, directly reach out to patients, pharmacies, and prescribing physicians to convince them to switch to the diabetes

[57] *Id.* at 6-7.

medications that are more profitable for the PBMs and Manufacturers, even drafting and editing letters together to send to diabetes patients on behalf of the PBMs' clients [58]. The Defendants also petition these recipients to use the PBM Defendants' mail-order pharmacies and have succeeded in convincing patients, pharmacies, and prescribing physicians to do so.

376. The PBMs pocket the spread between the amount that the PBMs are paid by their clients for the at-issue drugs (which are based on the prices generated by the Insulin Pricing Scheme) and the amount the PBM reimburses the pharmacy (which often is less). In other words, the PBMs charge a client like Greene County more for a drug than the PBM pays the pharmacy and pockets the difference.

377. A bipartisan bill introduced in the Senate in 2022 (the Pharmacy Benefit Manager Transparency Act—S. 4293)—would have, criminalized spread pricing, which the bill defined as "[c]harg[ing] a health plan or payer a different amount for a prescription drug's ingredient cost or dispensing fee than the amount the pharmacy benefit manager reimburses a pharmacy for the prescription drug's ingredient cost or dispensing fee where the pharmacy benefit manager retains the amount of any such difference." The bill has not yet been enacted.[59]

378. Not coincidentally, the PBMs' industry-funded trade association PCMA spent $7.8 million on federal lobbying in 2021 and more $6 million through the third quarter of 2022.[60]

379. The PBMs often disclose the concept of spread pricing to payors, but only in vague terms that require no accountability and are not subject to the payors' audit rights because the revenue is not defined as a "rebate" in the PBM contracts with payors.

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[58] See supra 326(c).

[59] https://www.govtrack.us/congress/bills/117/s4293 (last visited Jan. 10, 2023).

[60] https://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2021&id=D000028342 (2021); https://www.opensecrets.org/federallobbying/clients/summary?cycle= 2022&id=D000028342 (2022) (last visited Jan. 10, 2023).

380. This spread pricing, like the secret Manufacturer Payment negotiation, happens behind closed doors. There is no transparency, no commitment from the PBM Defendants to account for the cost effectiveness of a drug, and no communication to either the payor or the pharmacy to let them know if they are getting a fair deal.

381. The higher the Manufacturers' list prices, the more money the PBMs make off this spread. At the same time, a Beneficiary's out-of-pocket co-pay or deductible cost often is more than if the client had simply paid cash outside of his or her plan. On top of this, the PBM contracts generally allow no rebates to payors where the Beneficiary is responsible for 100% of the drug cost, e.g., under his or her deductible.

382. The PBMs also use the Insulin Pricing Scheme to generate additional profits from pharmacies by charging the pharmacies post-purchase fees, including DIR (Direct or Indirect Remuneration) fees, based on the list prices—and again, the higher the list price for each diabetes medication sold, the more fees the PBMs generate—or by applying "retrospective" discounts. So, for example, a payor's (and member's co-pay or deductible) cost may be $100, but the price is discounted post-purchase (between the PBM and the (often self-owned) pharmacy) to $90 with the spread going to the PBM.

383. CMS addressed these and similar DIR issues in a proposed rule in 2017. While noting the growth of "pharmacy price concessions" that "are negotiated between pharmacies and their sponsors or PBMs," CMS nevertheless concluded:[61]

> When manufacturer rebates and pharmacy price concessions are not reflected in the price of a drug at the point of sale, beneficiaries might see lower premiums, but they do not benefit through a reduction in the amount they must pay in cost-sharing, and thus, end up paying a larger share of the actual cost of a drug. Moreover, given the increase in manufacturer rebates and pharmacy price concessions in recent

[61] Medicare Program; Contract Year 2019 Policy and Technical Changes, 82 Fed. Reg. 56336 (Nov. 29, 2017), https://www.govinfo.gov/content/pkg/FR-2017-11-28/pdf/2017-25068.pdf. Last visited Aug 23, 2023.

> years, the point-of-sale price of a drug that a Part D sponsor reports on a PDE record as the negotiated price is rendered less transparent . . . .

CMS expressed further concern that when rebates and other price concessions are not reflected in the negotiated point-of-sale drug price, it "can impede beneficiary access to necessary medications, which leads to poorer health outcomes and higher medical care costs for beneficiaries . . . ."

384. PBMs thus make money coming and going. In a pre-PBM world, a competitively priced drug might have a (hypothetical) net cost to a health plan $50 and that is what it paid. PBMs enter the picture and coordinate with Manufacturers to increase the list price to $150. The PBMs then "negotiate" the inflated price down to $100 and take a $50 rebate, some of which may be forwarded to the payor, whose net cost is less than the inflated list price, but whose real-world cost is considerably more than if the PBMs were not involved.

385. At the same time, the PBM receives "administrative fees" for including certain drugs on its formularies, which are not considered "rebates." The PBM also receives "service fees" or other payment for "administrative services" provided to the Manufacturers such as "formulary compliance initiatives," "education services," or "the sale of non-patient identifiable claim information." All of these revenues are outside the definition of "rebates."

386. The PBM then charges payors like the County for administrative fees for providing pharmacy benefit management services and charges for drug costs (i.e. ingredient costs) and per-prescription dispensing fees, as well as additional administrative fees for services not included in the PBM's general administrative obligations. The PBM also receives rebates and/or discounts (pre-purchase or post-purchase) from the pharmacies, which it often owns. These too are excluded from the definition of "rebates." These and other vaguely described revenue streams are sometimes disclosed but only in hazy, overly generalized terms. And they are beyond a payor's contractual

rights to audit for "transparency" purposes because they are not defined "rebates." Additionally, the PBM may take months to pay rebates to payors and the PBM retains all interest on, and the time-value of, the rebates pending payment.

387. Payors have no access to, and no knowledge of, the intricacies of the dealings between the PBM Defendants and the Manufacturers that are shrouded by such vague "disclosures" (which vary in detail, but not in substance, in all three of the PBM Defendants' adhesive contracts).

The Insulin Pricing Scheme Increases PBM Mail-Order Profit

388. Another way PBMs profit from the Insulin Pricing Scheme is through the PBM Defendants' own mail-order pharmacies. The higher the price that PBM Defendants are able to get customers, such as Plaintiff, to pay for diabetes medications, the higher the profits PBM Defendants realize through their mail-order pharmacies.

389. Because the PBMs base the price they charge for the at-issue diabetes medications on the Manufacturers' price, the more the Manufacturers inflate their prices, the more money the PBMs make. For example, the PBMs have colluded with the Manufacturers so that the PBMs often know when the Manufacturers are going to raise their prices. The PBMs use this opportunity to purchase a significant amount of the at- issue drugs prior to the price increase, at the lower rate. Then, after the Manufacturers raise their price, the PBMs charge their mail-order customers based on the higher, increased prices and pocket the difference. The PBMs make significant amounts of money through this arbitrage scheme.

390. The PBMs also charge the Manufacturer Defendants fees related to their mail-order pharmacies, such as pharmacy supplemental discount fees, that are directly tied to the

Manufacturers' price. Thus, once again, the higher the price, the more money the PBMs make on these fees.

391. In sum, every way in which the PBMs make money on diabetes medications is tied directly to creating higher prices and inducing larger secret Manufacturer Payments. The PBMs are not lowering the price of diabetes medications as they publicly represent; they are making billions of dollars by fueling these skyrocketing prices.

H. Plaintiff Purchases the At-Issue Drugs Directly from Defendants

392. As a government employer, Plaintiff serves its residents by providing public safety, emergency management, and health services, among other vital roles. As more federal and state responsibilities are mandated to local government, Plaintiff has a growing list of demands on a limited budget. Consequently, any significant increase in spending can have a severe detrimental effect on Plaintiff's overall budget and, in turn, negatively impact its ability to provide necessary services to the community.

393. One benefit Plaintiff provides the Beneficiaries of its healthcare plan is payment for a large portion of their pharmaceutical purchases. In this role, Plaintiff spent significant amounts on the at-issue diabetes medications during the relevant period.

394. Because Plaintiff maintains a self-funded plan for County employees, Plaintiff does not rely on a third-party insurer to pay for insured employees' medical care, pharmaceutical benefits, or prescription drugs. Rather, Plaintiff directly contracts with, and directly pays, PBMs (and their affiliated pharmacies) for pharmaceutical benefits and prescription drugs, including the at-issue medications.

395. Plaintiff also purchased, and still purchases, the at-issue drugs directly from these PBMs (and their affiliated pharmacies) for use in Plaintiff's county-run facilities.

396. In the context of Plaintiff's purchases of the at-issue drugs, Plaintiff and its Beneficiaries are the only victims of the Insulin Pricing Scheme. Plaintiff is the only named party that pays the full purchase price for the at-issue drugs, and the only named party that has not knowingly participated in the Insulin Pricing Scheme. Neither the PBM Defendants nor the Manufacturers Defendants suffer losses from the Insulin Pricing Scheme.

397. As part of purchasing the at-issue drugs from the PBMs, Plaintiff directly pays the PBMs artificially inflated costs resulting from the Insulin Pricing Scheme, including "administrative fees," "inflation fees," "discount fees," and more—all of which are associated with Plaintiff's purchase of the at-issue drugs from the PBM Defendants. Because the at-issue medications are potentially life-saving drugs, and because the Manufacturers control the market for these drugs, Plaintiff has no choice but to pay these exorbitant, artificially inflated prices directly to PBM Defendants.

398. Plaintiff also relies (and has relied) on PBM Defendants as administrative agents, for the alleged purposes of limiting its administrative burden and controlling pharmaceutical drugs costs.

399. In providing PBM services to Plaintiff, including developing and offering formularies for Plaintiff's prescription plan, constructing and managing Plaintiff's pharmacy network (which included the PBMs' retail and mail-order pharmacies), processing pharmacy claims, and providing mail-order pharmacy services, PBM Defendants set the amount Plaintiff paid in coordination with the Manufacturer Defendants and, utilizing the false prices, generated by the Insulin Pricing Scheme. Plaintiff paid PBM Defendants directly for the at-issue drugs.

I. Defendants Deceived Plaintiff

400. At no time has either Defendant group disclosed the Insulin Pricing Scheme or the reasons for the false list prices produced by it.

The Manufacturer Defendants Deceived Plaintiff

401. At all times during the relevant period, the Manufacturer Defendants knew that the list prices, net prices, and payors' net costs (purchase prices) generated by the Insulin Pricing Scheme were false, excessive, and untethered to any legal, competitive, or fair market price.

402. The Manufacturer Defendants knew that these prices did not bear any rational relationship to the actual costs incurred or prices realized by Defendants, did not result from transparent or competitive market forces, and were artificially and arbitrarily inflated for the sole purpose of generating profits for Defendants.

403. The insulin market, and Defendants' business arrangement relating thereto, exhibit the key features of oligopolies (see Fig. 14)—concentration of numerous competitors into a small group of firms that dominates the market, high barriers to entry, ability to set and control prices, firm interdependence, and maximal revenues.

404. The Manufacturer Defendants also knew that payors, including Plaintiff, relied on the false list prices generated by the Insulin Pricing Scheme to pay for the at-issue drugs.

405. The Manufacturer and PBM Defendants further knew that Plaintiff—like any reasonable consumer, and particularly one with fiduciary obligations to its Beneficiaries—wanted and expected to pay a price reflecting the lowest fair market value for the drugs (which was not necessarily the same as the lowest price in the market, given that all prices were inflated due to the Insulin Pricing Scheme).

406. Despite this knowledge, the Manufacturer Defendants published the prices generated by the Insulin Pricing Scheme throughout the United States and Tennessee through

publishing compendia, in various promotional and marketing materials distributed by entities downstream in the drug supply chain, and directly to pharmacies which then used these prices to set the amount that the pharmacies charged for the at-issue drugs.

407. The Manufacturer Defendants also publish these prices to the PBMs and pharmacies, which then use them to charge diabetics and payors like Plaintiff for the at-issue drugs.

408. By publishing their prices throughout Tennessee, the Manufacturer Defendants held these prices out as a reasonable price upon which to base the prices that payors actually pay for the at-issue drugs.

409. These representations are false. The Manufacturer Defendants knew that their artificially inflated list prices were not remotely related to their cost, their fair market value in a competitive market, or the net price received for the at-issue drugs.

410. During the relevant period, the Manufacturer Defendants published prices in Tennessee at hundreds of dollars per dose for the same at-issue drugs that would have been profitable to Manufacturers at prices less than $10 per dose.

411. The Manufacturer Defendants also have publicly represented that they price the at-issue drugs according to each drug's value to the health care system and the need to fund innovation. For example, briefing materials prepared for Dave Ricks, Eli Lilly's CEO, as a panelist at the 2017 Forbes Healthcare Summit included "Reactive Key Messages" on pricing that emphasized the significant research and development costs for insulin. During the relevant period, executives from Sanofi and Novo Nordisk also falsely represented that research and development costs were key factors driving the at-issue price increases.[62]

[62] Drug Pricing Investigation, H.R. Comm. On Oversight and Reform, 117th Cong. (2021), https://web.archive.org/web/20211215170722/https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf (last visited Jan. 10, 2023).

412. To the contrary, between 2005 and 2018, Eli Lilly spent $680 million on R&D costs related to Humalog while earning $31.35 billion in net sales during that same time period. In other words, Eli Lilly made more than 46 times its reported R&D costs on Humalog during this portion of the relevant period, i.e., R&D costs amounted to about 2% of net sales (whereas R&D costs for pharmaceuticals typically amount to around 20% of total revenues). Novo Nordisk has spent triple the amount it spends on R&D on stock buyouts and shareholder dividend payouts in recent years.[63]

413. The January 2021 Senate Insulin Report found that the PBMs consider insulins to be "interchangeable" from "a clinical perspective" and that Manufacturers focus their R&D efforts on new insulin-related device, equipment, and other mechanical parts which are separate from insulin's formulation."[64]

414. A House Oversight Committee staff report concluded that "drug companies' claims that reducing U.S. prescription drug prices will harm innovation is overblown" and that "[m]any drug companies spent a significant portion of their R&D budget on finding ways to suppress generic and biosimilar competition while continuing to raise prices, rather than on innovative research."[65]

415. In sum, the Manufacturer Defendants affirmatively withheld the truth from Plaintiff and specifically made these misrepresentations in furtherance of the Insulin Pricing Scheme and

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[63] *Id.*

[64] Grassley & Wyden, *supra* note 2 at 5, 17.

[65] U.S. House of Reps., *Drug Pricing Investigation: Industry Spending on Buybacks, Dividends and Executive Compensation* (July 2021), https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/COR%20Staff%20Report%20-%20Pharmaceutical%20Industry%20Buybacks%20Dividends%20Compared%20to%20Research.pdf (last visited Aug. 23, 2023).

to induce Plaintiff's reliance to purchase the at-issue drugs. The PBM Defendants Deceived Plaintiff

416. The PBM Defendants ensured that the Manufacturer Defendants' artificially inflated list prices harmed diabetics and payors by selecting the highest price at-issue drugs for preferred formulary placement and by requiring that their contracts with both pharmacies and with payors include such prices as the basis for payment.

417. The PBM Defendants perpetuate the use of the artificially inflated insulin prices because it allows them to obscure the actual price any entity in the drug pricing chain is paying for the at-issue drugs. This lack of transparency affords Defendants the opportunity to construct and perpetuate the Insulin Pricing Scheme and to profit therefrom at the expense of Tennessee payors, including Plaintiff.

418. At all times throughout the relevant period, the PBMs have purposefully, consistently, and routinely misrepresented that they negotiate with Manufacturer Defendants and construct formularies for the benefit of payors and patients by lowering the price of the at-issue drugs and by promoting the health of diabetics. Representative examples include: [66]

- Defendant CVS Caremark has for the past decade consistently stated in its annual reports that its design and administration of formularies are aimed at reducing the costs and improving the safety, effectiveness, and convenience of prescription drugs. CVS Caremark has further stated that it maintains an independent panel of doctors, pharmacists, and other medical experts to review and approve the selection of drugs based on safety and efficacy for inclusion on one of Caremark's template formularies and that CVS Caremark's formularies lower the cost of drugs.

- Likewise, Defendant Express Scripts has consistently represented that it works with clients, manufacturers, pharmacists, and physicians to increase efficiency in the drug distribution chain, to manage costs in the pharmacy benefit chain, and to improve members' health outcomes. Its annual reports consistently claim that in making formulary recommendations, Express Scripts' Pharmacy & Therapeutics Committee considers the drug's safety and efficacy, without any information on or

[66] CVS Health Annual Reports (Form 10-K) (FY 2010-2019); OptumRx Annual Reports (Form 10-K) (FY 2010-2019); Express Scripts Annual Reports (Form 10-K) (FY 2010-2019).

consideration of the cost of the drug, including any discount or rebate arrangement that Express Scripts negotiates with the Manufacturer, and that Express Scripts fully complies with the P&T Committee's clinical recommendations regarding drugs that must be included or excluded from the formulary based on their assessment of safety and efficacy.

- Similarly, Defendant OptumRx has consistently stated in its annual reports over the past decade that OptumRx's rebate contracting and formulary management assist customers in achieving a low-cost, high-quality pharmacy benefit. It has consistently claimed that it promotes lower costs by using formulary programs to produce better unit costs, encouraging patients to use drugs that offer improved value and that OptumRx's formularies are selected for health plans based on their safety, cost and effectiveness.

419. In addition to these general misrepresentations, the PBM Defendants have during the relevant period purposefully, consistently, and routinely made misrepresentations about the at-issue diabetes medications. Representative examples include:

- In a public statement issued in November 2010, CVS Caremark represented that it was focused on diabetes to "help us add value for our PBM clients and improve the health of plan members . . . a PBM client with 50,000 employees whose population has an average prevalence of diabetes could save approximately $3.3 million a year in medical expenditures."[67]

- In 2010, Andrew Sussman, Chief Medical Officer of CVS Caremark, stated on national television that "CVS is working to develop programs to hold down [diabetes] costs."[68]

- In a public statement issued in November 2012, CVS Caremark represented that formulary decisions related to insulin products "is one way the company helps manage costs for clients."[69]

- In 2016, Glen Stettin, Senior Vice President and Chief Innovation Officer at Express Scripts, said in an interview with a national publication that "[d]iabetes is wreaking havoc on patients, and it is also a runaway driver of costs for payors . . .

[67] Chain Drug Review, *CVS Expands Extracare for Diabetes Products* (May 11, 2010), https://www.chaindrugreview.com/cvs-expands-extracare-for-diabetes-products/ (last visited Jan. 15, 2023).

[68] CBS News, Diabetes Epidemic Growing (June 22, 2010, 11:29 AM), https://www.cbsnews.com/news/diabetes-epidemic-growing/ (last visited Aug. 23, 2023).

[69] Jon Kamp & Peter Loftus, *CVS' PBM Business Names Drugs It Plans to Block Next Year*, WSJ (Nov. 8, 2012), https://www.wsj.com/articles/SB10001424127887324439804578 107040729812454 (last visited Jan. 15, 2023).

[Express Scripts] helps our clients and diabetes patients prevail over cost and care challenges created by this terrible disease."[70] Mr. Stettin also claimed that Express Scripts "broaden[s] insulin options for patients and bend[s] down the cost curve of what is currently the costliest class of traditional prescription drugs."[71]

- In a 2018 Healthline interview, Mark Merritt, longtime President of the PBM trade association PCMA, stated: "[Through their formulary construction], PBMs are putting pressure on drug companies to reduce insulin prices."[72]

- CVS Caremark's Chief Policy and External Affairs Officer claimed in the April 2019 hearings that CVS Caremark "has taken a number of steps to address the impact of insulin price increases. We negotiate the best possible discounts off the manufacturers' price on behalf of employers, unions, government programs, and beneficiaries that we serve."[73]

- Dr. Sumit Dutta, SVP and Chief Medical Officer of OptumRx, testified before the U.S. Congress in the April 2019 hearing that for "insulin products . . . we negotiate with brand manufacturers to obtain significant discounts off list prices on behalf of our customers."[74]

- The PBM-funded trade association PCMA's website acknowledges, "the insulin market is consolidated, hindering competition and limiting alternatives, leading to higher list prices on new and existing brand insulins," but then misleadingly claims that "PBMs work hard to drive down costs using formulary management and rebates."[75]

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[70] https://www.bizjournals.com/stlouis/news/2016/08/31/express-scripts-launchesprogram-to-control.html (last visited Jan. 15, 2023).

[71] Angela Mueller, *Express Scripts Launches Program to Control Diabetes Costs*, St. Louis Bus. J. (Aug. 31, 2016), https://drugstorenews.com/pharmacy/express-scriptsimplements-latest-diabetes-care-value-program (last visited Jan. 15, 2023).

[72] Dave Muoio, *Insulin Prices: Are PBMs and Insurers Doing Their Part?*, Population Health Learning Network (Dec. 2016), https://www.hmpgloballearningnetwork.com/site/frmc/ article/insulin-prices-are-pbms-and-insurers-doing-their-part (last visited Jan. 15, 2023).

[73] *Priced Out of a Lifesaving Drug*, *supra* note 35.

[74] *Id*.

[75] PCMA, *PCMA on National Diabetes Month: PBMs Lowering Insulin Costs, Providing Support to Patients* (Nov. 16, 2020), https://www.pcmanet.org/pcma-on-nationaldiabetes-month-pbms-lowering-insulin-costs-providing-support-to-patients/ (last visited Aug. 23, 2023); Visante, *Insulins: Managing Costs with Increasing Manufacturer Prices* (2020), https://www. pcmanet.org/ wpcontent/uploads/2020/08/PCMA_Visante-Insulins-Prices-and-Costs-.pdf.

420. The PBM Defendants not only falsely represent that they negotiate with the Manufacturer Defendants to lower the price of the at-issue diabetes medications for *payors*, but also for diabetic *patients* as well. Representative examples include:

- Express Scripts' code of conduct, effective beginning in 2015, states: "At Express Scripts we're dedicated to keeping our promises to *patients and clients* . . . This commitment defines our culture, and all our collective efforts are focused on our mission to make the use of prescription drugs safer and more affordable."[76] (emphasis added)

- Amy Bricker, former President of Express Scripts and PCMA board member, testified before Congress in April 2019: "At Express Scripts we negotiate lower drug prices with drug companies on behalf of our clients, *generating savings that are returned to patients* in the form of lower premiums and reduced out-of-pocket costs."[77] (emphasis added)

- Ms. Bricker of Express Scripts also testified that "Express Scripts remains committed to . . . *patients* with diabetes and creating affordable access to their medications."[78] (emphasis added)

- OptumRx CEO John Prince testified to the Senate: "We *reduce the costs of prescription drugs* [and] we are leading the way to ensure that *those discounts directly benefit consumers*. . . . OptumRx's pharmacy care services business is *achieving better health outcomes for patients, lowering costs* for the system, and *improving the healthcare experience for consumers*. . . . OptumRx negotiates better prices with drug manufacturers *for our customers and for consumers*.[79] (emphasis added)

- In its 2017 Drug Report, CVS Caremark stated that the goal of its pharmacy benefit plans is to ensure "that the cost of a drug is aligned with the value it delivers in terms of *patient* outcomes . . . in 2018, we are doing even more to help keep drugs affordable with our new Savings *Patients* Money initiative." (emphasis added)[80]

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[76] Express Scripts, *Code of Conduct*, https://www.expressscripts.com/aboutus/codeconduct/ExpressScriptsCodeOfConduct.pdf (last visited Jan. 10, 2023).

[77] *Priced Out of a Lifesaving Drug*, *supra* note 35.

[78] *Id.*

[79] Grassley & Wyden, *supra* note 2—*Hearing Transcript* at 174, https://www.finance.senate.gov/imo/media/doc/435631.pdf (last visited Aug. 23, 2023).

[80] CVS Health, *2017 Drug Trend Report* (Apr. 5, 2018), https://payorsolutions.cvshealth.com/insights/2017-drug-trend-report (last visited Aug. 23, 2023).

- The PCMA website touts PBMs as "the only entity in the prescription drug supply and payment chain dedicated to reducing drug costs" and (contradicting the PBM representatives' Congressional testimony), that "when new manufacturers enter the market at a lower list price, PBMs use the competition to drive costs down."[81]

421. Not only have PBM Defendants intentionally misrepresented that they use their market power to save payors money, but they have specifically and falsely disavowed that their conduct drives prices higher. Representative examples include:

- On an Express Scripts' earnings call in February 2017, CEO Tim Wentworth stated: "Drugmakers set prices, and we exist to bring those prices down."[82]

- Larry Merlo, head of CVS Caremark sounded a similar refrain in February 2017: "Any suggestion that PBMs are causing prices to rise is simply erroneous."[83]

- In 2017, Express Scripts' Wentworth went on CBS News to argue that PBMs play no role in rising drug prices, stating that PBMs work to "negotiate with drug companies to get the prices down."[84]

- During the April 2019 Congressional hearings, when asked if PBM-negotiated rebates and discounts were causing the insulin price to increase, OptumRx's Chief Medical Officer Sumit Dutta answered: "we can't see a correlation when rebates raise list prices."[85]

- In 2019, when testifying under oath before Congress on the rising price of insulins, Amy Bricker—former President of Express Scripts and PCMA board member—testified: "I have no idea why the prices [for insulin] are so high none of it is the fault of rebates."[86]

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[81] PCMA, *PBMs Reduce Insulin Costs: PBMs are working to improve the lives of patients living with diabetes and their families*, https://www.pcmanet.org/insulin-managingcosts-with-increasing-manufacturer-prices/ (last visited Jan. 10, 2023).

[82] Samantha Liss, *Express Scripts CEO Addresses Drug Pricing 'Misinformation'*, St. Louis Post-Dispatch (Feb. 17, 2017), https://www.stltoday.com/business/local/expressscripts-ceo-addresses-drug-pricing-misinformation/article_8c65cf2a-96ef-5575-8b5c-95601ac51840.html (last visited Jan. 11, 2023).

[83] Lynn R. Webster, *Who Is To Blame For Skyrocketing Drug Prices?*, The Hill (July 27, 2017, 11:40 AM), https://thehill.com/blogs/pundits-blog/healthcare/344115-who-is-toblame-for-skyrocketing-drug-prices (last visited Jan. 11, 2023).

[84] CBS News, *Express Scripts CEO Tim Wentworth Defends Role of PBMs in Drug Prices* (Feb 7, 2017), https://www.cbsnews.com/news/express-scripts-tim-wentworth-pbmrising-drug-prices-mylan-epipen-heather-bresh/ (last visited Jan. 11, 2023).

[85] *Priced Out of a Lifesaving Drug*, *supra* note 35.

[86] *Id.*

422. All of Defendants' public statements regarding insulin pricing have been consistent with the misrepresentations above and those detailed below. None have contradicted those misrepresentations or revealed the Insulin Pricing Scheme.

423. The PBM Defendants understand that payors like Plaintiff rely on the PBMs to achieve the lowest prices for the at-issue drugs and to construct formularies designed to improve access to medications. Plaintiff did so rely.

424. Throughout the relevant period, the PBM Defendants also falsely claimed they are transparent about the Manufacturer Payments and that the amounts they remit (or not) to payors. In fact, the PBM Defendants' disclosures of their ties to the Manufacturer Defendants were vague, equivocal, and misleading. Their manner of defining "rebates" in payor contracts was illusory and subject to indeterminate conditions and exceptions. The PBM Defendants thereby facilitated and obtained secret Manufacturer Payments far above and beyond the amount of "rebates" remitted to payors.

425. The PBMs' internal processes and accounting were and are abstruse and opaque, allowing them to overtly mislead the public and payors like Plaintiff.

426. In 2011, for example, OptumRx's President stated: "We want our clients to fully understand our pricing structure . . . [e]very day we strive to show our commitment to our clients, and one element of that commitment is to be open and honest about our pricing structure."[87]

[87] UnitedHealth Group, *Prescription Solutions by OptumRx Receives 4th Consecutive TIPPS Certification for Pharmacy Benefits Transparency Standards* (Sept. 13, 2011), https://web.archive.org/web/20210805182422/https://www.unitedhealthgroup.com/newsroom/2011/0913tipps.html (last visited Jan. 11, 2023). *See also, e.g.*, published version of press release at https://www.businesswire.com/news/home/20110913006224/en/Prescription-Solutions-by-OptumRx-Receives-4th-Consecutive-TIPPSSM-Certification-for-Pharmacy-Benefits-Transparency-Standards (last visited Aug. 23, 2023).

427. In a 2017 CBS News interview, Express Scripts' CEO represented, among other things, that Express Scripts was "absolutely transparent" about the Manufacturer Payments they receive and that payors "know exactly how the dollars flow" with respect to these Manufacturer Payments.[88]

428. When testifying before the Senate Finance Committee, CVS Executive Vice President Derica Rice stated: "[A]s it pertains to transparency overall, we at CVS Caremark are very supportive. We provide full visibility to our clients of all our contracts and the discounts that we negotiate on their behalf. . . . And transparency—today we report and fully disclose not only to our clients, but to CMS [Medicare]."[89]

429. At the same hearing, Steve Miller of Cigna (Express Scripts) testified: "we are a really strong proponent for transparency for those who pay for health care. So the patient should know exactly what they are going to pay. Our plan sponsors should know exactly what is in their contract."[90]

430. John Prince of OptumRx chimed in: "Senator, if our discounts were publicly available, it would hurt our ability to negotiate effectively. Our discounts are transparent to our clients."[91]

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[88] CBS News, *supra* note 79.

[89] Grassley & Wyden, *supra* note 2—*Hearing Transcript* at 28, 32, https://www.finance.senate.gov/imo/media/doc/ 435631.pdf (last visited Jan. 11, 2023).

[90] *Id.* at 32.

[91] *Id.*

431. When testifying before Congress in April 2019, Amy Bricker, then a Senior Vice President of Defendant Express Scripts, claimed transparency with payors and echoed Mr. Prince's need for confidentiality around discounts:[92]

> Ms. Bricker. The rebate system is 100 percent transparent to the plan sponsors and the customers that we service. To the people that hire us, employers of America, the government, health plans, what we negotiate for them is transparent to them. . . The reason I'm able to get the discounts that I can from the manufacturer is because it's confidential [to the public].
>
> ***
>
> Mr. Sarbanes. Yeah, because it's a secret. What about if we made it completely transparent? Who would be for that?
>
> ***
>
> Ms. Bricker. Absolutely not . . . [i]t will hurt the consumer. . . . prices will be held high.

432. As recently as May 2022, JC Scott—President of the PBM trade group PCMA—testified as follows before the Senate Commerce Committee:

> PBMs are proud of the work they do to reduce prescription drug costs, expand affordable access to medications, and improve patient outcomes. PBMs negotiate with drug companies to lower prescription drug costs PBMs advocate for patients in the fight to keep prescription drugs accessible and affordable.

433. Mirroring the PCMA website (¶¶ 429, 430, *supra*), Mr. Scott also testified, "The PBM industry is the only stakeholder in the chain dedicated to seeking lower costs."

434. During the relevant period—as seen above—PBM Defendants represented to Plaintiff that they constructed formularies and negotiated with the Manufacturer Defendants for the benefit of payors and patients to maximize drug cost savings while promoting the health of diabetics.

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[92] *Priced Out of a Lifesaving Drug, supra* note 35.

435. Throughout the relevant period, the PBMs made the foregoing and similar misrepresentations consistently and directly to Tennessee payors, including Greene County, through bid proposals, member communications, invoices, formulary change notifications, and through extensive direct-to-consumer pull through efforts engaged in with the Manufacturers.

436. All of these representations are false. The Manufacturer and PBM Defendants in fact coordinated to publish the false prices and to construct the PBM formularies, causing the price of the at-issue drugs to skyrocket. For example:

a. In 2018, the US spent $28 billion (USD) on insulin compared with $484 million in Canada. The average American insulin user spent $3,490 on insulin in 2018 compared with $725 among Canadians.

b. Diabetics who receive their medications from federal programs that do not utilize PBMs also pay significantly less. For example, in December 2020, the United States House of Representatives Committee on Oversight and Reform issued a Drug Pricing Investigation Report finding that federal health care programs that negotiate directly with the Manufacturers (such as the Department of Veterans Affairs), and are thus outside the PBM Defendants' scheme, paid $16.7 billion less from 2011 through 2017 for the at-issue drugs than the Medicare Part D program, which relies on the PBM Defendants to set their at-issue drug prices (and are thus victims of the PBMs' concerted efforts to drive up the list prices).

437. Defendants knew their representations were false when they made them and coordinated to affirmatively withhold the truth from payors, including Plaintiff.

438. Defendants concealed the falsity of their representations by closely guarding their pricing negotiations, structures, agreements, sales figures, and the flow of money and other consideration between them.

439. The Defendants have never revealed the full amount of any drug-specific Manufacturer Payments exchanged between them.

440. The PBM Defendants do not disclose the terms of their agreements with the Manufacturers or the Manufacturer Payments they receive. Nor do they disclose the details related

to their agreements (formal or otherwise) with pharmacies. All of these revenue streams are beyond the scope of the payors' contractual audit rights.

441. Further, although PBMs negotiate drug-specific rebates with Manufacturers,[93] the PBM rebate payments to payor clients and summaries of such payments are in the aggregate, rather than on a drug-by-drug basis. It is impossible for payors like Plaintiff to tease out drug-specific rebates, much less the other undisclosed Manufacturer Payments. This allowed the PBM Defendants to hide the large Manufacturer Payments that they receive for the at-issue diabetes medications.

442. The PBM Defendants have gone so far as to sue governmental entities to block the release of details on their pricing agreements with the Manufacturers and pharmacies.

443. Even when audited by payors, the PBM Defendants routinely refuse to disclose their agreements with the Manufacturers and pharmacies, relying on overly broad confidential agreements, claims of trade secrets, and erecting other unnecessary roadblocks and restrictions.

444. Beneficiaries of the Plaintiff's health plans have no choice but to pay prices flowing from Defendants' inflated list prices because Beneficiaries need these medications to survive and the Manufacturer Defendants make virtually all diabetes medications available in the United States. The list prices generated by the Defendants' coordinated efforts directly impact out-of-pocket costs at the point of sale.

445. In sum, the entire insulin pricing structure created by the Defendants—from the false prices to the Manufacturers' misrepresentations related to the reason behind the price, to the inclusion of the false prices in payor contracts, to the non-transparent Manufacturer Payments, to

[93] Grassley & Wyden, *supra* note 2 at 40.

the misuse of formularies, to the PBMs' representations that they work to lower prices and promote the health of diabetics—is unconscionable, deceptive, and immensely lucrative.

446. Plaintiff did not know, because the Defendants affirmatively concealed, that (1) the Manufacturers and PBMs coordinated to create the PBM formularies in exchange for money and other consideration; (2) the list prices were falsely inflated; (3) the list prices were manipulated to satisfy PBM profit demands; (4) the list prices and net costs (purchase prices) paid by Plaintiff bore no relationship to the fair market value of the drugs themselves or the services rendered by the PBMs in coordinating their pricing; or (5) the entire insulin pricing structure Defendants created was false.

J. The Insulin Pricing Scheme Has Damaged Plaintiff

447. Plaintiff Greene County provides health and pharmacy benefits to its Beneficiaries, including employees, retirees, and their dependents, who have numbered in the thousands throughout the relevant period.

448. One benefit Plaintiff provides the Beneficiaries of its healthcare plan is paying for their pharmaceutical needs.

449. Plaintiff entered into an agreement with CVS Caremark, whereby CVS Caremark agreed to provide Plaintiff prescription drug benefits and other at-issue services.

450. Plaintiff and Medco entered into an agreement whereby Medco agreed to provide Plaintiff prescription drug benefits and other at-issue services.

451. Express Scripts acquired Medco in 2012.

452. Plaintiff and OptumRx entered into an agreement whereby OptumRx agreed to provide Plaintiff prescription drug benefits and other at-issue services.

453. Plaintiff has renewed and had an active agreement in place with either Express Scripts, Medco, CVS Caremark, or Optum Rx.

454. Plaintiff requested proposals from the PBM Defendants for the at issue services.

455. In response to Plaintiff's requests, all PBM Defendants submitted proposals.

456. Plaintiff was unaware of the Insulin Pricing Scheme. Plaintiff relied on Defendants' public statements and material omissions.

457. Plaintiff contracted with Defendant Express Scripts, Inc., CVS Caremark, and OptumRx for PBM services.

458. Defendants' Insulin Pricing Scheme has cost Plaintiff an exorbitant amount of money in overcharges.

459. Indeed, since 2003 Greene County has spent exorbitant amounts of money on the at-issue diabetes medications.

460. CVS Caremark's, Express Scripts', and OptumRx's respective relationships with Plaintiff were inherently unbalanced and their contracts adhesive. PBM Defendants had superior bargaining power and superior knowledge of their relationships with the Manufacturer Defendants, including those that ultimately dictate the drug costs Plaintiff incurred. Although PBM Defendants were supplying a vital service of a quasi-public nature, they exploited their superior positions to mislead Plaintiff and thwart its expectations, all at great expense to Greene County.

461. The Defendants' misrepresentations, omissions, and misconduct—including and as manifested in the Insulin Pricing Scheme—directly and proximately caused economic damage to Plaintiff as a payor/purchaser of Defendants' at-issue diabetes medications.

462. A substantial proportion of the money Plaintiff spent on diabetes medications is attributable to Defendants' inflated prices, which did not arise from competitive market forces but, instead, exist solely by virtue of the Insulin Pricing Scheme.

463. Because of Defendants' success in concealing the Insulin Pricing Scheme through act and omission, no payor, including Plaintiff, knew (or should have known) during the relevant period that the prices for the at-issue diabetes medications were (and are) artificially inflated due to the Insulin Pricing Scheme.

464. As a result, despite receiving some rebates and incurring drug costs based on discounts off list prices, Plaintiff has unknowingly overpaid for the Manufacturer Defendants' diabetes medications, which would have cost far less but for the Insulin Pricing Scheme.

465. In short, the Insulin Pricing Scheme has directly and proximately caused Plaintiff to substantially overpay for diabetes medications.

466. Because Defendants continue to generate exorbitant, unfair, and deceptive prices for the at-issue drugs through the Insulin Pricing Scheme, the harm to Plaintiff is ongoing.

K. Defendants' Recent Efforts in Response to Rising Insulin Prices

467. In reaction to mounting political and public outcry, Defendants have taken action both on Capitol Hill and in the public relations space.

468. First, in response to public criticism, Defendants have increased their spending to spread their influence in Washington D.C.

469. For example, in recent years Novo Nordisk's political action committee ("PAC") has doubled its spending on federal campaign donations and lobbying efforts. In 2017 alone, Novo Nordisk spent $3.2 million lobbying Congress and federal agencies, its biggest ever investment in

directly influencing U.S. policymakers. Eli Lilly and Sanofi also have contributed millions of dollars through their PACs in recent years.

470. Second, Defendants have recently begun publicizing programs ostensibly aimed at lowering the cost of insulins.

471. These affordability measures fail to address the structural issues that caused the price hikes. Rather, these are public-relations measures that do not solve the problem.

472. For example, in March 2019, Defendant Eli Lilly announced that it would produce an authorized generic version of Humalog, "Insulin Lispro," and promised that it would "work quickly with supply chain partners to make [the authorized generic] available in pharmacies as quickly as possible."

473. However, in the months after Eli Lilly's announcement, reports raised questions about the availability of "Insulin Lispro" in local pharmacies.

474. Following this the staff of the Offices of U.S. Senators Elizabeth Warren and Richard Blumenthal prepared a report examining the availability of this drug. The investigative report, *Inaccessible Insulin: The Broken Promise of Eli Lilly's Authorized Generic*, concluded that Eli Lilly's lower-priced, authorized generic insulin is widely unavailable in pharmacies across the country, and that the company has not taken meaningful steps to increase insulin accessibility and affordability.[94]

475. Eli Lilly did lower the price of Lispro by 40% effective January 1, 2022; but it is not included in any of the PBM Defendants' formularies as of January 2023.

[94] Sen. Elizabeth Warren & Sen. Richard Blumenthal, *Inaccessible Insulin: The Broken Promise of Eli Lilly's Authorized Generic*, (Dec. 2019), https://www.warren.senate.gov/imo/media/doc/Inaccessible%20Insulin%20report.pdf (last visited Aug. 23, 2023).

476. In 2019, Novo Nordisk partnered with Walmart to offer ReliOn brand insulins for a discounted price at Walmart. However, experts have warned that the Walmart/Novo Nordisk insulins are not substitutes for most diabetics' regular insulins and should only be used in an emergency or when traveling. In particular, for many diabetics, especially Type 1 diabetics, these insulins can be dangerous. In any event, ReliOn is not included in any of the PBM Defendants' formularies as of January 2023.

477. Thus, Defendants' "lower priced" insulin campaigns have not addressed the problem, and the PBMs continue to exclude drugs with lower list prices despite their assurances of cost-savings for payors and Beneficiaries. Plaintiff continues to suffer harm caused by the Insulin Pricing Scheme.

478. Likewise, FDA in 2020 approved the biosimilar Insulin Glargine-yfgn (branded as Semglee), which is manufactured and sold by newcomers to the market—Viatris and Biocon Biologics.[95] Insulin Glargine-yfgn (Semglee) is interchangeable with Defendant Sanofi's Lantus product and, according Viatris, its list price is three times cheaper than Lantus. It is not included in any of the PBM Defendants' formularies as of January 2023.

[95] As explained in n.3, insulin now is regulated as a biologic rather than a drug. Biosimilars are analogous to generic drugs—approved versions of original products that are virtually identical to, and interchangeable with, the original product.

CLAIMS FOR RELIEF

First Cause of Action (Count I)
Violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962(c)

(against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx)

479. Plaintiff Greene County re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

480. Plaintiff brings this count against all Defendants for violations of 18 U.S.C. § 1962(c).

481. Defendants Eli Lilly, Novo Nordisk, Sanofi, CVS Caremark, Express Scripts and OptumRx are (a) culpable "persons" who (b) willfully and knowingly (c) committed and conspired to commit two or more acts of mail and wire fraud (d) through a "pattern" of racketeering activity that (e) involves an "association in fact" enterprise, (f) the results of which had an effect on interstate commerce.

A. Defendants Are Culpable "Persons" Under RICO

482. Defendants Eli Lilly, Novo Nordisk, Sanofi, CVS Caremark, Express Scripts, and OptumRx, separately, are "persons" as that term is defined in 18 U.S.C. § 1961(3) because each is capable of holding a legal or beneficial interest in property.

483. Each one of Defendants Eli Lilly, Novo Nordisk, Sanofi, CVS Caremark, Express Scripts, and OptumRx are separate entities and "persons" that are distinct from the RICO enterprises alleged below.

B. The Manufacturer-PBM RICO Enterprises

484. For the purposes of this claim, the RICO enterprises are six separate associations-in-fact consisting of one of each of the PBM Defendants and one of each of the Manufacturer

Defendants, including those entities' directors, employees, and agents: the Eli Lilly-CVS Caremark Enterprise; the Eli Lilly-OptumRx Enterprise; the Eli Lilly-Express Scripts Enterprise; the Novo Nordisk-CVS Caremark Enterprise; the Novo Nordisk-OptumRx Enterprise; the Novo Nordisk-Express Scripts Enterprise; the Sanofi-CVS Caremark Enterprise; the Sanofi-OptumRx Enterprise; and the Sanofi-Express Scripts Enterprise.

485. These association-in-fact enterprises are collectively referred to herein as the "Manufacturer-PBM Enterprises."

486. Each Manufacturer-PBM Enterprise is a separate, ongoing, and continuing business organization consisting of corporations and individuals associated for the common purpose of manufacturing, selling, and facilitating the purchase of the Manufacturer Defendants' products, including the at-issue drugs. For example:

a. The Eli Lilly-OptumRx Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Eli Lilly medications including Prozac, Cymbalta, and Zyprexa, as well as the at-issue Eli Lilly insulin and insulin-analog medications (Trulicity, Humulin N, Humulin R, Humalog, and Basaglar), which are Eli Lilly's primary source of revenue.

b. The Eli Lilly-Express Scripts Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Eli Lilly medications including Prozac, Cymbalta, and Zyprexa, as well as the at-issue Eli Lilly insulin and insulin-analog medications (Trulicity, Humulin N, Humulin R, Humalog, and Basaglar), which are Eli Lilly's primary source of revenue.

c. The Eli Lilly-CVS Caremark Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Eli Lilly

medications including Prozac, Cymbalta, and Zyprexa, as well as the at-issue Eli Lilly insulin and insulin-analog medications (Trulicity, Humulin N, Humulin R, Humalog, and Basaglar), which are Eli Lilly's primary source of revenue.

d. The Novo Nordisk--OptumRx Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Novo Nordisk medications for the treatment of obesity, hemophilia, and hormone imbalance, as well as the at-issue Novo Nordisk insulin and insulin-analog medications (Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic), which account for more than three-quarters of Novo Nordisk's revenue.

e. The Novo Nordisk-Express Scripts Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Novo Nordisk medications for the treatment of obesity, hemophilia, and hormone imbalance, as well as the at-issue Novo Nordisk insulin and insulin-analog medications (Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic), which account for more than three-quarters of Novo Nordisk's revenue.

f. The Novo Nordisk-CVS Caremark Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Novo Nordisk medications for the treatment of obesity, hemophilia, and hormone imbalance, as well as the at-issue Novo Nordisk insulin and insulin-analog medications (Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic), which account for more than three-quarters of Novo Nordisk's revenue.

g. The Sanofi--OptumRx Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Sanofi medications

including Ambien, Plavix, and Dupixent, as well as the at-issue Sanofi insulin and insulin-analog medications (Lantus, Toujeo, Apidra, and Soliqua).

h. The Sanofi-Express Scripts Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Sanofi medications including Ambien, Plavix, and Dupixent, as well as the at-issue Sanofi insulin and insulin-analog medications (Lantus, Toujeo, Apidra, and Soliqua).

i. The Sanofi-CVS Caremark Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Sanofi medications including Ambien, Plavix, and Dupixent, as well as the at-issue Sanofi insulin and insulin-analog medications (Lantus, Toujeo, Apidra, and Soliqua).

487. Each Manufacturer-PBM Enterprise engaged in the shared purpose of exchanging false list prices and secret Manufacturer Payments for preferred formulary positions for the at issue drugs in order to control the market for diabetes medications and profit off diabetics and payors, including Plaintiff.

488. The members of each enterprise are bound by contractual relationships, financial ties, and the ongoing coordination of activities.

489. There also is a common communication network by which Eli Lilly and OptumRx, Eli Lilly and Express Scripts, Eli Lilly and CVS Caremark, Novo Nordisk and OptumRx, Novo Nordisk and Express Scripts, Novo Nordisk and CVS Caremark, Sanofi and OptumRx, Sanofi and Express Scripts, and Sanofi and CVS Caremark share information and meet on a regular basis. These communications include, but are not limited to, communications relating to the use of false list prices for the at-issue diabetes medications and the regular flow of Manufacturer Payments from each Manufacturer Defendant to each PBM Defendant in exchange for formulary placement.

490. Each Manufacturer-PBM Enterprise functions as a continuing but separate unit separate and apart from the pattern of racketeering activity in which it engages. Each Manufacturer-PBM Enterprise, for example, engages in the manufacture, distribution and sale of medications and other products other than the at-issue insulin and insulin-analog medications. Additionally, each Manufacturer engages in conduct other than mail fraud and wire fraud in furtherance of the Insulin Pricing Scheme.

491. At all relevant times, each of the Manufacturer-PBM Enterprises was operated and conducted for unlawful purposes by each Manufacturer Defendant and PBM Defendant, namely, carrying out the Insulin Pricing Scheme.

492. Each Manufacturer-PBM Enterprise derived secret profits from these activities that were greater than those any one of the Manufacturer Defendants or PBM Defendants could obtain absent their misrepresentations regarding their pricing schemes.

493. To accomplish this common purpose, each Manufacturer Defendant periodically and systematically inflated the prices of the at-issue drugs and then secretly paid a significant, yet undisclosed, portion of this inflated price back to the PBM Defendants in the form of Manufacturer Payments.

494. Each Manufacturer-PBM Enterprise did so willfully and with knowledge that Plaintiff paid for the at-issue drugs at prices directly based on the false list prices.

495. Each Manufacturer-PBM Enterprise's inflation of the list prices and secret Manufacturer Payments was a quid pro quo exchange for preferred formulary placement.

496. Each Manufacturer-PBM Enterprise concealed from Plaintiff that these false prices and secret Manufacturer Payments resulted in each Manufacturer gaining formulary access without requiring significant price reductions and resulted in higher profits for each PBM Defendant,

whose earnings increase the more inflated the price is and the more payment it receives from each Manufacturer Defendant.

497. Each Manufacturer-PBM Enterprise also shares a common purpose of perpetuating the use of the false list prices for the at-issue drugs as the basis for the price that payors, including Plaintiff, and diabetics pay for diabetes medications.

498. The Manufacturer Defendants would not be able to offer large pricing spreads to the PBM Defendants in exchange for favorable formulary positions without the use of the false list prices as the basis for the price paid by diabetics and payors, including Plaintiff, for the at-issue drugs.

499. The PBM Defendants share this common purpose because nearly all the revenue and profit generated from the at-issue drugs is tied to the false inflated prices generated by the Insulin Pricing Scheme. Without diabetics and payors, including Plaintiff, paying for diabetes medications based on the inflated list prices, their profits from the Insulin Pricing Scheme would decrease.

500. As a result, the PBM Defendants have, with the knowing and willful participation and assistance of each Manufacturer Defendant, engaged in hidden profit-making schemes falling into four general categories: (a) garnering undisclosed Manufacturer Payments from each Manufacturer Defendant that the PBM Defendants retain to a large extent; (b) generating substantial profits from pharmacies because of the falsely inflated prices; (c) generating profits on the diabetes medications sold through the PBM Defendants' own mail-order and retail pharmacies; and (d) keeping secret discounts each Manufacturer Defendant provides in association with the PBM Defendants' mail-order and retail operations.

501. At all relevant times, each PBM Defendant and each Manufacturer Defendant have been aware of their respective Manufacturer-PBM Enterprise's conduct, have been knowing and willing participants in and coordinator of that conduct and have reaped profits from that conduct.

502. None of the PBM Defendants or the Manufacturer Defendants alone could have accomplished the purposes of the Manufacturer-PBM Enterprises without the other entities.

C. The Enterprises Misrepresent and Fail to Disclose Material Facts in Furtherance of the Insulin Pricing Scheme

503. Each Manufacturer-PBM Enterprise knowingly made material misrepresentations to the public and Plaintiff in furtherance of the Insulin Pricing Scheme, including publishing artificially inflated prices for insulin on published indices and representing that:

a. the false list prices for the at-issue diabetes medications were reasonably related to the actual prices realized by Defendants and were a reasonable and fair basis on which to base the price Plaintiff paid for these drugs;

b. each Manufacturer priced its at-issue drugs according to each drug's value to the healthcare system and the need to fund innovation;

c. the Manufacturer Payments paid back to each PBM Defendant for each at-issue drug were for Plaintiff' benefit;

d. all "rebates and discounts negotiated by the PBM Defendants with the Manufacturer Defendants were remitted to Plaintiff;

e. the "rebates" negotiated by the members of each enterprise saved Plaintiff money;

f. each Manufacturer Defendant and each PBM Defendant were transparent with Plaintiff regarding the Manufacturer Payments and the PBMs did not retain any funds associated prescription drug rebates or the margin between guaranteed reimbursement rates and the actual amount paid to the pharmacies; and

g. the PBM Defendants constructed formularies in a manner that lowered the price of the at-issue drugs and promoted the health and safety of diabetics.

504. Each false list price published by the Manufacturer Defendants constituted a material misrepresentation to Plaintiff and the public, in that each purported to be a fair market price for an at-issue drug, and each omitted to disclose the fraudulent spread between the list price and the net price of the medication or the basis therefor. Examples of other affirmative representations by each RICO Defendant in furtherance of each enterprise's Insulin Pricing scheme are alleged herein.

505. At all times relevant to this Complaint, each Manufacturer-PBM Enterprise knew the above-described representations to be false.

506. At all times relevant to this Complaint, each Manufacturer-PBM Enterprise intentionally made these representations for the purpose of inducing Plaintiff into paying artificially inflated prices for diabetes medications.

507. Plaintiff relied on the material misrepresentations and omissions made by each Manufacturer-PBM Enterprise in paying prices for the at-issue diabetes medications based upon the false prices generated by Insulin Pricing Scheme.

508. Additionally, each PBM-Manufacturer Enterprise relied on the list prices negotiated and published by the other PBM-Manufacturer enterprises in setting their own list prices and determining the value of the kickbacks paid to the PBMs. Plaintiff were injured by the inflated prices that arose as a result.

509. PBM Defendants convinced Plaintiff to pay prices for the at-issue drugs based on the false list price by utilizing the misrepresentations listed above to convince Plaintiff that they

had secured lower prices when, in fact, they did the opposite, all while concealing the Insulin Pricing Scheme.

510. Without these misrepresentations and each RICO Defendant's failure to disclose the Insulin Pricing Scheme, each Manufacturer-PBM Enterprise could not have achieved its common purpose, as Plaintiff would not have been willing to pay these false list prices.

D. Defendants' Use of the U.S. Mails and Interstate Wire Facilities

511. Each of the Manufacturer-PBM Enterprises engaged in and affected interstate commerce because each engaged in the following activities across state boundaries: the sale, purchase and/or administration of diabetes medications; the setting and publishing of the prices of these drugs; and/or the transmission of pricing information of diabetes medications; and/or the transmission and/or receipt of sales and marketing literature; and/or the transmission of diabetes medications through mail-order and retail pharmacies; and/or the transmission and/or receipt of invoices, statements, and payments related to the use or administration of diabetes medications; and/or the negotiations and transmissions of contracts related to the pricing of and payment for diabetes medications.

512. Each Manufacturer-PBM Enterprise participated in the administration of diabetes medications to millions of individuals located in all 50 states, including in this District.

513. Each Manufacturer Defendant's and each PBM Defendant's illegal conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information and products and funds through the U.S. mails and interstate wire facilities.

514. The nature and pervasiveness of the Insulin Pricing Scheme, which included each Manufacturer Defendant's and each PBM Defendant's corporate headquarters operations,

necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities with each other and with pharmacies, physicians, payors, and diabetics throughout the United States.

515. Each Manufacturer-PBM Enterprise's use of the U.S. mails and interstate wire facilities to perpetrate the Insulin Pricing Scheme involved thousands of communications including:

a. marketing materials about the published prices for diabetes medications, which each Manufacturer Defendant sent to each PBM Defendant across the country, in Greene County, and throughout Tennessee;

b. written and oral representations of the false list prices of diabetes medications that each Manufacturer Defendant and each PBM Defendant made at least annually and, in many cases, several times during a single year to the public;

c. thousands of written and oral communications discussing, negotiating, and confirming the placement of each Manufacturer Defendant's diabetes medications on each PBM Defendant's formularies;

d. written and oral representations made by each Manufacturer Defendant regarding information or incentives paid back to each PBM Defendant for each diabetes medications sold and/or to conceal these incentives or the Insulin Pricing Scheme;

e. written communications made by each Manufacturer Defendant, including checks, relating to Manufacturer Payments paid to each PBM Defendant to persuade them to advocate the at-issue diabetes medications;

f. written and oral communications with U.S. government agencies that misrepresented what the published prices were or that were intended to deter investigations into the

true nature of the published prices or to forestall changes to reimbursement based on something other than published prices;

g. written and oral communications with payors, including Plaintiff, regarding the price of diabetes medications;

h. written and oral communications to Plaintiff, including marketing and solicitation material sent by each PBM Defendant regarding the existence, amount, or purpose of payments made by each Manufacturer Defendant to each PBM Defendant for the diabetes medications described herein and the purpose of each PBM Defendants formularies;

i. transmission of published prices to third parties and payors, including Plaintiff; and

j. receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities-the wrongful proceeds of the Insulin Pricing Scheme.

516. Although Plaintiff plead the dates of certain communications in allegations incorporated into this Count, it cannot allege the precise dates of others without access to books and records within each RICO Defendant's exclusive custody and control. Indeed, an essential part of the successful operation of the Insulin Pricing Scheme depended upon secrecy, and each Manufacturer Defendant and PBM Defendant took deliberate steps to conceal its wrongdoing.

E. Conduct of the Manufacturer-PBM Enterprises' Affairs

517. Each Manufacturer Defendant and PBM Defendant participates in the operation and management of Manufacturer-PBM Enterprises with which it is associated and, in violation of Section 1962(c) of RICO, and conducts or participates in the conduct of the affairs of those association-in-fact RICO enterprises, directly or indirectly. Such participation is carried out in the following ways:

a. Each Manufacturer Defendant directly controls the secret Manufacturer Payments it provides to each PBM Defendant for its diabetes medications.

b. The PBM Defendants directly manage and control their respective drug formularies and the placement of the at-issue diabetes medications on those formularies.

c. The PBM Defendants intentionally select higher-priced diabetes medications for formulary placement and exclude lower priced ones in order to generate larger profits and they coordinate with the Manufacturer Defendants to increase the availability and use of higher-priced medications because they are more profitable for both groups of Defendants.

d. Each Manufacturer Defendant directly controls the publication of the false list prices generated by the Insulin Pricing Scheme.

e. Each Manufacturer Defendant directly controls the creation and distribution of marketing, sales and other materials used to inform each PBM Defendant of the profit potential from its diabetes medications.

f. Each PBM Defendant directly controls the creation and distribution of marketing, sales and other materials used to inform payors and the public of the benefits and cost-saving potential of each PBM Defendant's formularies and negotiations with the Manufacturers.

g. Each PBM Defendant directs and controls each enterprise's direct relationships with payors such as Plaintiff by negotiating the terms of and executing the contracts that govern those relationships.

h. Each PBM Defendant directs and controls each enterprise's Insulin Pricing Scheme by hiding, obfuscating, and laundering Manufacturer Payments through their affiliated

entities in order to retain a large and undisclosed proportion of the Manufacturer Payments to the detriment of payors, including Plaintiff.

i. Each PBM Defendant distributes through the U.S. mail and interstate wire facilities, promotional and other materials that claim the Manufacturer Payments paid from each Manufacturer Defendant to each PBM Defendant save Plaintiff and other payors money on the at-issue drugs.

j. Each Manufacturer Defendant represented to Plaintiff-by publishing and promoting false list prices without stating that these published prices differed substantially from the prices realized by each Manufacturer Defendant and each PBM Defendant-that the published prices of diabetes medications reflected or approximated the actual price realized by Defendants and resulted from transparent and competitive, fair market forces.

F. Defendants' Pattern of Racketeering Activity

518. Each Manufacturer Defendant and each PBM Defendant have conducted and participated in the affairs of their respective Manufacturer-PBM Enterprises through a pattern of racketeering activity, including acts that are unlawful under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud.

519. Each Manufacturer Defendant's and each PBM Defendant's pattern of racketeering involved thousands, if not hundreds of thousands of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of the Insulin Pricing Scheme. Each of these mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Collectively, these violations constitute a "pattern of racketeering activity," within the

meaning of 18 U.S.C. § 1961 (5), in which each Manufacturer Defendant and each PBM Defendant intended to defraud Plaintiff.

520. By intentionally and falsely inflating the list prices, by misrepresenting the purpose behind both the Manufacturer Payments made from each Manufacturer Defendant to each PBM Defendant and each PBM Defendant's formulary construction, and by subsequently failing to disclose such practices to Plaintiff, each Manufacturer Defendant and each PBM Defendant engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

521. Each Manufacturer Defendant's and each PBM Defendant's racketeering activities amounted to a common course of conduct, with similar patterns and purposes, intended to deceive Plaintiff.

522. Each separate use of the U.S. mails and/or interstate wire facilities employed by each Manufacturer Defendant and each PBM Defendant was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiff.

523. Each Manufacturer Defendant and each PBM Defendant engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the respective Manufacturer-PBM Enterprises with which each of them is and was associated in fact.

G. The RICO Defendants' Motive

524. Each Manufacturer Defendant's and each PBM Defendant's motive in creating and operating the Insulin Pricing Scheme and conducting the affairs of the Manufacturer-PBM Enterprises described herein was to control the market for diabetes medications and falsely obtain sales of and profits from diabetes medications.

525. The Insulin Pricing Scheme was designed to, and did, encourage others, including payors like Plaintiff, to advocate the use of each Manufacturer Defendant's products and to pay for those diabetes medications based on a falsely inflated price. Each Manufacturer Defendant used the Insulin Pricing Scheme to obtain formulary placement to sell more of its drugs without having to cut into its profits. Each PBM Defendant used the Insulin Pricing Scheme to falsely inflate the price payors like Plaintiff paid for diabetes medications in order to profit off the Insulin Pricing Scheme, as discussed above.

H. The Manufacturer-PBM Enterprises' Insulin Pricing Scheme Injured Plaintiff

526. Each Manufacturer-PBM Enterprise's violations of federal law and pattern of racketeering activity have directly and proximately caused Plaintiff to be injured in their business or property.

527. The prices Plaintiff pay for the at-issue drugs are tied directly to the false list prices generated by the Insulin Pricing Scheme.

528. No other intermediary in the supply chain has control over or is responsible for the list prices on which nearly all Plaintiff' payments are based other than the Manufacturer-PBM Defendant Enterprises.

529. Defendants collectively set the prices that Plaintiff paid for the at-issue diabetes medications.

530. During the relevant period, Express Scripts, CVS Caremark, and OptumRx provided PBM services to Plaintiff and benefited therefrom.

531. During the relevant period, Plaintiff paid Express Scripts, CVS Caremark, and OptumRx for the at issue drugs.

532. Each Manufacturer-PBM Enterprise controlled and participated in the Insulin Pricing Scheme that was directly responsible for the false list prices upon which the price Plaintiff paid was based.

533. Thus, Plaintiff was damaged by reason of the Insulin Pricing Scheme. But for the misrepresentations and false prices created by the Insulin Pricing Scheme that each Manufacturer-PBM Enterprise employed, Plaintiff would have paid less for diabetes medications.

534. While Defendants' scheme injured an enormous number of payors and plan members, Plaintiff's damages are separate and distinct from those of any other victim that was harmed by the Manufacturer-PBM Defendant Enterprises' Insulin Pricing Scheme.

535. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(c) of RICO, Defendants are jointly and severally liable to Plaintiff for three times the damages that were sustained, plus the costs of bringing this action, including reasonable attorneys' fees.

536. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(a) of RICO, Plaintiff seeks injunctive relief against each Manufacturer Defendant and each PBM Defendant for their fraudulent reporting of their prices and their continuing acts to affirmatively misrepresent and/ or conceal and suppress material facts concerning their false and inflated prices for diabetes medications, plus the costs of bringing this suit, including reasonable attorneys' fees.

537. Absent an injunction the effects of this fraudulent, unfair, and unconscionable conduct will continue. Plaintiff continues to purchase the at-issue diabetes medications. Plaintiff will continue to pay based on the Defendants' false list prices. This continuing fraudulent, unfair, and unconscionable conduct is a serious matter that calls for injunctive relief as a remedy. Plaintiff

seeks injunctive relief, including an injunction against each Manufacturer and each PBM Defendant, to prevent them from affirmatively misrepresenting and/or concealing and suppressing material facts concerning their conduct in furtherance of the Insulin Pricing Scheme.

Second Cause of Action (Count II)
Violations of RICO, 18 U.S.C. § 1962(d)
By Conspiring to Violate 18 U.S.C. § 1962(c)
(against all Defendants)

538. Plaintiff re-alleges and incorporates herein by reference the allegations set forth in the preceding paragraphs.

539. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

540. Defendants have violated § 1962(d) by agreeing and conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in the Insulin Pricing Scheme.

541. As set forth in detail above, Defendants each knowingly agreed to facilitate the Insulin Pricing Scheme and each has engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy. Specifically, Defendants agreed to and did inflate the prices of the at-issue drugs in lockstep to achieve an unlawful purpose; Defendants agreed to and did make false or misleading statements or material omissions regarding the reasons for these price increases, the purpose of the Manufacturer Payments exchanged between Defendants and the PBMs' formulary construction; and PBMs agreed to and did, in concert, request and receive larger Manufacturer Payments and higher prices in exchange for formulary placement.

542. The nature of the above-described Defendant co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that

they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

543. Defendants have engaged and continue to engage in the commission of overt acts, including the following unlawful racketeering predicate acts:

a. Multiple instances of mail fraud in violations of 18 U.S.C. § 1341;

b. Multiple instances of wire fraud in violations of 18 U.S.C. § 1343; and

c. Multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

544. Defendants' conspiracy to violate the above federal laws and the effects thereof detailed above are continuing and will continue. Plaintiff has been injured in its property by reason of these violations: Plaintiff has paid more for the at-issue drugs than it would have but for Defendants' conspiracy to violate 18 U.S.C. § 1962(c).

545. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are jointly and severally liable to Plaintiff for three times the damages this District has sustained, plus the cost of this suit, including reasonable attorneys' fees.

Third Cause of Action (Count III)
Unlawful Restraint of Trade
Tenn. Code Ann. §§ 47-25-101, *et seq*.
(against all Defendants)

546. Plaintiff Greene County re-alleges and incorporates herein by reference each of the allegations from the preceding paragraphs.

547. As detailed in the foregoing paragraphs, Defendants entered into, established, and maintained a continuing contract, agreement, arrangement, or combination in unreasonable restraint of trade.

548. The purpose and effect of the arrangement was to effect the Insulin Pricing Scheme.

549. The contract, agreement, arrangement, or combination had a direct, substantial, and reasonably foreseeable effect upon commerce within the United States and within Tennessee by: (a) increasing prices paid by Plaintiff for the at-issue diabetes medications; (b) depriving Plaintiff of savings that they would otherwise have received in the absence of the conspiracy; and (c) depriving Plaintiff of free, open, and unrestricted competition in the purchase of the at-issue drugs sold by Defendants.

550. As a result of Defendants' unlawful conduct, Plaintiff has been injured by paying inflated prices for the at-issue diabetes medications.

551. By engaging in the conduct described above, Defendants formed a contract, agreement, arrangement, or combination in restraint of trade in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*

Fourth Cause of Action (Count IV)
Violation of Tennessee Consumer Protection Act
Tenn. Code Ann. §§ 47-18-101, *et seq*.
(against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx)

552. Plaintiff Greene County re-alleges and incorporates herein by reference each of the allegations from the preceding paragraphs.

553. The Tennessee Consumer Protection Act of 1977 makes unlawful "[u]nfair or deceptive acts or practices affecting the conduct of any trade or commerce[.]."[96]

554. Plaintiff is a "person" within the meaning of Tenn. Code Ann. § 47-18-103(18).

555. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx are each a "person" within the meaning of Tenn. Code Ann. § 47-18-103(18).

[96] Tenn. Code Ann. § 47-18-104(a).

556. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark's conduct, collectively and as individuals, as described in this Complaint, constitutes deceptive acts in violation of the Tennessee Consumer Protection Act.

557. Because these Defendants' willful and knowing conduct caused injury to Plaintiff, Plaintiff seeks to recover actual damages; discretionary treble damages; punitive damages; reasonable attorneys' fees and costs; an order enjoining Defendants' unlawful conduct; and any other just and proper relief available under.

558. By engaging in the Insulin Pricing Scheme, as described herein, Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx have committed acts of unfair and deceptive trade practices in the conduct of trade or commerce within Tennessee and Greene County causing harm to Plaintiff as a reimbursor for, and purchaser and payor of, the at-issue drugs.

559. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx have engaged in the following materially misleading conduct, which constitutes deceptive trade practice in violations of the Tennessee Consumer Protection Act:

- Making false and misleading misrepresentations of fact that the prices for the at-issue diabetes medications were legal, competitive, and fair market value prices. In particular:
    - A characteristic of every commodity in Tennessee's economy is its price, which is represented by every seller to every buyer that the product being sold is being sold at a legal, competitive, and fair market value.
    - At no point did these Defendants reveal that the prices associated with the lifesaving diabetic treatments at issue herein were not legal, competitive, or at fair market value.
    - At no point did these Defendants disclose that the prices associated with the at-issue drugs were generated by the Insulin Pricing Scheme.

- At least once per year for each year during the relevant period, these Defendants reported and published false prices for each at-issue drug and in doing so represented that the reported prices were the actual, legal and fair prices for these drugs and resulted from competitive market forces.

- In addition, by granting the at-issue drugs preferred formulary position—formulary positions that the PBMs represent are reserved for reasonably priced drugs and that are meant to promote the health of diabetics—the PBM Defendants knowingly and purposefully utilized the false prices that were generated by the Insulin Pricing Scheme.

- By granting the at-issue diabetes medications preferred formulary positions, the PBM Defendants ensured that prices generated by the Insulin Pricing Scheme would harm Plaintiff.

- The PBM Defendants also misrepresented their formularies promoted the cost-savings to Plaintiff.

- Defendants' representations are false, and Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark knew they were false. Defendants knew that the prices they reported and utilized are artificially inflated for the purpose of maximizing profits through the Insulin Pricing Scheme.

- These Defendants also knew that the PBMs' formulary construction fueled the precipitous price increases that damaged Plaintiff's financial well-being.

- Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark affirmatively withheld this truth from Plaintiff Greene County, even though these Defendants knew that the Plaintiff's intention was to pay the lowest possible price for diabetes medications and expectation was to pay a legal, competitive price that resulted from transparent market forces.

- Making false and misleading misrepresentations of fact related to the Manufacturer Payments and the negotiations that occurred between the PBM and Manufacturer Defendants.

- The PBM Defendants knowingly made false and misleading statements concerning the reasons for, existence of, and amount of price reductions by misrepresenting that the Manufacturer Payments lower the overall price of diabetes medications and promote the health of diabetics.

- These representations were false, and Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark knew they were false. The PBM Defendants knew that the Manufacturer Payments were not reducing the overall price of diabetes medications but rather are an integral part of the Insulin Pricing Scheme and are responsible for the inflated prices.

560. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx continue to make these misrepresentations and publish prices generated by the Insulin Pricing scheme, and Plaintiff continues to purchase diabetes medications at inflated prices.

561. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx acted knowingly and in a willful, wanton or reckless disregard for the safety of others in committing the violation of the Tennessee Consumer Protection Act described herein.

562. Each at-issue purchase Plaintiff made for diabetes medications at the prices generated by the Insulin Pricing Scheme constitutes a separate violation of the Tennessee Consumer Protection Act.

563. The acts and practices alleged herein are ongoing, repeated, and affect the public interest.

564. The acts and practices alleged herein substantially impact the community of diabetics, their families, healthcare providers, and the public, and have caused substantial actual harm, including to Plaintiff and its beneficiaries.

565. These Defendants' acts and practices in violation of the Tennessee Consumer Protection Act caused Plaintiff to suffer injuries alleged herein, including but not limited to paying excessive and inflated prices for diabetes medications as described herein.

566. As a direct and proximate result of these Defendants' conduct in committing the above and foregoing violations of the Tennessee Consumer Protection Act, these Defendants are directly and jointly and severally liable to Plaintiff for all restitution, damages, punitive damages, treble damages, penalties and disgorgement for which recovery is sought herein, including but not limited to the Plaintiff paying excessive and inflated prices for diabetes medications described herein every time it paid for an at-issue drug.

567. Additionally, Plaintiff did not receive the benefit of its bargain, or otherwise paid a price premium, for the at-issue diabetes medications because it paid an artificially inflated price due to these Defendants' illegal practices.

Fifth Cause of Action (Count V)
Breach of Contract
(against Defendants Express Scripts, CVS Caremark, and OptumRx)

568. Plaintiff Greene County re-alleges and incorporates herein by reference each of the allegations from the preceding paragraphs.

569. In Tennessee, all contracts—including those between the PBM Defendants and Plaintiff—imply a covenant of good faith and fair dealing in the course of performance (the "Covenant").[97]

570. The Covenant protects "the parties' reasonable expectations as well as their right to receive the benefits of their agreement"[98] and is breached when "a party to the contract exercises discretion authorized in a contract in an unreasonable way."[99]

571. By engaging in the conduct alleged in this Complaint, specifically by arranging with Insulin Manufacturers to hide portions of their rebates by, *inter alia*, relabeling a portion of the rebates as "administrative fees" such that they do not have to be "passed through" to Plaintiff, the PBM Defendants deprived Plaintiff of its rights to receive the benefits of their agreement.

572. PBM Defendants made such arrangements willfully, with the dishonest purpose of enriching themselves at the expense of payors such as Plaintiff. Furthermore, they took efforts to

[97] *See, e.g.*, *Wallace v. Nat'l Bank of Commerce*, 938 S.W.2d 684, 686 (Tenn. 1996).

[98] *Dick Broad. Co. v. Oak Ridge FM, Inc.*, 395 S.W.3d 653, 666 (Tenn. 2013).

[99] *Universal Props. v. Regions Bank*, No. 3:11-cv-538, 2012 U.S. Dist. LEXIS 135256, at *23 (E.D. Tenn. Sep. 21, 2012)).

conceal the terms of these arrangements so that payors such as Plaintiff could not discover that they were not receiving the fruits of their contract.

573. As a direct and proximate result of PBM Defendants' breach of the covenant of good faith and fair dealing, Plaintiff did not receive the benefit of its bargain and paid a price-premium for the at-issue diabetes medications because it paid an artificially inflated price due to these Defendants' illegal practices.

Sixth Cause of Action (Count VI)
Unjust Enrichment
(against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx)

574. Plaintiff Greene County re-alleges and incorporates herein by reference each of the allegations from the preceding paragraphs.

575. This cause of action is alleged in the alternative to any claim Plaintiff may have for legal relief.

576. Plaintiff conferred a benefit upon Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx. These Defendants deceived Plaintiff Greene County and have received a financial windfall from the Insulin Pricing Scheme at Plaintiff's expense.

577. These Defendants wrongfully secured and retained unjust benefits from Plaintiff in the form of amounts paid for diabetes medications and fees and payments collected based on the prices generated by the Insulin Pricing Scheme. They did not adequately compensate Plaintiff therefor.

578. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx were aware of the benefit, voluntarily accepted it, and retained and appreciated the benefit, to which it was not entitled, at Plaintiff's expense.

579. It is inequitable and unfair for these Defendants to retain these benefits.

580. The benefit these Defendants have wrongfully retained is in an amount not less than the difference between the reasonable or fair market value of the at-issue drugs for which Plaintiff paid and the actual value of the at-issue drugs these Defendants delivered.

581. Accordingly, Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx should not be permitted to retain the proceeds from the benefits conferred upon them by Plaintiff, which seeks disgorgement of these Defendants' unjustly acquired profits and other monetary benefits resulting from their unlawful conduct and seeks restitution and/or recission, in an equitable and efficient fashion to be determined by the Court.

582. As a direct and proximate cause of these Defendants' unjust enrichment at the expense of Plaintiff as referenced above, Plaintiff has suffered and continues to suffer ascertainable losses and damages as specified herein in an amount to be determined at trial.

MOTION FOR INJUNCTION

583. Plaintiff Greene County re-alleges and incorporates the preceding paragraphs.

584. By Defendants' violations of the Tennessee Consumer Protection Act, RICO, and common law, Plaintiff has suffered, and will continue to suffer, immediate and irreparable injury, loss, and damage, as discussed herein.

585. The ongoing and threatened injury to Plaintiff and its beneficiaries outweighs the harm that an injunction might cause Defendants.

586. As a direct and proximate result of the conduct of the Defendants in committing the above and foregoing acts, Plaintiff moves the Court for injunctive relief against the Defendants pursuant Tenn. Code Ann. § 47-18-109(b) and 18 U.S.C. § 1964(a), thereby enjoining Defendants from committing future violations of the Tennessee Consumer Protection Act and RICO.

587. Granting an injunction is consistent with the public interest because it will protect the health and economic interests of Plaintiff, as well as the integrity of the Tennessee marketplace.

PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiff Greene County prays for entry of judgment against the Defendants for all the relief requested herein and to which the Plaintiff may otherwise be entitled, specifically, but without limitation, to-wit:

A. That the Court determine that Defendants have violated the Tennessee Consumer Protection Act, have violated RICO, have breached their contract with Defendants, and have been unjustly enriched;

B. Judgment in favor of Plaintiff and against the Defendants for damages in excess of the minimum jurisdictional requirements of this Honorable Court, in a specific amount to be proven at trial;

C. That Plaintiff be granted the following specific relief:

1. In accordance with Tenn. Code Ann. § 47-18-109(b) and 18 U.S.C. § 1964(a), that Defendants, their affiliates, successors, transferees, assignees, and the officers, directors, partners, agents, and employees thereof, and all other persons acting or claiming to act on their behalf or in concert with them, be enjoined and restrained from in any manner continuing, maintaining or renewing the conduct, contract, conspiracy or combination alleged herein in violation of the and RICO, or from entering into any other contract, conspiracy or combination having a similar purpose or effect, and from adopting or following any practice, plan, program or device having a similar purpose or effect;

2. That Plaintiff:

i. be awarded restitution, damages, disgorgement, penalties and/or all other legal and equitable monetary remedies available under the state laws set forth in this Complaint and the general equitable powers of this Court in an amount according to proof;

ii. be awarded punitive damages because Defendants knowingly, willfully, wantonly and intentionally harmed the health, wellbeing and financial interests Plaintiff and its Beneficiaries;

iii. be awarded pre- and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of the initial complaint in this action;

iv. recover its costs of suit, including its reasonable attorney's fees, as provided by law and pursuant to the Tennessee Consumer Protection Act and 18 U.S.C. § 1964(c); and

v. be awarded such other, further and different relief as the case may require and the Court may deem just and proper under the circumstances.

JURY DEMAND

Plaintiff Greene County demands trial by jury on all issues so triable.

Dated: June 10, 2024

/s/ Michael J. Fuller, Jr.

Michael J. Fuller, Jr., BPR No. 024906
Farrell & Fuller Law
270 Munoz Rivera Ave. Ste. 201
San Juan, PR 00918
Telephone: 939-293-8244
Fax: 939-293-8245
mike@farrellfuller.com

Crystal Jessee, BPR No. 024445
Jessee Law Office
120 N. Main Ext.
Greeneville, TN 37745
Telephone: 423-638-4006
crystaljessee@jesseelawoffice.com

Counsel for Plaintiff

AUTHORITY TO REPRESENT

RE: City of Greeneville, Tennessee School Board, civil suit against those legally responsible for the wrongful distribution of prescription insulin, or the generics.

The City School Board for the City of Greeneville, Tennessee (hereinafter "CLIENT") hereby retains the law firm MCHUGH FULLER LAW GROUP, PLLC, pursuant to the Tennessee Rules of Professional Conduct, on a contingent fee basis, to pursue ***all*** civil remedies against those in the chain of distribution of Insulin and the price fixing of the product in Greeneville City, Tennessee, including, but not limited to, filing a claim for price fixing, RICO, and any other civil remedies allowed to abate the damages caused thereby. **Michael J. Fuller, Esq.** of the law firm FARRELL AND FULLER LAW GROUP, PLLC, shall serve as LEAD COUNSEL. CLIENT authorizes lead counsel to employ and/or associate additional counsel, with consent of CLIENT, to assist LEAD COUNSEL in the just prosecution of the case. CLIENT consents to the participation of the following firms:

FARRELL AND FULLER
270 MUNOZ RIVERA AVENUE, SUITE 201
SAN JUAN, PR 00918

JESSEE LAW OFFICE
CRYSTAL JESSEE
120 N. Main Ext.
Greeneville, Tennessee

In consideration, CLIENT agrees to pay thirty percent (30%) of the total recovery (gross) in favor of the CLIENT as an attorney fee whether the claim is resolved by compromise, settlement, or trial and verdict (and appeal). The gross recovery shall be calculated on the amount obtained before the deduction of costs and expenses. CLIENT grants Attorneys an interest in a fee based on the gross recovery. If a court awards attorneys' fees, Attorneys shall receive the "greater of" the gross recovery-based contingent fee or the attorneys' fees awarded. **There is no fee if there is no recovery.**

FARRELL AND FULLER LAW GROUP, PLLC and the other law firms, hereinafter referred to as the "Attorneys," agree to advance all necessary litigation expenses necessary to prosecute these claims. All such litigation expenses, including the reasonable internal costs of electronically stored information (ESI) and electronic discovery generally or the direct costs incurred from any outside

contractor for those services, will be deducted from any recovery after the contingent fee is calculated. **There is no reimbursement of litigation expenses if there is no recovery.**

The CLIENT acknowledges this fee is reasonable given the time and labor required, the novelty and difficulty of the questions involved, and the skill requisite to perform the legal service properly, the likelihood this employment will preclude other employment by the Attorneys, the fee customarily charged in the locality for similar legal services, the anticipated (contingent) litigation expenses and the anticipated results obtained, the experience, reputation, and ability of the lawyer or lawyers performing the services and the fact that the fee is contingent upon a successful recovery.

This litigation is intended to address a significant problem in the community. The litigation focuses on the manufacturers, distributors, retailers and pharmacy benefit managers and their role in the price fixing of insulin to drive up the cost for the counties that self-fund their health insurance. There is no easy solution. Many of the facts of the case are locked behind closed doors. The billion-dollar industry denies liability. The litigation will be very expensive and the litigation expenses will be advanced by the Attorneys with reimbursement contingent upon a successful recovery. The outcome is uncertain, as is all civil litigation, with compensation contingent upon a successful recovery. Consequently, there must be a clear understanding between the CLIENT and the Attorneys regarding the definition of a "successful recovery." Based upon the City's request, the City and Counsel will not purse pharmacies in the city that are locally owned and locally managed. Also, the City requests and we agree that any proposed settlement or resolution of the matter, other than by a fully adjudicated contested judgment which has become final, must be approved in writing by the client. The client agrees that they will not enroll in any other litigation concerning the price fixing of insulin, with any other firms, while this lawsuit is pending.

The Attorneys intend to present a damage model designed to abate the price fixing crisis. This damage model may take the form of money damages or equitable remedies (e.g., abatement fund). The purpose of the lawsuit is to seek reimbursement of the costs incurred in the past for the overpricing of insulin, that has led counties to pay substantially more for the product, and health insurance for their citizens. The CLIENT agrees to compensate the Attorneys, contingent upon prevailing, by paying 30% of any settlement/resolution/judgment, in favor of the CLIENT, whether it takes the form of monetary damages or equitable relief. For instance, if the remedy is in the form of monetary damages, CLIENT agrees to pay 30% of the gross amount to Attorneys as compensation and then reimburse the reasonable litigation expenses. If the remedy is in the form of equitable relief (e.g., abatement fund), CLIENT agrees that the first 30% of the relief shall be paid to Attorneys as compensation for their legal services and reasonable litigation expenses. To be clear, Attorneys shall not be paid nor receive reimbursement from public funds. However, any judgment arising from successful prosecution of the case, or any consideration arising from a settlement of the matter, whether monetary or equitable, shall not be considered public funds for purposes of calculating the contingent fee. Under no circumstances shall the CLIENT be obligated to pay any Attorneys fee or any litigation expenses except from moneys expended by defendant(s) pursuant to the resolution of the CLIENT's claims.

The division of fees, expenses and labor between the Attorneys will be decided by private agreement between the law firms and subject to approval by the CLIENT. Any division of fees will be governed by the Tennessee Rules of Professional Conduct including: (1) the division of fees is in proportion to the services performed by each lawyer or each lawyer assumes joint responsibility for

the representation; (2) the CLIENT agrees to the arrangement, and the agreement is confirmed in writing; and (3) the total fee is reasonable.

LEAD COUNSEL shall appoint a contact person to keep the CLIENT reasonably informed about the status of the matter in a manner deemed appropriate by the CLIENT. The CLIENT at all times shall retain the authority to decide the disposition of the case and personally oversee and maintain absolute control of the litigation. For your city, the contact person will be Crystal Jessee, from the Jessee Law Firm.

Upon conclusion of this matter, LEAD COUNSEL shall provide the CLIENT with a written statement stating the outcome of the matter and, if there is a recovery, showing the remittance to the client and the method of its determination. The closing statement shall specify the manner in which the compensation was determined under the agreement, any costs and expenses deducted by the lawyer from the judgment or settlement involved, and, if applicable, the actual division of the lawyers' fees with a lawyer not in the same firm, as required in Rule 1.5 (e) of the Tennessee Rules of Professional Conduct. The closing statement shall be signed by the CLIENT and each attorney among whom the fee is being divided.

Nothing in this Agreement and nothing in the Attorneys' statement to the CLIENT may be construed as a promise or guarantee about the outcome of this matter. The Attorneys make no such promises or guarantees. Attorneys' comments about the outcome of this matter are expressions of opinion only and the Attorneys make no guarantee as to the outcome of any litigation, settlement or trial proceedings.

SIGNED, this _____day of _____, 2024.

CITY of GREENEVILLE, TENNESSEE
School Board

Approve by: _____
Steve Starnes

Accepted By:_____
Michael J. Fuller, Esq.

Lead Counsel: FARRELL AND FULLER
270 MUNOZ RIVERA AVENUE, SUITE 201
SAN JUAN, PR 00918

Local Counsel:

CRYSTAL JESSEE
JESSEE LAW OFFICE
120 NORTH MAIN EXT.
GREENEVILLE, TN 37745

Request for Consideration of Addition of Lacrosse as GHS Team Sport

Daniel Lewis, MD

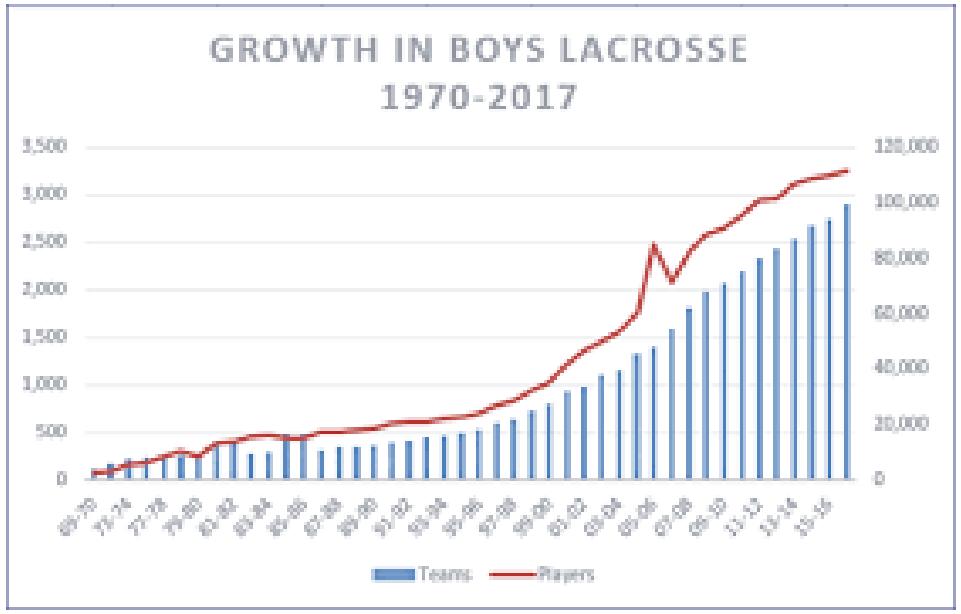
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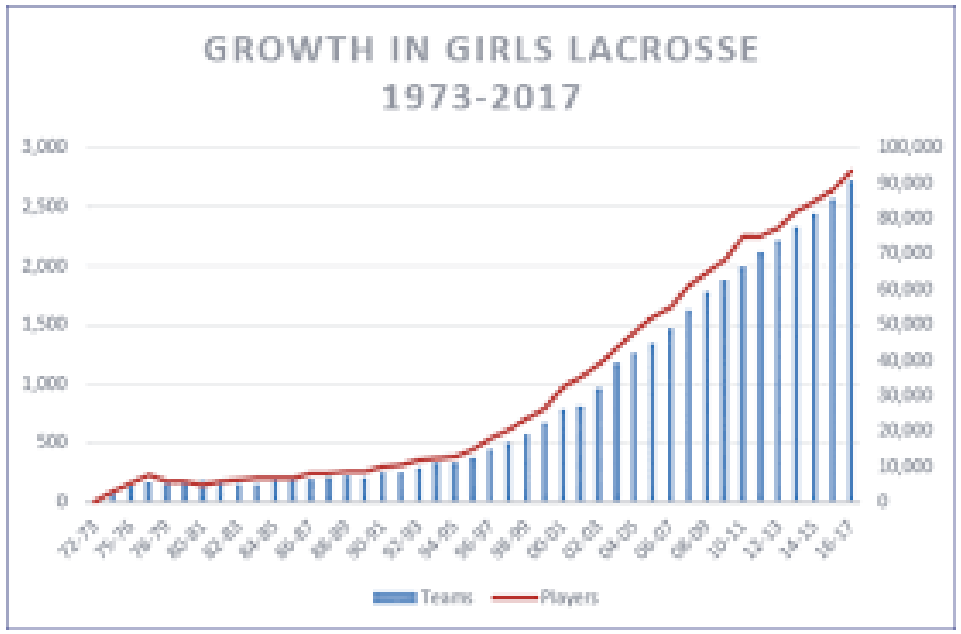
Greeneville City School Board Meeting

December 10, 2025

Greeneville Lacrosse Club

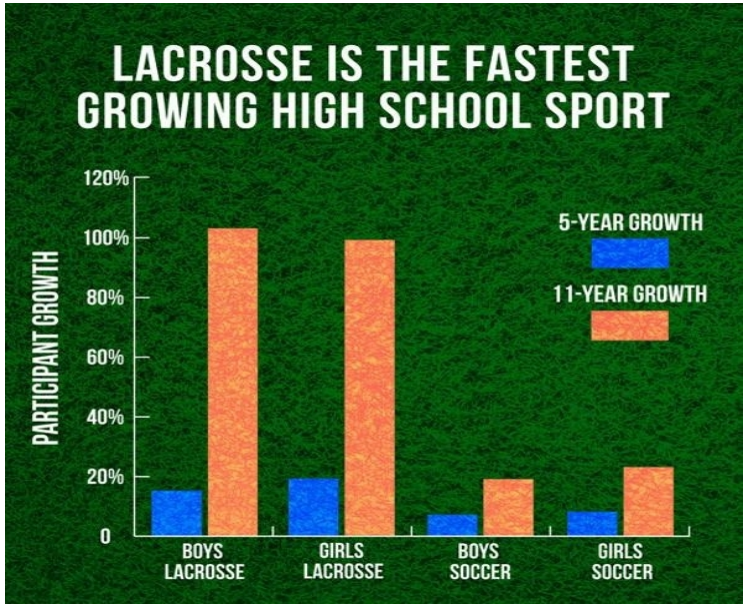
- Established Nov 2017
- Goal of offering No/Low Cost Lacrosse to the community
  - Players from 6U to High School
  - Typically have 30-40 players per season
  - Have had a HS team for 7 years, operated as a Club Team
    - Last year- played 14 game schedule, never traveled further than Maryville
  - TSSAA Sanctioning makes operating as a HS Club team onerous, nigh impossible





TOP SPORTS BEING ADDED AT SCHOOLS

SPORT	PERCENTAGE OF SCHOOLS
LACROSSE (GIRLS)	22.6%
LACROSSE (BOYS)	18.3%
GOLF (GIRLS)	14%
BOWLING (GIRLS)	9.7%
BOWLING (BOYS)	9.7%
VOLLEYBALL (BOYS)	9.7%
SWIM/DIVE (GIRLS)	7.5%
SWIM/DIVE (BOYS)	7.5%
ARCHERY	6.5%
SOCCER (GIRLS)	6.5%
WRESTLING	6.5%



Local Teams (Public)

Science Hill(*)

Dobyns Bennett(*)

Pigeon Forge

Gatlinburg-Pittman(*)

Sevier County(*)

West

Gibbs (**)

Farragut

Kingston

Maryville (**)

Hardin Valley Academy

Bearden(*)

William Blount (**)

- *- Brand new Program 2025
- **- 2 years or less

TN HS Lacrosse Teams 2025

Public

1	Gatlinburg-Pittman High School	544	A
2	Pigeon Forge High School	610	A
3	Kingston High School	618	A
4	Lakeland Preparatory School	754	A
5	Signal Mountain High School	772	A
6	Valor College Prep	879	A
7	Upperman High School	904	A
8	Seymour High School	928	A
9	Heritage High School	1033	A
10	Gibbs High School	1037	A
11	Soddy Daisy High School	1103	A
12	Hillsboro High School	1206	A
13	Sevier Co. High School	1236	A
14	Ooltewah High School	1251	A
15	Page High School	1353	A
16	Centennial High School	1387	A
17	Hunters Lane High School	1397	A
18	West High School	1471	A
19	William Blount High School	1473	A
20	Nolensville High School	1480	A
21	Walker Valley High School	1481	A
22	Wilson Central High School	1607	A
23	Bradley Central High School	1630	AA
24	Summit High School	1637	AA
25	Maryville High School	1637	AA
26	Brentwood High School	1642	AA
27	Green Hill High School	1648	AA
28	Franklin High School	1734	AA
29	Arlington High School	1854	AA
30	Siegel High School	1859	AA
31	White Station High School	1912	AA
32	Oakland High School	1914	AA
33	Houston High School	1925	AA
34	Ravenwood High School	1948	AA
35	Bearden High School	1974	AA
36	Hardin Valley Academy	1996	AA
37	Independence High School	2080	AA
38	Farragut High School	2082	AA
39	Cookeville High School	2149	AA
40	Dobyns Bennett High School	2335	AA
41	Science Hill High School	2408	AA
42	Bartlett High School	2822	AA
43	Collierville High School	2989	AA

Private

Two classes; split evenly by participating schools.

Class	No. of Schools	Enrollment Range
A	14	0-515
AA	13	516 and greater
	27	

#	School	Enrollment	Class
1	The Webb School	241	A
2	St. George's Independent School	286	A
3	Evangelical Christian School	329	A
4	Lausanne Collegiate School	362	A
5	Christian Academy of Knoxville	376	A
6	Boyd Buchanan High School	390	A
7	Franklin Road Academy	396	A
8	St. Benedict at Auburndale	397	A
9	University School of Nashville	404	A
10	St. Cecilia Academy	424	A
11	Pope Saint John Paul II Preparatory School	465	A
12	Webb School of Knoxville	479	A
13	Ensworth High School	488	A
14	Christ Presbyterian Academy	515	A
15	St. Mary's Episcopal School	554	AA
16	St. Agnes Academy	566	AA
17	Hutchison School	584	AA
18	Girls Preparatory School	592	AA
19	Briarcrest Christian School	599	AA
20	Knoxville Catholic High School	709	AA
21	Baylor School	765	AA
22	Harpeth Hall School	820	AA
23	Father Ryan High School	831	AA
24	Memphis University School	856	AA
25	Montgomery Bell Academy	1146	AA
26	McCallie School	1456	AA
27	Christian Brothers High School	1474	AA

BACK TO TOP

Division II: All Other Sports

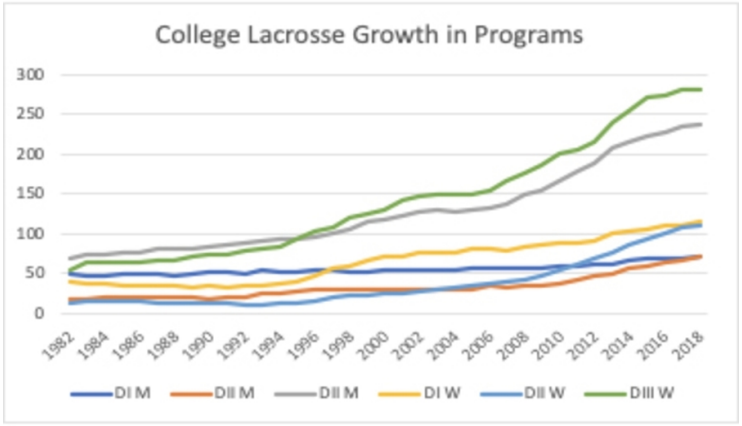
Two classes; A: 0-425, AA: 426+.

Class	No. of Schools	Enrollment Range
A	56	0-424
AA	20	425 and greater

College Opportunities

NUMBER OF NCAA LACROSSE SCHOLARSHIPS BY DIVISION LEVEL

Division Level	Number of Teams	Total Athletes	Average Team Size	Scholarships Limits Per Team*	Scholarship Type**
NCAA D1	72	3,657	50.8	12.6	Equivalency
NCAA D2	79	3,526	44.6	10.8	Equivalency
NCAA D3	244	8,847	36.3	–	N/A
NAIA	31	639	23	–	Equivalency
JUCO	16	727	24	24	Equivalency
Totals	442	17,396	36		



- NCAA Division 1/2/3
  - Including **Tusculum**, Emory and Henry, Lincoln Memorial, Lees McCrae, Lenoir-Rhyne, Mars Hill (D2), Sewanee (D3)
- NAIA (National Association of Intercollegiate Athletics)
  - Including Tennessee Wesleyan
- Junior College
- Men's Collegiate Lacrosse Association (MCLA)/Club
  - Including **UT-Knoxville**

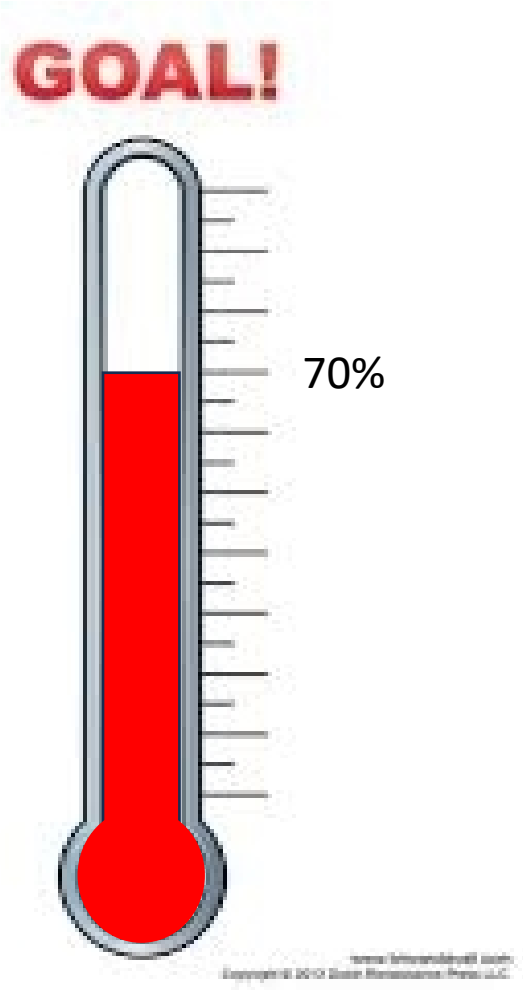
❖ 5786 players competing for 1578 scholarships;

1 scholarship for every 3.6 players

❖College Players from GLC: 6

Fundraising

- Start-Up Costs $15,280
- Annual Expenses $18,450 (including Coaches Stipends)
- Total $33,730



Request

- That Greeneville City School Board endorse offering Men's/Women's High School Lacrosse beginning Spring 2026
  - Via cooperative agreement with South Greene High School
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Request for Consideration of Addition of Lacrosse as GHS Team Sport

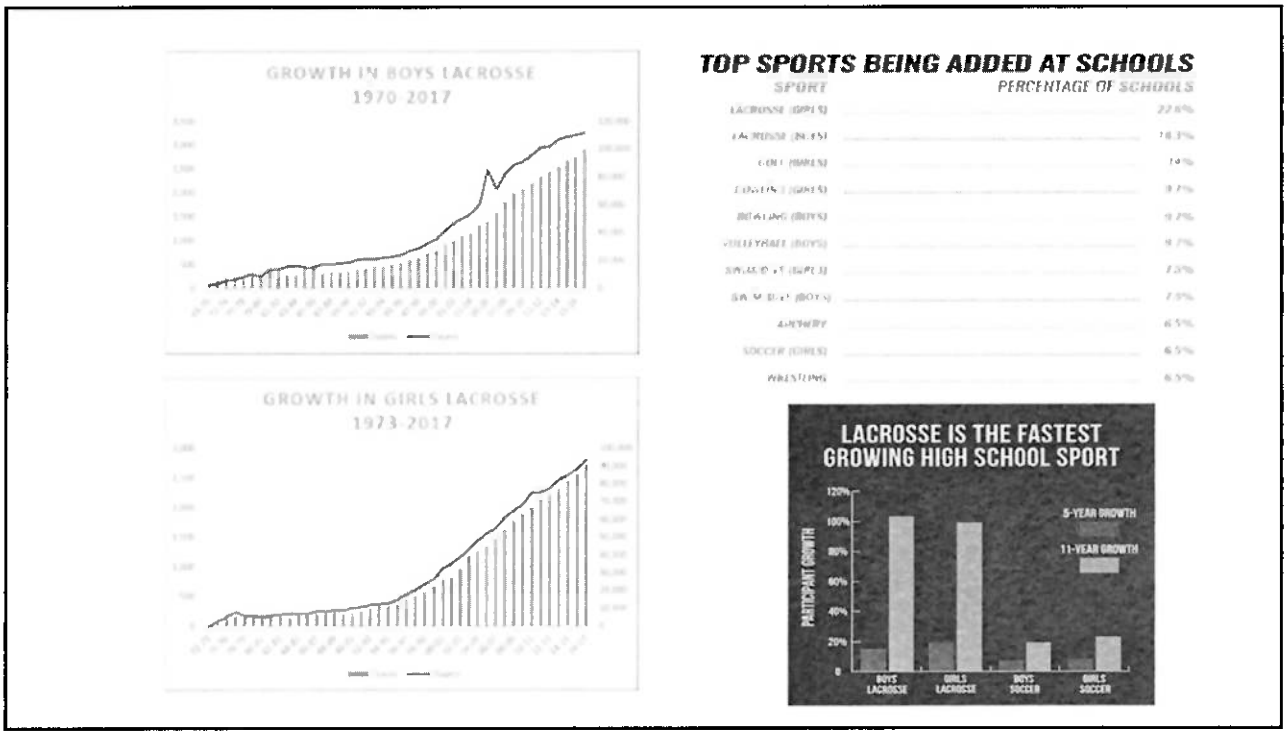
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1

Greeneville Lacrosse Club

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2



3

Local Teams (Public)

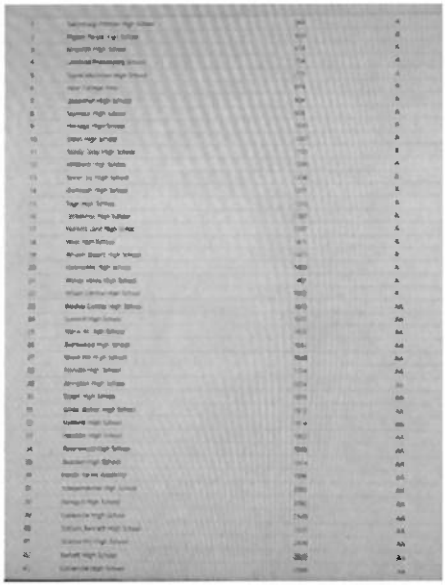
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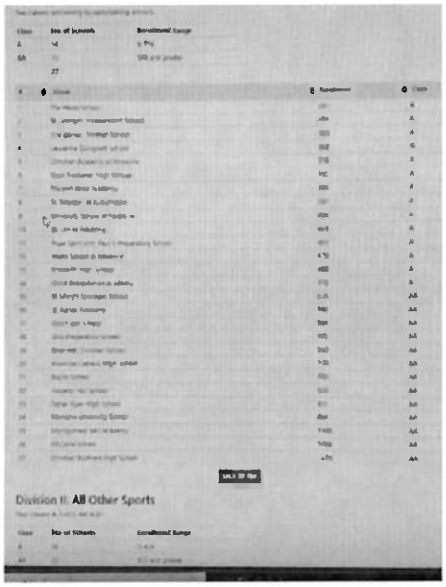
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TN HS Lacrosse Teams 2025

Public



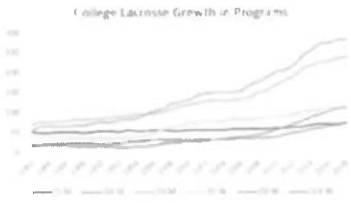
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5

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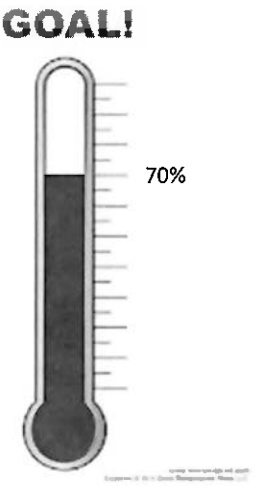
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8

GHS-SGHS Lacrosse Transition

Requirements:		Timeline	Status	
1. Signed Co-Op Agreement with GHS and SGHS				
2. Projected Budget to Jeff		Summer 2024	In pro...	Expectations of Athletes:
3. Presentation to GCS School Board		Dec 2024	Under ...	Lacrosse Stick
				Elbow Protection
Projected Expenses- Combined				Mouthpieces
Gillman Goals	2 goals	$1,100.00		Athletic Cups
Practice Goals	2 goals	$525.00		
Field Paint	3 cases	$240.00		
Field Striper	1	$130.00		
Field Pylons	1 set	$90.00		
Referee Fees	2/game @10 home games	$3,000.00		
Bus Fees	10 away games	$2,500.00		
GMS Scoreboard Repair		$1,000.00		
Funds for Various Expenses/Overrun		$2,000.00		
Total		**$10,585.00**		
Projected Expenses- Boys				
Men's Head Coach		$4,128.60		
Men's Asst Head Coach		$2,064		
White Balls	2 cases	$325		
Lacrosse Helmets	20	$5,000.00	In Kind	
Lacrosse Chest Pads	20	$1,400.00	Partially accounted for by TSLA Grant	
Lacrosse Gloves	20 pair	$1,240.00	Partially accounted for by TSLA Grant	
Goalie Gear	1 complete set	$294		
Uniforms	20	$2,400.00		
Total		**$16,851.90**		
Projected Expenses- Girls				
Women's Head Coach		$4,128.60		
Women's Asst Coach		$2,064.30		
Yellow balls	2 cases	$325.00		
Women's Goggles	20	$2,000.00		
Women's Goalie Gear		$375.00		
Uniforms	20	$2,400.00		
Total		**$11,292.90**		
Cummulative Total		$38,729.80		
Minus In Kind		$5,000.00		
Team Totals		**$33,729.80**		

OFFICIAL MINUTES OF THE GREENVILLE CITY BOARD OF EDUCATION
Thursday, October 24, 2024

The Greeneville City Board of Education met in Regular session on Thursday, October 24, 2024, at the Greene Technology Center, 1121 Hal Henard Rd. Board Members **Present:** Pam Botta (Board Member), Crystal Hirschy (Board Member), Cindy Luttrell (Chair), Josh Quillen (Treasurer), Dr. Craig Shepherd (Vice-Chair). The Chairman called the meeting to order and welcomed all in attendance.

BUSINESS TRANSACTED

I. **Call to Order**

II. **Recognition of Visitors**

III. **Public Comment Period**

There were no requests to speak on any agenda item.

IV. **Conflict of Interest Statement**

Chair Cindy Luttrell read the following statement, reminding those present of the importance of transparency and integrity in decision-making.

Chair to Board Members:

1. "If you have any relative who is employed by the Board of Education, meaning a spouse, parent, parent-in-law, child, son-in-law, daughter-in-law, grandparent, grandchild, brother, sister, uncle, aunt, nephew, niece, or any person who resides in the same household as you, please acknowledge the same at this time by raising your hand."

Chair to Board Members:

2. "To those board members who just raised their hands, do you hereby certify that any and all votes you will cast during this meeting are in the best interest of the school system? If so, please say, ‘Aye.’"

Chair to Board Secretary:

3. "Please reflect within the minutes that Luttrell and Botta acknowledged possible conflicts and confirmed their intent to act in the best interest of the school system."

V. Approval of Agenda

It was recommended to approve the Agenda as presented. Board approval was unanimous on a motion from Hirschy (Board Member) and a second from Botta (Board Member).

VI. Consent Agenda

It was recommended to approve the Consent Agenda as presented. Board approval was unanimous on a motion from Botta (Board Member) and a second from Hirschy (Board Member).

A. Consideration of Approving Minutes of September 24, 2024, Board Meeting

The minutes of the September 24, 2024, Board meeting were unanimously approved as presented. A copy is on file in the Director of Schools' office.

B. Consideration of Accepting Personnel Report

Board approval was unanimous for acceptance of the changes in personnel since the September report. A copy of the report is attached to the minutes.

C. Consideration of Approving Board Policy Revisions (2nd Reading)

Copies of these policies are attached to the minutes. Board approval was unanimous on 2nd reading for the following policies:

1.204 Board Member Development Opportunities

1.205 Board-Director Relations

1.300 Board Committees

1.301 Executive Committee

1.303 Consultants

2.401 Gifts and Bequests

2.402 Investment Earnings

2.500 Deposit of Funds

3.208 Facilities Planning

3.209 Estimating Facility Costs

3.210 Naming Facilities

4.205 Enrollment in Advanced Courses

4.206 Homebound Instruction

4.207 English Learners

4.209 Alternative Credit Options

4.210 Credit Recovery

4.600 Grading System

4.700 Testing Programs

5.110 Compensation Guides & Contracts

5.113 In-Service and Professional Learning Opportunities

5.114 Personnel Records

5.1141 Teacher Effect Data

5.115 Assignment & Transfer

6.301 Rights and Responsibilities of Students

6.302 Procedural Due Process

6.303 Interrogations and Searches

6.3031 Use of Metal Detectors

6.304 Student Discrimination, Harassment, Bullying, Cyber-bullying, and Intimidation

6.3041 Title IX & Sexual Harassment

D. **Consideration of Approving Board Policy Revisions - No Changes (1st Reading)**

Board approval was unanimous on 1st reading for the following policies:

1.302 School Attorney

1.401 Public Hearings

1.403 Agendas

1.405 Rules of Order

1.406 Minutes

1.407 School District Records

2.600 Bonded Employees

2.703 Audits

3.211 New Project Planning

3.212 District Water Testing

3.218 Service Animals in District Facilities

4.211 Work-Based Learning Program

4.212 Virtual Education Program

4.300 Extracurricular Activities

4.302 Field Trips, Excursions, Competitions

4.400 Textbooks and Instructional Materials

4.402 Reconsideration of Textbooks and Instructional Materials

5.1151 Telework During Emergencies

5.116 Staff Positions

5.117 Procedure for Granting Tenure

5.118 Transitional Duty

5.119 Background Investigations

6.306 Interference/Disruption of School Activities

6.307 Drug-Free Schools

6.308 Bus Safety and Conduct

6.310 Dress Code

6.311 Care of School Property

6.314 Corporal Punishment

6.315 Detention

E. **Consideration of Approving Disposal of Surplus under $500.00**

GCS Board Policy 2.403 gives the Greeneville Board of Education the authority to declare district property that is no longer useful nor necessary as surplus and to authorize the disposal of such equipment, books, or materials. The Board unanimously approved the disposal of the surplus.

F. **Consideration of Approving Science Textbook Adoption Committee Members**

All textbook adoption committees require school board approval. The members have been sworn in by Judge Leonard. The committee is led by Ms. Shelia Newland, Teaching and Learning Coordinator. Committee Members: Shelia Newland, Elisa Bentley, Christie Carter, Jordyn Ricker, Rachel Ratheal, Marsha Hybarger, McKayla Ramsey, Derek Jeffers, Jenn Hartley, Sara Smock, Robin Jones, Erica Worrell, Jerry Graham, Laura Lenker, Cindy Propst, Jessica Miller, Eric Simpkins, Sarah Smith, Jeni Donahue, Richard Tipton, Stacy King, Tallye Gass, Amy Haynie, Aundrea Gunter, Melanie Williams. The Board unanimously approved the Science Textbook Adoption Committee Members.

G. **Consideration of Approving School Trip Request**

Board Policy 4.302 specifies that the Board must approve field trips that are both overnight and out-of-state. Additionally, approval is required when students must leave school early for participation in athletic events. The Board unanimously approved the following trips:

- Greeneville High School requested approval to travel to Chattanooga, TN to participate in the TSSAA Girls Soccer State Tournament from 10/22/2024 - 10/26/2024. Executive Approval was granted on 10/14/2024.
- Greeneville Middle School requested approval to travel to Washington, D.C. for an 8th grade reward trip from 5/6/2025 - 5/9/2025.
- Greeneville Middle School requested approval to travel to Cleveland, TN for Middle School All-East Honor Choir from 11/22/2024 - 11/23/2024.
- Greeneville High School requested approval to travel to Cleveland, TN to participate in the All-East Choir from 11/21/2024 - 11/23/2024.
- Greeneville High School JROTC requested approval to travel to Cleveland, TN to participate in an Archery Tournament from 11/22/2024 - 11/23/2024.

H. **Consideration of Approving Sick Leave Bank Trustees**

On June 19, 1997, the Board approved the establishment of a sick leave bank for teachers within the Greeneville City School system. The sick leave bank actually went into effect on August 1, 1997. As part of the operation of the sick leave bank,

the Board is required to appoint two trustees and the teachers' association is required to appoint two trustees. The appointed trustees are to serve staggered terms and can be replaced only because of death, retirement, resignation, and/or discontinuation of employment with the Board of Education or at the end of a term. In the spring of 2014, House Bill 2133 was passed, amending Tennessee Code Annotated, Title 49, Chapter 5, Part 7 and Title 49, Chapter 5, Part 8, relative to the sick leave bank. This allowed all full-time employees who accrue sick leave, not just teachers, to participate in the sick leave bank, if the employee elects to do so. Greeneville City Schools will have open enrollment for the sick leave bank during October for all full-time employees (certified and non-certified). The following individuals are recommended for appointment to the Board as sick leave back trustees:

· Melissa Batson (CHRO), who will serve the 3rd year of a 3-year term

· Ellen Lipe (CFO), who will serve the 1st year of a new 3-year term.

State law requires that the local teacher association appoint two trustees. The GEA representatives serving on the Sick Leave Trustees Board for 2024-2025 will be:

· Katie Smelcer (GMS), who will serve the 3rd year of a 3-year term.

· Randy Shelton (GHS), who will serve the 1st year of a new 3-year term.

As required by law, Steve Starnes, in his position as Director of Schools, serves as Chair. The Board unanimously approved Sick Leave Bank Trustees.

I. **Consideration of Approving 2024-2025 General Purpose Budget Amendment #1**

Budget Amendments are made periodically throughout the year to more accurately reflect revenues and expenditures. This Budget Amendment budgets rollover funding from the 2023-2024 school year for the Highland Roof Project, the annual school bus purchase, and Unbound Digital. The Board unanimously approved the 2024-2025 General Purpose Budget Amendment.

VII. Action Items

A. Consideration of Accepting September 2024 Financial Statements

Chief Financial Officer Ellen Lipe presented the September financial statements to the Board for acceptance. Lipe stated that local revenue collected year-to-date through Month is $1,514,418, which is 16.7% of the total budgeted projection. The amount collected year-to-date is $105,975 more than during the same time period last year. This reflects an actual percentage change of 7.44% compared to last year. The district has 581 tuition students as of Oct. 16, 2024. The General-Purpose Financial Report showed that encumbrances comprise $1,146,395 year-to-date. The Federal Projects Financial Reports reflected $208,266.04 in revenue and $384,387.13 in expenditures year-to-date. Federal Projects are reimbursement based, meaning funds have to be expended before requesting reimbursement. Copies of the financial statements are on file in the Chief Financial Officer's office. It was recommended to approve the September 2024 financial statements. Board approval was unanimous on a motion from Quillen (Treasurer) and a second from Hirschy (Board Member).

B. **Consideration of Approving Board Policy Revisions - 1st Reading**

Revisions are recommended to the following policies on 1st reading:

6.305 Student Concerns

6.317 Student Disciplinary Hearing Authority

6.319 Alternative Education

It was recommended to approve the revisions to the policies as presented on 1st reading. Board approval was unanimous on a motion from Botta (Board Member) and a second from Dr. Shepherd (Vice-Chair).

C. **Consideration of Approving the TISA Accountability Plan**

Richard Tipton, Director of Instruction, presented the TISA Accountability Plan. He

emphasized the importance of accountability in the utilization of the allocated budget to meet and exceed the set goals for student achievement. Greeneville has set a specific target of 70% proficiency in 3rd-grade Math and English Language Arts (ELA) by 2032. Tipton highlighted that for the 2023-2024 academic year, the

percentage of proficiency in 3rd grade ELA stood at 41.2%. The aim is to narrow this gap between current performance and the goal of 70% by 15% over the next three years.

He reported that Greeneville City Schools improved ELA performance across grades 3-8, rising from 43.9% in 2023 to 47.4% in 2024, surpassing the district target. Fourth grade excelled with 58.6% proficiency, while third grade, at 41.2%, highlighting a need for additional support. The district's action plan will focus on strengthening early literacy through targeted interventions for third grade and a new K-2 pilot program. Building effective strategies for grades 4-8, the district aims to use data-driven instruction to sustain progress. It was recommended to approve the TISA Accountability Plan. Board approval was unanimous on a motion from Quillen (Treasurer) and a second from Botta (Board Member).

D. **Consideration of Joining Lawsuit Against Insulin Manufacturers and PBM's**

The litigation surrounding insulin pricing highlights a systemic issue where the costs of this essential medication have been artificially inflated, impacting millions. Diabetes affects over 34.2 million people in the U.S., with insulin serving as a life-saving necessity for more than 7 million individuals daily. Despite insulin being around for over 100 years, with few innovations since the 1980s, prices have surged by more than 1,000% since 2003. This dramatic increase far exceeds manufacturing costs, which have actually decreased due to process optimization. The inflated prices are attributed to the alleged collusion between insulin manufacturers (Eli Lilly, Novo Nordisk, and Sanofi) and pharmacy benefit managers (PBMs) like Express Scripts, CVS Caremark, and Optum Rx, who dominate the market. This scheme involves PBMs demanding larger rebates from manufacturers in exchange for favorable placement on formularies, which in turn prompts manufacturers to raise prices. This practice has led to a heavy financial burden on individuals and health plans, sparking legal claims for violations of RICO, deceptive trade practices, and unjust enrichment, aiming to recover overpayments and prevent future harm. The litigation seeks monetary damages, disgorgement of profits, and injunctive relief to end these practices. The Frantz Law Group firm has agreed to

represent all school districts who elect to join the litigation on a contingent fee basis. This means there is no cost to any school district unless there is ultimately a financial recovery. The board amended the motion to table taking any action on joining the Frantz Law Group for the Lawsuit Against Insulin Manufacturers and PBM's until its December meeting. Board approval was unanimous on the amended motion from Quillen (Treasurer) and a second from Dr. Shepherd (Vice-Chair).

VIII. **Director's Report**

Starnes congratulated, recognized, and informed:

1. The State Board of Education announced today the selection of its 21-member Educator Advisory Team (EAT) to review Tennessee's current English Language Arts standards. The members were selected from 297 applications, the highest number the State Board office has received, and will utilize comments based on our public feedback survey and their personal experience as distinguished educators. Starnes congratulated Nicolle Moore, sixth grade ELA Teacher at Greeneville Middle School, for her selection to the Educator Advisory Team. Under Tennessee statute (T.C.A. § 49-1-311-313) and State Board Policy (Standards Review Policy 3.209), the State Board of Education is charged with reviewing and approving the English Language Arts (ELA), math, science, and social studies standards at least every eight years. Each standards review process follows the same two -year rigorous, legislatively mandated process to promote collaboration and transparency. This process entails significant public feedback and coordination across educators, state government, and appointed representatives.
2. Karen Wilhoit, Brianna Fannon, Miriam Shackleford, and the school nutrition team for their outstanding efforts to feed students during our recent school closure due to Hurricane Helene. They prepared and served 15,861 meals (7 days' worth of breakfast and lunch) during the week of September 30 through October 4. This is approximately 3000 meals more than we serve during a typical week.

3. School Administration Teams and their staff, who were instrumental in delivering meals and other items to our families, who could not attend the distribution points. They also shared information on available resources within the community. They have done a tremendous job!
4. Transportation department, maintenance crew, custodial team, instructional technology, finance, volunteers, and everyone that supported our students, families, and staff. Starnes stated it was a source of pride to see the way that everyone pulled together, as one, to respond to the challenge.
5. Blount County Schools, Knox County Schools, Jefferson County High School, Dobyns-Bennett High School, Science Hill High School, and North Greene High School for their support in the aftermath of the hurricane. Their generosity is greatly appreciated.
6. GHS Lady Devils Golf Team on their fifth-place finish in the recent TSSAA Class AA State Girl's Golf Championships.
7. GHS Lady Devil Soccer Team on their Region 1-2A Championship and qualifying for their tenth consecutive TSSAA Class AA Girl's Soccer State Championship.
8. GMS 7th grader, Maggie Moore, on winning the 2024 Conference and Sectional Championships and qualifying for the TMSAA Class AA State Cross-Country Championships.

IX. **Legislative Update**

There were no Legislative Updates.

X. **Adjournment**

The meeting was adjourned at approximately 7:52 p.m. Board approval was unanimous on a motion from Dr. Shepherd (Vice-Chair) and a second from Hirschy (Board Member).

Respectfully submitted,

_____

Cindy Luttrell, Chair

_____

Steve Starnes, Director of Schools

FIELD TRIP & EXCURSION REQUEST
FORM Out-of-State *or* Overnight

Name of the school: Greeneville High School

Person Requesting: Larry Blalock

Purpose of the Field Trip: State XC Meet

Destination of Field Trip: Hendersonville, TN

Grade(s) of students attending: 9-12

Dates requested: Nov 6-7, 2024 Departure Time: 9:00A Return Time: 8:00 PM

Approximate # of students to attend: 11

Number, names and affiliation of chaperones attending:

1 female List names and affiliation: Teresa Gibson - GMS Employee

1 male List names and affiliation: Larry Blalock - Head Coach

("There must be at least one female and one male chaperone if the trip is for a mixed group. A chaperone of the same sex will accompany students on overnight trips")

All Greeneville City Schools guidelines for out-of-state and overnight field trips shall be followed in planning and conducting this field trip per BOE policy 4.302, and approval of my principal, the Director of Schools, and Board of Education is required. For an Overnight or Out-of-State Field Trip Request to be considered for approval; it must be received in the director of school's office 10 days prior to the scheduled date of the Board meeting at which it will be considered for approval.

_____, Principal date approved 10-31-24

Steve Starnes (Oct 31, 2024 17:00 EDT)
_____, Director of Schools date approved Oct 31, 2024

Cindy Luttrell (Oct 31, 2024 09:46 EDT)
_____, Chairman, BOE date approved Oct 31, 2024

Cultivate the Mind and Impact the Heart through Excellence and Equity

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Final Audit Report 2024-10-31

Created:	2024-10-31
By:	Jamie Galyon (galyonj@gcschools.net)
Status:	Signed
Transaction ID:	CBJCHBCAABAAh9DbHaerqVMBKtLCH2ZfIkRNaJuXwxPc

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RESOLUTION SUPPORTING PUBLIC SCHOOLS

WHEREAS the Greeneville City Board of Education is charged with governing the school district so that all students receive the best educational opportunities to graduate prepared to enter a postsecondary institution or the workforce and

WHEREAS Greeneville City Schools consists of five elementary schools, one middle school, one high school, one career and technical school, and

WHEREAS Greeneville City Schools provides an exceptional education to approximately 2900 students and

WHEREAS public schools are a foundational element of local communities and

WHEREAS Greeneville City Schools is committed to maintaining local control over its schools, ensuring that they are reflective of the community's needs and values, and

WHEREAS local taxpayers contribute taxes to support and maintain Greeneville City Schools and

WHEREAS keeping public dollars within public schools is crucial to maintaining the quality and accessibility of education for all students and

WHEREAS diverting those public dollars to private institutions reduces the financial resources available to public schools.

NOW, THEREFORE, BE IT RESOLVED that we express our unwavering support for public education in our city and in our state and

BE IT FURTHER RESOLVED that the Greeneville City Schools Board of Education affirms the importance of prioritizing and protecting funding for public schools, ensuring

that they have the necessary resources to provide a high-quality education for all students and

BE IT FURTHER RESOLVED that the Greeneville City Board of Education maintains that public funds should exclusively support public schools and remain separate from private school funding.

This Resolution was duly approved by the Greeneville City Board of Education at its regularly scheduled meeting on December 10, 2024, as reflected by the signatures below.

_____	_____
Cindy Luttrell, Board Chair	Dr. Craig Shepherd, Board Vice Chair
_____	_____
Josh Quillen, Board Treasurer	Pam Botta, Board Member
_____	_____
Crystal Hirschy, Board Member	Attestation; Steve Starnes, Superintendent

This sheet has been updated as of December 2nd, 2024, with preliminary information through October 2024

GREENEVILLE CITY SCHOOLS
2024 - 2025
ACTUAL LOCAL REVENUE COLLECTIONS

	Property Tax		Property Tax - Prior Year		Clerk & Master		Interest & Penalty		Pick-up Taxes		In Lieu of - Local Utility		In Lieu of - Other	
	2023-2024	2024-2025	2023-2024	2024-2025	2023-2024	2024-2025	2023-2024	2024-2025	2023-2024	2024-2025	2023-2024	2024-2025	2023-2024	2024-2025
July	$ -	$ -	$ 10,188.94	$ 7,215.08	$ 2,979.58	$ 3,350.75	$ 2,414.16	$ 1,685.50	$ -	$ -	$ 11,499.77	$ 28,078.93	$ 203.70	$ 150.39
August	$ -	$ -	$ 4,842.06	$ 4,666.21	$ 3,048.78	$ 3,458.14	$ 2,206.12	$ 1,887.89	$ -	$ -	$ 11,499.77	$ 42,118.39	$ -	$ -
September	$ -	$ -	$ 13,393.57	$ 4,804.03	$ 3,492.41	$ 3,041.59	$ 3,545.99	$ 2,156.26	$ -	$ -	$ -	$ -	$ -	$ -
October	$ 300,200.18	$ 248,703.61	$ 13,256.39	$ 10,069.51	$ 2,550.59	$ 1,801.49	$ 3,113.41	$ 2,506.17	$ -	$ -	$ 25,443.45	$ 28,078.92	$ -	$ -
November														
December														
January														
February														
March														
April														
May														
ADA Adj.														
June														
Totals	$ 300,200.18	$ 248,703.61	$ 41,680.96	$ 26,754.83	$ 12,071.36	$ 11,651.97	$ 11,279.68	$ 8,235.82	$ -	$ -	$ 48,442.99	$ 98,276.24	$ 203.70	$ 150.39
Commission	$ 6,004.00	$ 4,974.07	$ 833.62	$ 535.10	$ 120.71	$ 116.52	$ 225.59	$ 164.72	$ -	$ -	$ 484.43	$ 982.76	$ 2.04	$ 1.50
Total Net	$ 294,196.18	$ 243,729.54	$ 40,847.34	$ 26,219.73	$ 11,950.65	$ 11,535.45	$ 11,054.09	$ 8,071.10	$ -	$ -	$ 47,958.56	$ 97,293.48	$ 201.66	$ 148.89
Difference		$ (51,496.57)		$ (14,926.13)		$ (419.39)		$ (3,043.86)		$ -		$ 49,833.25		$ (53.31)

	Sales Tax		Bank Excise Tax		Mixed Drink Tax		Statutory Local Tax		Marriage Licenses		Subtotal		2023-24% of	2024-25% of
	2023-2024	2024-2025	2023-2024	2024-2025	2023-2024	2024-2025	2023-2024	2024-2025	2023-2024	2024-2025	2023-2024	2024-2025	Actual	Actual
July	$ 454,782.19	$ 475,495.29	$ -	$ -	$ -	$ -	$ -	$ -	$ 102.50	$ 100.74	$ 482,170.84	$ 516,076.68	22.0%	22.5%
August	$ 462,239.10	$ 477,493.70	$ -	$ -	$ -	$ -	$ -	$ -	$ 65.89	$ 83.55	$ 483,901.72	$ 529,707.88	22.1%	23.1%
September	$ 437,371.98	$ 474,027.78	$ -	$ -	$ -	$ -	$ -	$ -	$ 90.29	$ 127.78	$ 457,894.24	$ 484,157.44	20.9%	21.1%
October	$ 419,680.05	$ 468,789.74	$ -	$ -	$ -	$ 4,274.59	$ -	$ -	$ 129.34	$ 144.97	$ 764,373.41	$ 764,369.00	34.9%	33.3%
November											$ -	$ -	0.0%	0.0%
December											$ -	$ -	0.0%	0.0%
January											$ -	$ -	0.0%	0.0%
February											$ -	$ -	0.0%	0.0%
March											$ -	$ -	0.0%	0.0%
April											$ -	$ -	0.0%	0.0%
May											$ -	$ -	0.0%	0.0%
ADA Adj.											$ -	$ -	0.0%	0.0%
June											$ -	$ -	0.0%	0.0%
Totals	$ 1,774,073.32	$ 1,895,806.51	$ -	$ -	$ -	$ 4,274.59	$ -	$ -	$ 388.02	$ 457.04	$ 2,188,340.21	$ 2,294,311.00		
Commission	$ 17,740.73	$ 18,958.07	$ -	$ -	$ -	$ 42.75	$ -	$ -	$ 3.88	$ 4.57	$ 25,415.01	$ 25,780.05		
Total Net	$ 1,756,332.59	$ 1,876,848.44	$ -	$ -	$ -	$ 4,231.84	$ -	$ -	$ 384.14	$ 452.47	$ 2,162,925.20	$ 2,268,530.95		
Difference		$ 121,733.19		$ -		$ 4,274.59		$ -		$ 69.02		$ 105,970.79		

Total budgeted projection for 2024 - 2025 is $ 9,090,072 The year-to-date collection of $ 2,268,531 is 25.0% of the total budgeted projection.

The amount collected year-to-date is $ 105,971 more than this time last year. (This amount does not reflect commission fees.)

Greeneville City Schools
Comparative Summary of Revenue Collections
For the Month Ended October 31, 2024

LOCAL REVENUE	2023-2024	2024-2025	Variance	Actual % Change
Property Tax	**$ 300,200.18**	**$ 248,703.61**	**$ (51,496.57)**	**-17.15%**
Property Tax - Prior Year	41,680.96	26,754.83	$ (14,926.13)	-35.81%
Clerk & Master	12,071.36	11,651.97	$ (419.39)	-3.47%
Interest & Penalty	11,279.68	8,235.82	$ (3,043.86)	-26.99%
Pick-Up Taxes	-	-	$ -	0.00%
In Lieu Of - Local Utility	48,442.99	98,276.24	$ 49,833.25	102.87%
In Lieu Of - Other	203.70	150.39	$ (53.31)	-26.17%
Sales Tax	**1,774,073.32**	**1,895,806.51**	**$ 121,733.19**	**6.86%**
Bank Excise Tax	-	-	$ -	0.00%
Mixed Drink Tax	-	4,274.59	$ 4,274.59	100.00%
Statutory Local Taxes	-	-	$ -	0.00%
Marriage Licenses	388.02	457.04	$ 69.02	17.79%
Totals	**$ 2,188,340.21**	**$ 2,294,311.00**	**$ 105,970.79**	**4.84%**

***Note:** Amounts reflected do not take into consideration commission fees. Property tax, Interest & Penalty and Pick-Up Tax commission fees are calculated at 2% of total collections, while all other categories are calculated at 1% of total collections.*

*** Total budgeted amount of local revenue attributable to the GTC is $567,916***

TISA REVENUE	2023-2024	2024-2025	Variance
July	$ 416,759.00	$ 498,328.00	$ 81,569.00
August	1,995,544.00	2,083,131.49	$ 87,587.49
September	1,995,544.43	2,083,131.48	$ 87,587.05
October	1,995,544.43	2,083,131.48	$ 87,587.05
November			$ -
December			$ -
January			$ -
February			$ -
March			$ -
April			$ -
May			$ -
June			$ -
Totals	**$ 6,403,391.86**	**$ 6,747,722.45**	**$ 344,330.59**

Greeneville City Schools
General Purpose Financial Report
For the Month of October 2024

Account #	Description	Month-to-Date	Year-to-Date	Total Budget	YTD % of Total Budget	
	REVENUE					
34760	Assigned for Instruction	$ -	$ -	328,632.00	0.0%	
34765	Assigned for Support Services	$ -	$ -	20,558.00	0.0%	
34785	Assigned for Capital Projects	$ -	$ -	115,767.00	0.0%	
34790	Assigned for Other Purposes	$ -	$ -	138,868.00	0.0%	
39000	Unassigned Fund Balance	$ -	$ -	402,883.00	0.0%	
40000	Local Taxes	$ 431,519.75	$ 1,363,551.02	8,521,151.00	16.0%	
41000	Marriage Licenses	$ 120.68	$ 290.77	1,005.00	28.9%	
43511	Tuition	$ 42,400.87	$ 389,111.36	748,335.00	52.0%	**(1)**
43570	Receipts from Individual Schools	$ 4,491.14	$ 29,022.59	164,650.00	17.6%	
44000	Other Local Revenue	$ 18,945.89	$ 80,819.77	139,318.00	58.0%	
46000	State Education Funds	$ 2,052,364.01	$ 6,350,534.39	20,950,205.00	30.3%	
47100	Federal Through State Grants	$ -	$ -	50,000.00	0.0%	
47590	Other Federal Funds (TEMA)	$ -	$ 13,113.71	-	N/A	
47600	Direct Federal Funds (ROTC)	$ 13,308.44	$ 19,962.66	55,493.00	36.0%	
49000	Operating Transfers & Insurance Recovery	$ 616,532.20	$ 1,193,727.40	6,088,874.00	19.6%	
	Total Revenues	**$ 3,179,682.98**	**$ 9,440,133.67**	**$ 37,725,739.00**	**25.0%**	
		MTD	**YTD**			
	EXPENDITURES					
71100	Regular Instruction	$ 1,557,366.46	$ 4,761,374.94	$ 17,335,043.00	27.5%	
71150	Alternative Instruction	14,358.71	46,028.28	158,722.00	29.0%	
71200	Special Education	219,405.75	680,430.14	2,795,651.00	24.3%	
71300	Vocational Education	47,215.18	161,760.48	695,450.00	23.3%	
71400	Student Body	-	120.00	500.00	24.0%	
72110	Attendance	7,201.32	31,250.58	126,838.00	24.6%	
72120	Health Services	33,861.41	127,888.09	489,984.00	26.1%	
72130	Other Student Support	105,068.50	341,637.70	1,589,121.00	21.5%	
72210	Regular Instruction Support	101,171.73	384,329.25	1,483,861.00	25.9%	
72220	Special Education Support	23,425.56	89,106.98	334,787.00	26.6%	
72230	Vocational Education Support	-	361.40	2,400.00	15.1%	
72250	Technology	59,454.37	304,682.69	1,178,593.00	25.9%	
72310	Board of Education	41,121.66	514,841.75	892,950.00	57.7%	**(2)**
72320	Office of Director	54,447.35	207,260.19	439,733.00	47.1%	
72410	Office of Principal	193,723.01	704,154.65	2,230,496.00	31.6%	
72510	Fiscal Services	33,139.40	121,931.75	387,084.00	31.5%	
72520	Human Resources	28,078.70	151,257.52	364,903.00	41.5%	**(3)**
72610	Operation of Plant	180,253.69	865,071.10	2,532,829.00	34.2%	**(3)**
72620	Maintenance of Plant	82,514.94	440,139.37	1,120,963.00	39.3%	**(3)**
72710	Transportation	81,078.96	290,691.31	1,257,682.00	23.1%	
73100	School Nutrition	1,371.96	1,371.96	-	N/A	
73300	Community Services	684.29	1,078.63	20,000.00	5.4%	
73400	Early Childhood Education	49,765.44	151,269.18	612,350.00	24.7%	
76100	Capital Outlay	2,500.00	257,306.49	835,767.00	30.8%	
81300	Education Debt Service	-	180,000.00	328,400.00	54.8%	
99100	Operating Transfers	21,245.60	63,736.80	511,632.00	12.5%	
	Total Expenditures	**$ 2,938,453.99**	**$ 10,879,081.23**	**$ 37,725,739.00**	**28.8%**	
	Net Revenue (Expense)	**$ 241,228.99**	**$ (1,438,947.56)**			

Explanation of Footnotes

(1) Tuition Count as of 12/03/2024 is 583 Students

(2) 2023-2024 Liability and Workers' Compensation Insurance Payments Reflected

(3) Reflects Routine Encumbrances for Liability Insurance Policies, Software, and Supplies

(4) Encumbrances Total $ 1,073,557

Greeneville City Schools
Federal Projects Financial Report
For the Month of October 2024

REVENUE	**Month-to-Date**	**Year-to-Date**	**Total Budget**	**YTD % of Total Budget**
Carl Perkins	$ -	$ -	$ 51,925.00	0.0%
Consolidated Administration	$ 11,807.36	$ 29,199.56	$ 113,250.00	25.8%
Title I-A	$ 21,750.28	$ 99,120.35	642,807.00	15.4%
Title I-A Neglected	$ 11,754.60	$ 11,754.60	70,528.00	16.7%
Title II-A	$ 6,876.67	$ 36,119.40	143,899.00	25.1%
Title III	$ -	$ 2,450.00	12,294.00	19.9%
Title IV	$ 3,737.29	$ 8,139.88	49,819.00	16.3%
21st Century	$ -	$ -	276,250.00	0.0%
Title V	$ 7,936.59	$ 14,731.05	92,026.00	16.0%
ARP Homeless	$ -	$ -	1,216.00	0.0%
IDEA Part B	$ 96,540.57	$ 167,154.56	709,247.00	23.6%
IDEA Pre-School	$ -	$ -	14,619.00	0.0%
ESSER 3.0	$ 50,618.45	$ 50,618.45	50,618.00	100.0%
Total Revenues	**$ 211,021.81**	**$ 419,287.85**	**$ 2,228,498.00**	**18.8%**

EXPENDITURES	***MTD***	***YTD***		
Carl Perkins	$ 271.22	$ 3,699.22	$ 51,925.00	7.1%
Consolidated Administration	$ 9,439.61	$ 38,639.17	$ 113,250.00	34.1%
Title I-A	$ 48,402.56	$ 147,558.88	642,807.00	23.0%
Title I-A Neglected	$ 5,877.30	$ 17,631.90	70,528.00	25.0%
Title II-A	$ 6,876.67	$ 42,996.07	143,899.00	29.9%
Title III	$ 192.29	$ 5,919.47	12,294.00	48.1%
Title IV	$ 3,737.29	$ 11,877.17	49,819.00	23.8%
21st Century	$ 22,394.78	$ 26,800.78	276,250.00	9.7%
Title V	$ 24,757.44	$ 39,488.49	92,026.00	42.9%
ARP Homeless	$ -	$ 1,215.80	1,216.00	100.0%
IDEA Part B	$ 78,739.52	$ 246,090.52	709,247.00	34.7%
IDEA Pre-School	$ -	$ -	14,619.00	0.0%
ESSER 3.0	$ 47,460.11	$ 50,618.45	50,618.00	100.0%
Total Expenditures	**$ 248,148.79**	**$ 632,535.92**	**$ 2,228,498.00**	**28.4%**
Net Revenue (Expense)	**$ (37,126.98)**	**$ (213,248.07)**	**$ -**	

***Encumbrances Total $43,965**

Greeneville City Schools
Greene Technology Center Financial Report
For the Month of October 2024

Account #	Description	Month-to-Date	Year-to-Date	Total Budget	YTD % of Total Budget	
	REVENUE					
39000	Unassigned Fund Balance	$ -	$ -	$ 86,688.00	0.0%	
40000	Local Taxes	56,784.50	170,353.50	567,845.00	30.0%	**(1)**
41000	Marriage Licenses	7.10	21.30	71.00	30.0%	**(1)**
43542	Contracts with Other LEAs (Greene County)	148,109.25	296,218.50	592,437.00	50.0%	**(2)**
44000	Other Local Revenue & Miscellaneous Refunds	5,825.00	16,116.70	39,888.00	40.4%	
46510	TISA	31,334.50	94,003.50	313,345.00	30.0%	**(1)**
49000	Operating Transfer (Grv City) & Insurance Recovery	21,245.60	63,736.80	213,956.00	29.8%	**(1)**
	Total Revenues	**$ 263,305.95**	**$ 640,450.30**	**$ 1,814,230.00**	**35.3%**	
	EXPENDITURES					
71300	Vocational Education	$ 73,669.88	$ 232,869.98	$ 935,073.00	24.9%	
72130	Other Student Support	7,605.95	23,692.70	91,908.00	25.8%	
72250	Technology	5,625.74	22,510.92	67,905.00	33.2%	
72310	Board of Education	4,228.32	83,305.49	133,885.00	62.2%	**(3)**
72410	Office of Principal	25,861.85	91,552.93	329,061.00	27.8%	
72610	Operation of Plant	14,433.93	75,647.21	233,402.00	32.4%	**(3)**
72620	Maintenance of Plant	1,561.39	8,540.56	22,996.00	37.1%	
76100	Capital Outlay	-	3,714.50	-	N/A	
	Total Expenditures	**$ 132,987.06**	**$ 541,834.29**	**$ 1,814,230.00**	**29.9%**	
	Net Revenue (Expense)	**$ 130,318.89**	**$ 98,616.01**			

Explanation of Footnotes

(1) Revenues Allocated to GTC are Paid in Equal Installments from GCS Over 9 Months- Beginning in August; Then Adjusted Per Actual Revenue for June

(2) Represents Total Amount Received From Greene County Schools

(3) Reflects cost of 2023-2024 Liability, Workers' Compensation, & Building and Grounds Insurance Payments

Encumbrances total $56,452

ATTORNEY-CLIENT FEE CONTRACT

The ATTORNEY-CLIENT FEE CONTRACT ("Agreement") is entered into by and between _____ ("Client" or "District") and Frantz Law Group, APLC ("Attorneys" or "We") and encompasses the following provisions:

1. CONDITIONS. This Agreement will not take effect, and Attorneys will have no obligation to provide legal services, until Client returns a signed copy of this Agreement.

2. AUTHORIZED REPRESENTATIVES

A. CLIENT REPRESENTATIVES. Client designates _____, or his/her designee, as the authorized representatives to direct Attorneys and to be the primary individual to communicate with Attorneys regarding the subject matter of Attorneys' representation of Client under this Agreement. The designation is intended to establish a clear line of authority and to minimize potential uncertainty but not to preclude communication between Attorneys and other representatives of Client.

B. ATTORNEY REPRESENTATIVES. James Frantz, William Shinoff and Regina Bagdasarian of Frantz Law Group, APLC will be primarily responsible for the work, either performing it himself/herself or delegating it to others as may be appropriate.

3. SCOPE AND DUTIES. Client hires Attorneys to provide legal services in connection with pursuing claims for damages associated with the Insulin pricing litigation, including the preparation and filing of the District's individual action, ("Action"). Attorneys shall provide those legal services reasonably required to represent Client and shall take reasonable steps to keep Client informed of progress and to respond to Client's inquiries. Client shall be truthful with Attorneys, cooperate with Attorneys, and keep Attorneys informed of developments.

4. FEES. Client will pay attorneys' fees of:

Thirty percent (30%) of any monetary settlement or recovery that Attorneys obtain for Client. Client is not responsible for paying Attorneys any money other than what has been recovered from Defendants

Fees shall be calculated on the basis of any settlement or recovery prior to the deduction of any expense or cost or common benefit fees; the "Gross Recovery." Contingency fee rates are not set by law but have been negotiated. If no recovery is

Initials _____

made, no fees will be charged.

The term "Gross Recovery" shall include, without limitation, the then present value of any monetary payments agreed or ordered to be made by the adverse parties or their insurance carriers as a result of the Services, whether by settlement, arbitration award, court judgment (after all appeals exhausted), or otherwise. Any statutory Attorneys' fee paid by Defendants shall be included in calculating the Gross Recovery, however, any such award of Attorneys' fees shall be proportionately applied as a credit against Client's obligation to pay its portion of the contingency fee amount and shall not be retained by the Attorneys as a separate payment in addition to the contingency fee.

(1) "Gross Recovery," if by settlement, also includes (1) the then-present value of any monetary payments to be made to the District; and (2) any Attorneys' fees and costs recovered by the District as part of any cause of action that provides a basis for such an award. "Recovery" may come from any source, including, but not limited to, the adverse parties to the District and/or their insurance carriers and/or any third party, whether or not a party to formal litigation. The contingent fee is calculated by multiplying the recovery by the fee percentage. This calculation is performed on the gross recovery amount before the deduction of expenses as discussed above.

Gross Recovery, except in the case of a settlement, does not contemplate nor include any amount or value for injunctive relief or for the value of an abatement remedy which may be obtained in a final arbitration award or court judgment.

(2) The District shall not be obligated to pay the Attorneys unless Attorneys are successful in collecting a monetary recovery on the District's behalf as a result of the Services.

A. Reasonable Fee if Contingent Fee is Unenforceable or if Attorney is Discharged Before Any Recovery. In the event that the contingent fee portion of this agreement is determined to be unenforceable for any reason or the Attorneys are prevented from representing Client on a contingent fee basis, Client agrees to pay a reasonable fee for the services rendered. If the parties are unable to agree on a reasonable fee for the services rendered, Attorneys and Client agree that the fee will be determined by arbitration proceedings before a mutually agreed upon neutral affiliated with either Signature Resolution; in any event, Attorney and Client agree that the fee determined by arbitration shall not exceed thirty percent (30%) of the gross recovery as defined in paragraph 5.

B. No General Fund Payments. Notwithstanding any other provision in this agreement, in no event will the Client be required to pay legal fees out of any fund other than the monies recovered from Defendants in this litigation. Under no circumstances shall School District general funds be obligated to satisfy the contingent Attorneys' fees as a result of this case or this contingency fee

Initials _____

contract.

6. COSTS AND EXPENSES. In addition to paying legal fees, Client shall reimburse Attorneys for all "costs/expenses", which includes but is not limited to the following: process servers' fees, fees fixed by law or assessed by courts or other agencies, court reporters' fees, long distance telephone calls, messenger and other delivery fees, parking, investigation expenses, consultants' fees, expert witness fees, and other similar items, incurred by Attorneys. Other costs and expenses include case management computer services, Document Management Services, case administration/accounting fees and costs, outside attorney services and other similar items. ATTORNEYS may find it necessary and/or in the CLIENT(S)' best interests to obtain the services of legal, clerical, and/or other personnel who are not ATTORNEYS regular employees, but outside independent contractors. The costs/expenses incurred that Attorneys advance will be owed in addition to attorneys' fees and Client will reimburse those costs/expenses after Attorneys' fees have been deducted. If there is no recovery, Client will not be required to reimburse Attorneys for costs and fees. In the event a recovery is less than incurred costs/expenses, Client will not be required to reimburse Attorneys for costs/expenses, above and beyond the recovery, and fees.

SHARED EXPENSES: Client understands that Attorneys may incur certain expenses that jointly benefit multiple clients, including, for example, expenses for travel, experts, and copying. Client agrees that Attorneys shall divide such expenses equally, or pro rata, among such clients, and deduct Client's portion of those expenses from Client's share of any recovery.

FEDERAL MDL COMMON BENEFIT FEES:
Various Attorneys, including Frantz Law Group, frequently serve on plaintiffs' steering or executive committees in Multi-District Litigations (MDLs) and perform work which benefits Attorneys' clients as well as clients of other attorneys involved in the same litigation. As a result, the court or courts where the cases are pending may order that Attorneys are to receive additional compensation for Attorneys time and effort which has benefitted all claimants. Compensation for this work and effort, which is known as "common benefit fees," may be awarded to Attorneys by a court or courts directly from the assessments paid by The District and others who have filed claims in this litigation. Court orders a 5% common benefit fee assessment for your claims, we will reduce our contingency fee to 25%

5. LIEN. In the event any third party attempts to lien any proceeds recovered from a recovery in this matter, Client hereby grants, and agrees, TO THE EXTENT PERMITTED BY APPLICABLE LAW, that Attorneys hold, a first priority and superior lien on any and all proceeds recovered from Defendants in this litigation in the amount of the Attorneys' fees and costs that the Attorneys are entitled to under this Agreement. This lien right is limited to only those monies recovered from Defendants and in no way affects any other rights of the Client in any way whatsoever.

Initials _____

6. DISCHARGE AND WITHDRAWAL.

A. Client may discharge Attorneys at any time. After receiving notice of discharge, Attorneys shall stop services on the date and to the extent specified by the notice of discharge, and deliver to Client all evidence, files and attorney work product for the Action. This includes any computerized indices, programs and document retrieval systems created or used for the Action.

B. Attorneys may withdraw with Client's consent or for good cause. Good Cause includes Client's breach of this Agreement, Client's refusal to cooperate with Attorneys, or any other fact or circumstance that would render Attorneys continuing representation unlawful or unethical. Attorneys may also discharge Client if Client at any time is dishonest with Attorneys or fails to provide relevant information to Attorneys.

7. ARBITRATION OF DISPUTES: ATTORNEY and CLIENT agree that should any Dispute arise between them, it must be mediated first, before any claims are filed. Specifically any and all disputes, controversies or claims arising out of, or related to this Agreement and/or ATTORNEY'S representation of CLIENT, including claims of malpractice (collectively referred to herein as "Dispute" or "Disputes"), shall be submitted to mediation at the offices of Signature Resolution at the location closest to the Client or at another mutually acceptable location before a retired judge or other mediator, agreed to between the parties and, if the parties cannot agree, before a retired judge selected by Signature Resolution. No petition for arbitration can be filed until after this agreed-upon mediation has occurred, and any petition for arbitration (or litigation) filed prior to conclusion of this mediation shall be subject to dismissal, pursuant to this Agreement. Client will pay one-half of the actual cost of the mediation, but each party will be responsible for his or her own attorneys' fees and preparation costs. The parties agree that any Dispute, whether submitted to mediation or not, will not be litigated in court. Rather, any Dispute, which is specifically defined above to include claims of malpractice, will be submitted to mandatory binding arbitration before Signature Resolution. By signing this Agreement, CLIENT and ATTORNEY agree to arbitration and waive the right to a court or jury trial and the right to appeal. Any Disputes shall be decided in at the Signature Resolution location closest to the Client or at such other mutually acceptable location, applying California law.

8. AUTHORITY OF ATTORNEY. Attorneys may, with prior Client approval, associate co-counsel if the Attorneys believe it advisable or necessary for the proper handling of Client's claim, and expressly authorize the Attorneys to divide any Attorneys' fees that may eventually be earned with co-counsel so associated for the handling of Client's claim. Attorneys understand that the amount of Attorneys' fees which Client pays will not be increased by the work of co-counsel associated to assist with the handling of Client's claim, and that such associated co-counsel will be paid by the Attorneys out of the Attorneys' fees Client pays to the Attorneys.

Initials _____

9. DISCLAIMER OF GUARANTEE. Nothing in this Contract and nothing in Attorneys' statements to Client will be construed as a promise or guarantee about the outcome of Client's matter. Attorneys make no such promises or guarantees. Attorneys' comments about the outcome of Client's matter are expressions of opinion only.

10. MULTIPLE REPRESENTATIONS: The District understands that Attorneys do or may represent many other individuals/entities with actual or potential litigation claims. Attorneys' representation of multiple claimants at the same time may create certain actual or potential conflicts of interest in that the interests and objectives of each client individually on certain issues are, or may become, inconsistent with the interests and objectives of the other. Attorneys are governed by specific rules and regulations relating to Attorneys professional responsibility in Attorneys representation of clients, and especially where conflicts of interest may arise from Attorneys representation of multiple clients against the same or similar Defendants, Attorneys are required to advise Attorneys' clients of any actual or potential conflicts of interest and obtain their informed written consent to Attorneys representation when actual, present, or potential conflicts of interest exist. By signing this agreement, The District is acknowledging that they have been advised of the potential conflicts of interest which may be or are associated with Attorneys representation of The District and other multiple claimants and that The District nevertheless wants the Attorneys to represent The District, and that The District consents to Attorneys representation of others in connection with the litigation. Attorneys strongly advise The District, however, that The District remains completely free to seek other legal advice at any time even after The District signs this agreement.

11. AGGREGATE SETTLEMENTS: Often times in cases where Attorneys represent multiple clients in similar litigation, the opposing parties or Defendants attempt to settle or otherwise resolve Attorneys' cases in a group or groups, by making a single settlement offer to settle a number of cases simultaneously. There exists a potential conflict of interest whenever a lawyer represents multiple clients in a settlement of this type because it necessitates choices concerning the allocation of limited settlement amounts among the multiple clients. However, a group settlement can be accomplished and a single offer can be fairly distributed among the clients by utilizing a neutral to assign settlement amounts based upon the strengths and weaknesses of each case, the relative nature, severity and extent of injuries, and individual case evaluations. In the event of a group or aggregate settlement proposal, Attorneys may implement a settlement program, overseen by a referee or special master, who may be appointed by a court, designed to ensure consistency and fairness for all claimants, and which will assign various settlement values and amounts to each client's case depending upon the facts and circumstances of each individual case. The District authorizes us to enter into and engage in group settlement discussions and agreements which may include The District's individual claims. Although The District authorizes us to engage in such group settlement discussions and agreements, The District will still retain the right to approve, and

Initials _____

Attorneys are required to obtain The District's approval of, any settlement of The District's case.

12. EFFECTIVE DATE AND TERM. This Agreement will take effect upon execution by District and Attorneys.

13. COUNTERPARTS. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which, taken together, shall constitute one and the same instrument. Facsimile or pdf versions of this Agreement shall have the same force and effect as signature of the original.

The above is approved and agreed upon by all parties.

[SIGNATURE PAGE FOLLOWS]

Initials _____

Dated: _____

_____
Print Name:
Frantz Law Group, APLC

Dated: _____

_____
Client Representative

_____ _____

Initials _____

INSULIN PRICING SCHEME LITIGATION

DIABETES IS AN EPIDEMIC

- Over 34.2 million people (10.5% of the U.S. Population) have diabetes and over 88 million people have prediabetes.
- Diabetes is the seventh leading cause of death in the country, despite the availability of effective treatment.
- Diabetes is the underlying cause of death of approximately 275,000 Americans per year.

INSULIN IS A NECESSITY

- Due to the prevalence and severity of diabetes, insulin is a necessary, life-saving medicine.
- More than 7 million people per day require insulin.

PRICE OF INSULIN ARE ARTIFICIALLY AND EXCESSIVELY HIGH

- Insulin Manufacturers and pharmacy benefit managers (PBMs) have artificially inflated the price of insulin at the expense of self-funded health plans and their members and beneficiaries.

INSULIN & ITS RISING COST

Insulin was discovered in 1921 and was harvested from animals until 1978 when the first biosynthetic human insulin was developed. Humulin, the first biosynthetic human insulin product, was reviewed and approved by the FDA on October 28, 1982. Additionally, very few scientific advances in insulin have occurred since the 1980s.

Despite the prominence of the disease and the longunderstood treatment with insulin, the costs associated with diabetes treatment in the United States are exceedingly high. A 2022 Yale study found that 14% of insulin users, approximately 1.2 million people, in the United States face "catastrophic" levels of spending on insulin, meaning they spent at least 40% of their post-subsistence income on insulin.

The over-pricing of insulin has led to countless articles, exposés, documentaries, and even congressional investigations all highlighting the gravity of the problem and its causes. The insulin manufacturers and PBMs' pricing scheme has exacerbated this epidemic, costing millions of dollars to organizations just like you.

DEFENDANTS & THEIR LIABILITY

Manufacturers

- Eli Lilly

- Novo Nordisk
- Sanofi

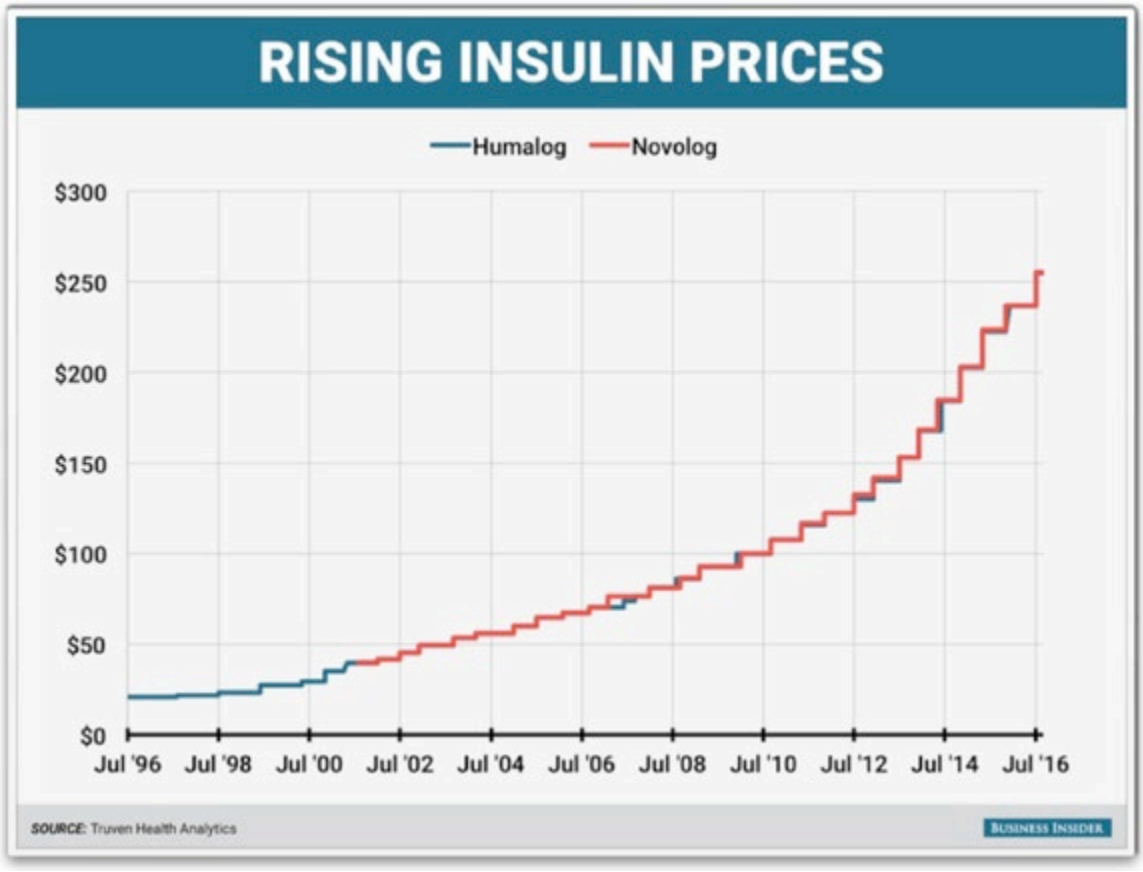
PBMs

- Express Scripts
- CVS Caremark
- Optum Rx

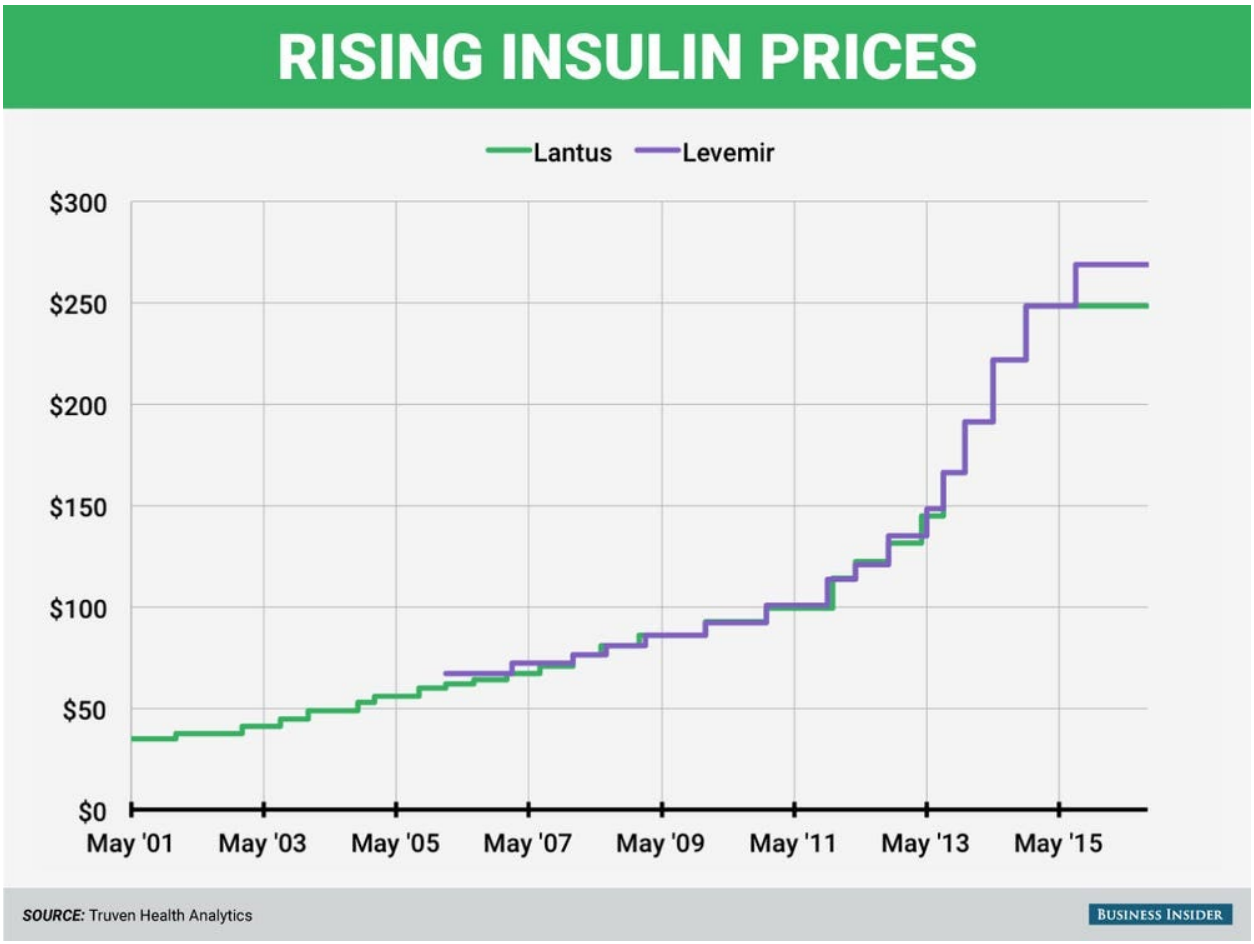
Liability

Insulin prices have skyrocketed over the past 20 years, despite the drug being over 100 years old, decreased manufacturing costs, and minimal innovations regarding the drug since its initial formulation. Since 2003, the list price of certain insulins has increased by more than 1000%, greatly outpacing the inflation rate for consumer goods and services.

Humalog (Eli Lilly) and Novalog (Nova Nordisk) Price Increases



Lantus (Sanofi) Price Increase



WHY THE SKYROCKETING PRICES?

Even though prices have increased dramatically, the production costs of insulin have decreased with efficiency and optimized processes. A September 2018 study found that a reasonable price of a year's supply of human insulin, based on production costs, should be $48 to $71 per person, which would still deliver generous profits to manufacturers. Another study found that manufacturers could be profitable charging less than $2 per vial for insulin. However, the average diabetic spent $5,705 on insulin in 2016.

What about research? There have been minimal innovations to insulin since the 1990s. Manufacturers have invested only a small fraction of their outsized profits on research and development and the investments they have made have largely been on delivery devices rather than drug formulations. For example, Eli Lilly spent $395 million on R&D between 2014 and 2018. During that time, Eli Lilly spent $1.5 billion on sales and marketing for insulin and generated $22.4 billion in revenue from its insulin line. Similarly, Sanofi reported net sales of nearly $37 billion for its insulin products while only investing $902 million on insulin R&D.

All of this begs the question: why have insulin prices increased so much? The answer is simple: greed.

HOW DOES THIS PRICING SCHEME WORK?

The insulin pricing scheme is based on two separate but related illegal activities:

- PBMs demand large, secret, and ever growing "rebates" and other payments for preferred formulary placement, leading to increased prices for payors and plan members.
- Manufacturers increase their insulin prices in lockstep to accommodate larger rebates and maintain access to lucrative placements on PBMs' standard formularies.

INSULIN MARKET DOMINATION

- **3 PBMS control 89% of the PBM Market**
  - Express Scripts
  - CVS Caremark
  - Optum RX
- **3 Manufacturers control 99% of the Insulin market by value and 96% by volume**
  - Novo Nordisk
  - Eli Lilly
  - Sanofi

EFFECT OF FRAUDULENT SCHEME

- Community Impact
- Public Entity Health Plan Impact
- Public Entity/ Purchaser Impact

CAUSES OF ACTION

This misconduct by insulin manufacturers and PBMs gives rise to several legal claims. As we have done with existing clients, we would bring claims on your behalf for violations of RICO, deceptive and unfair trade practices, and for unjust enrichment. Through these claims, we will demand money damages and disgorgement for the excessive insulin prices you have paid in the past and we will seek to ensure that those rates are not charged to you in the future.

RICO (Racketeer Influenced and Corrupt Organizations Act)

Insulin manufacturers and PBMs have colluded in an effort to artificially increase insulin prices to achieve profits far exceeding the fair market value of the drugs and the services the PBMs provided. The federal RICO statute is an ideal vehicle to ensure they are collectively held accountable for the harm they have caused. The misconduct also supports a claim for civil conspiracy, which typically requires evidence similar to the evidence supporting a RICO claim.

Unfair and/or Deceptive Trade Practices

In collaborating to artificially and excessively inflate the price of insulin, the insulin manufacturers and PBMs engaged in unfair and deceptive trade practices that are actionable in most States. PBMs misled payors regarding the fair market price for diabetes medications and concealed their agreements with insulin manufacturers and company-owned pharmacies while skimming profits that rightfully should have been passed along to payors.

Unjust Enrichment

This claim seeks reimbursement of monies paid over to the PBMs and manufacturers that rightfully should have remained in payors' pockets. The PBMs and manufacturers unjustly obtained monies through the insulin pricing scheme and they should not be permitted to retain them. Your overpayments should be returned to you

POTENTIAL REMEDIES

The claims described above will seek significant equitable and monetary relief. Potential remedies include:

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Insulin Pricing Scheme Lawsuit
MDL No. 3080
United States District Court District of New Jersey

Frantz Law Group, APLC







DIABETES IS AN EPIDEMIC

- Over 34.2 million people (10.5% of the U.S. Population) have diabetes and over 88 million people have prediabetes.
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- Due to the prevalence and severity of diabetes, insulin is a necessary, life-saving medicine.
- More than 7 million people per day require insulin.

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- Insulin Manufacturers and Pharmacy Benefit Managers (PBMs) have artificially inflated the price of insulin at the expense of self-funded health plans and their members and beneficiaries.

Insulin and its rising cost

- Insulin was discovered in 1921 and was harvested from until 1978 when the first biosynthetic human insulin was developed. Humulin, was the first biosynthetic human insulin product, was reviewed and approved by the FDA in October 1982.
- Despite the prominence of the disease and long understood treatment with insulin, the costs associated with diabetes treatment in the United States are exceedingly high.
- A 2022 Yale study found that 14% of insulin users, approximately 1.2 million people, in the United States face “catastrophic” levels of spending on insulin, meaning they spent at least 40% of their post-subsistence income on insulin.
- The over-pricing of insulin has lead to congressional investigations all highlighting the gravity of the problem and its causes.
- The insulin manufacturers and PBMs’ pricing scheme has exacerbated this epidemic, costing millions of dollars to organizations like yours.

United States Senate
Senate Finance Committee

Charles E. Grassley, Chairman
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Insulin:

Examining the Factors Driving the Rising Cost of a Century Old Drug

Staff Report

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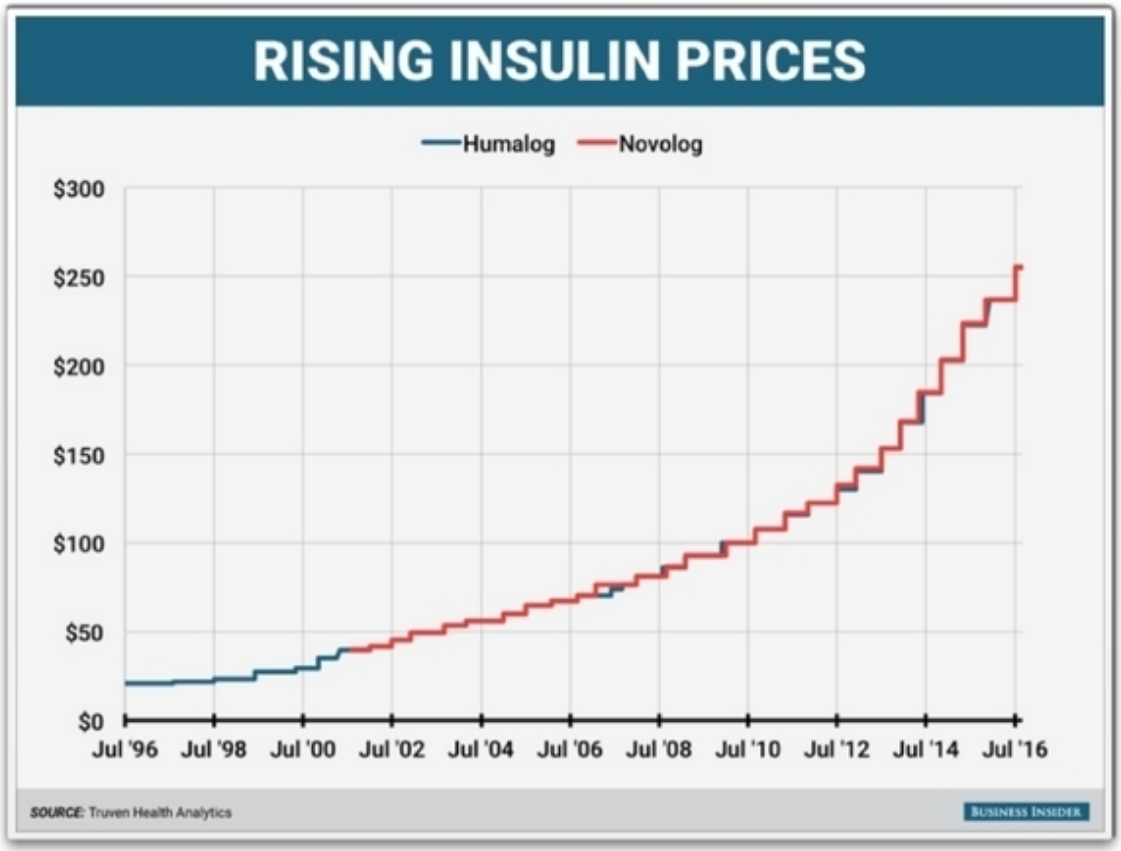
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- PBMs
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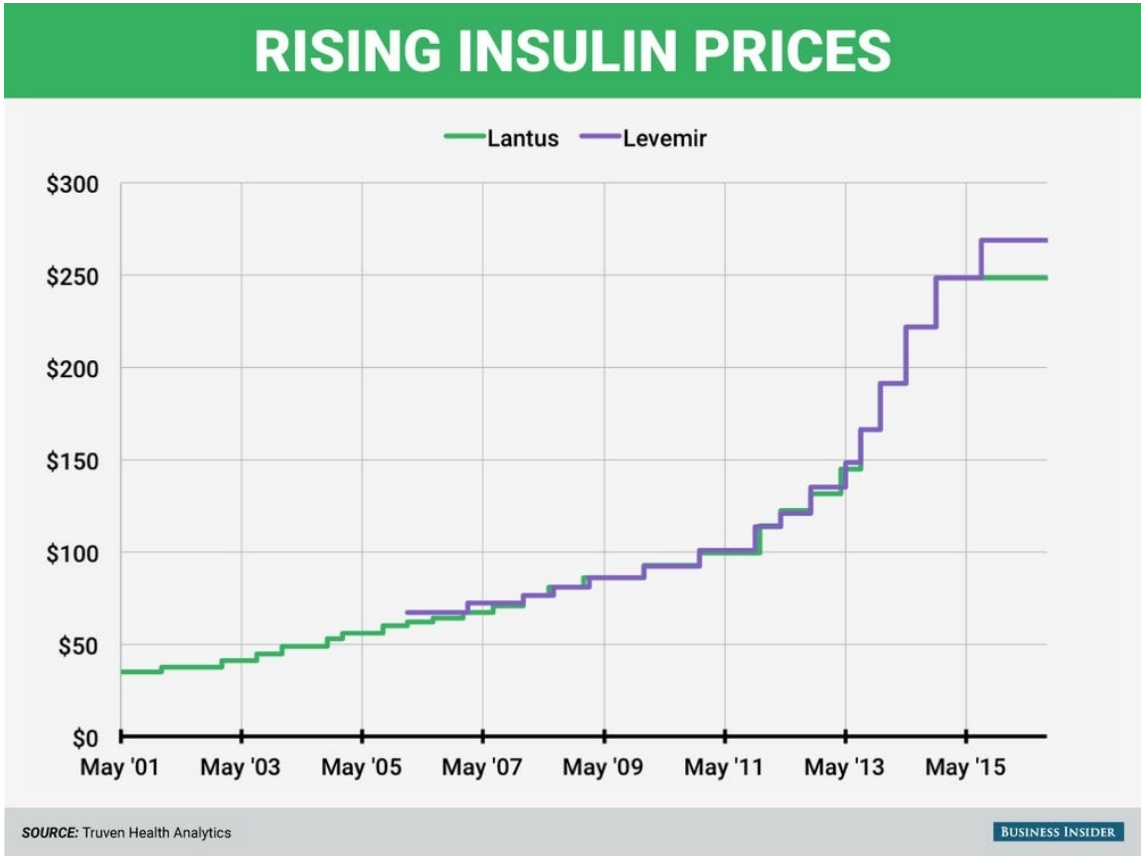
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- Insulin prices have skyrocketed over the past 20 years, despite the drug being over 100 years old, decreased manufacturing costs, and minimal innovations regarding the drug since its initial formulation.
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Why the skyrocketing prices?

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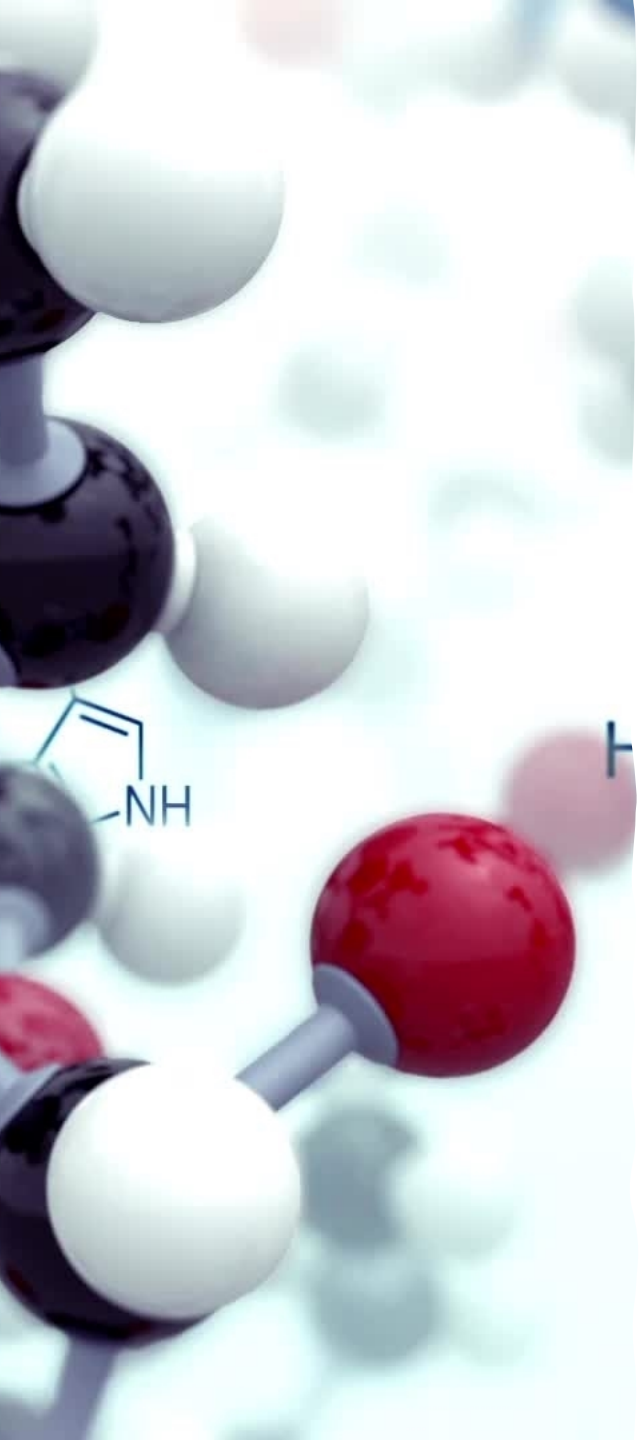
Why the skyrocketing Prices (cont.)

- There have been minimal innovations to insulin since the 1990s. Manufacturers have invested only a small fraction of their outsized profits on research and development and the investments they have made have largely been on delivery devices rather than drug formulations.
- For example, Eli Lilly spent $395 million on R&D between 2014 and 2018. During that time, Eli Lilly spent $1.5 billion on sales and marketing for insulin and generated $22.4 billion in revenue from its insulin line.
- Similarly, Sanofi reported net sales of nearly $37 billion for its insulin products while only investing $902 million on insulin R&D.
- All of this begs the question: why have insulin prices increased so much? The answer is simple: greed.



How does this pricing scheme work?

- The insulin pricing scheme is based on two separate but related illegal activities:
  - PBMs demand large, secret, and ever growing “rebates” and other payments for preferred formulary placement, leading to increased prices for payors and plan members.
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Insulin Market Domination

- **3 PBMS control 89% of the PBM Market**
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Effect of the Fraudulent Scheme



COMMUNITY IMPACT



PUBLIC ENTITY HEALTH PLAN IMPACT



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RICO (Racketeer Influenced and Corrupt Organization Act)

- Insulin manufacturers and PBMs have colluded in an effort to artificially increase insulin prices to achieve profits far exceeding the fair market value of the drugs and the services the PBMs provided. The federal RICO statute is an ideal vehicle to ensure they are collectively held accountable for the harm they have caused. The misconduct also supports a claim for civil conspiracy, which typically requires evidence similar to the evidence supporting a RICO claim.

Unfair and/or Deceptive Trade Practices

- In collaborating to artificially and excessively inflate the price of insulin, the insulin manufacturers and PBMs engaged in unfair and deceptive trade practices that are actionable in most States. PBMs misled payors regarding the fair market price for diabetes medications and concealed their agreements with insulin manufacturers and company-owned pharmacies while skimming profits that rightfully should have been passed along to payors.

Legal Causes of Action (cont.)

- **Unjust Enrichment**
  - This claim seeks reimbursement of monies paid over to the PBMs and manufacturers that rightfully should have remained in payors' pockets. The PBMs and manufacturers unjustly obtained monies through the insulin pricing scheme and they should not be permitted to retain them. Your overpayments should be returned to you

Potential Remedies

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- James P. Frantz's 43 years of legal experience includes litigating catastrophic injury claims, tractor-trailer collisions, amusement park accidents, products liability, motorcycle and automobile collisions, aviation accidents, fire and explosion related injuries, wrongful death claims, mass transit accidents, construction accidents, industrial accidents, complex business disputes, class actions, and mass torts. Mr. Frantz currently serves on the Plaintiffs' Steering Committee for the Porter Ranch Gas Leak litigation (one of the largest mass tort lawsuits in U.S. history), as well as the Plaintiffs' Steering Committee in the wildfire litigation against Pacific Gas & Electric (PG&E) and Southern California Edison (SCE).

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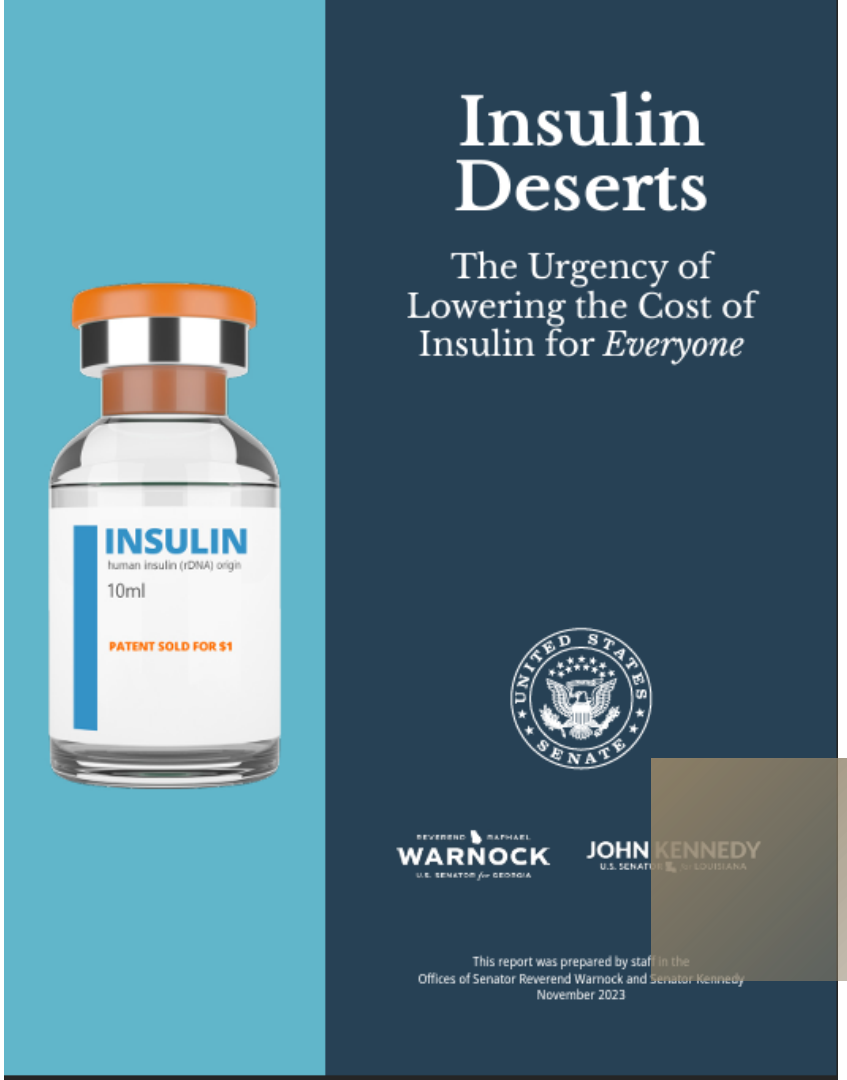
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SENATE INVESTIGATION



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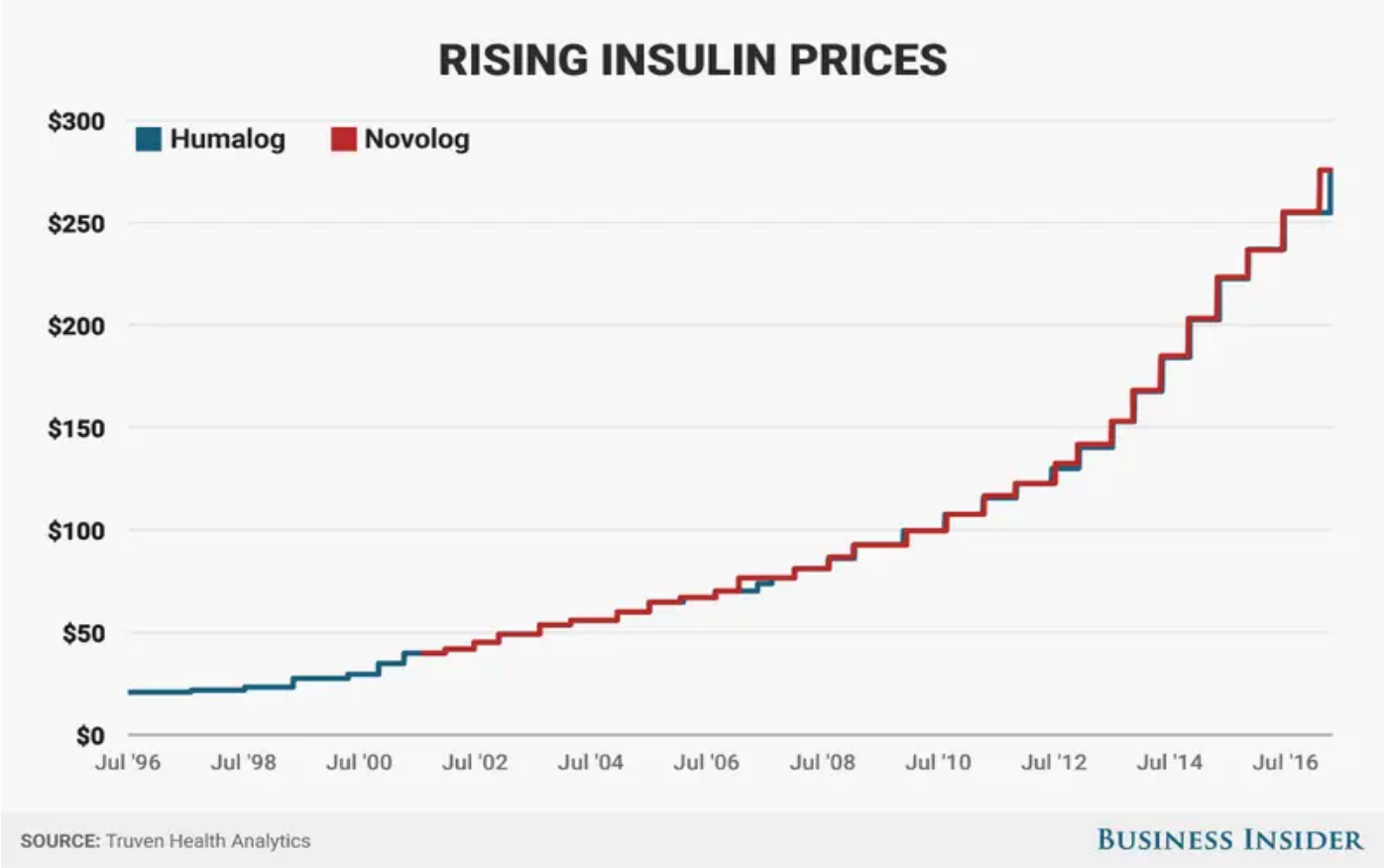


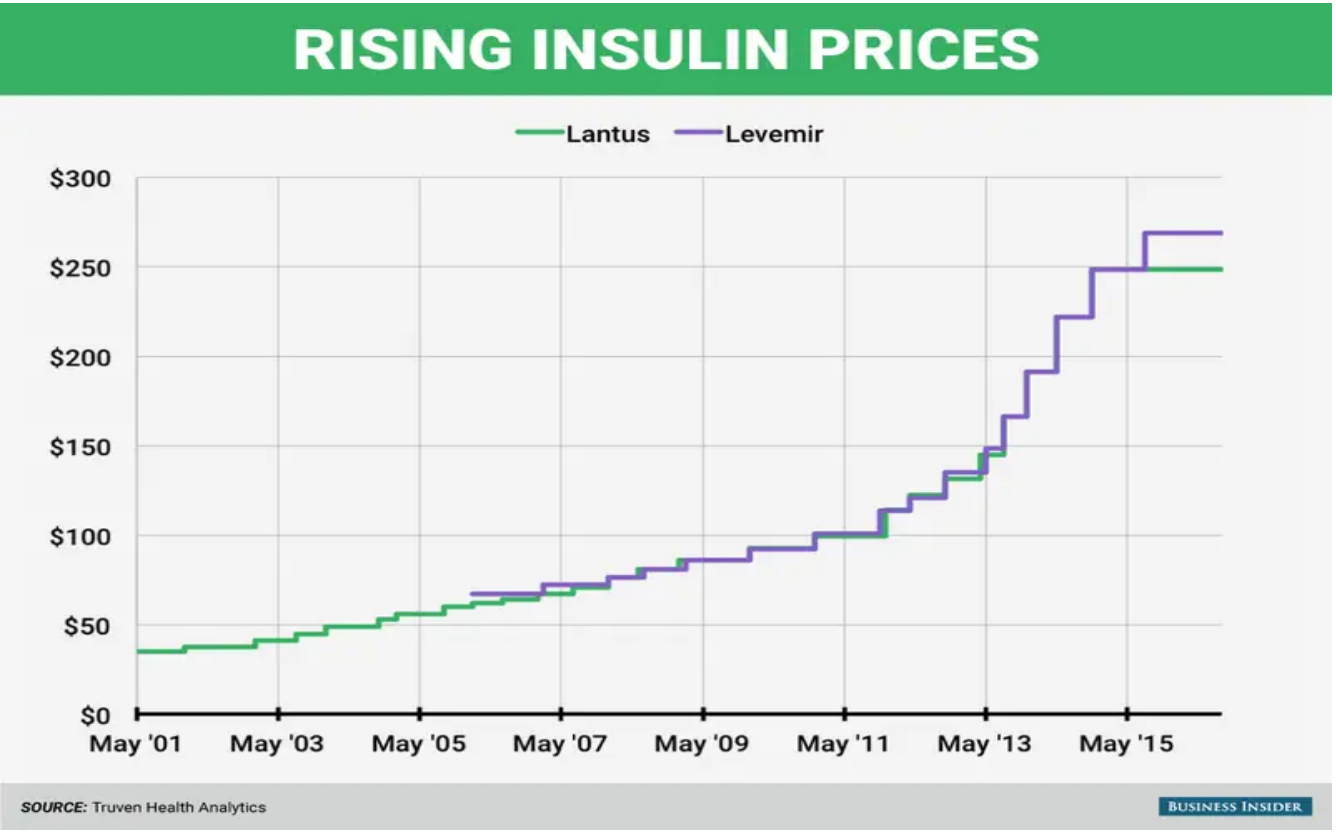
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Ron Wyden, Ranking Member

Insulin:

Examining the Factors Driving the Rising Cost of a Century Old Drug

Staff Report

Table of Contents

I. Introduction 4

II. Key Findings 6

a. Diabetes: The Disease 11

b. How the High Cost of Insulin Negatively Affects Individuals with Diabetes 13

II. Examining the Flow of Goods and Money in the U.S. Pharmaceutical Supply Chain . 15

a. Drug Manufacturers 16

i. Research & Development, Sales & Marketing 17

b. Wholesale Distributors and Pharmacies 23

c. Health Insurance 24

i. Medicare Part D 25

ii. Medicaid Drug Rebate Program 27

iii. Employer-sponsored health insurance 28

d. The PBM Industry 28

i. Formulary Development Process 34

ii. Rebates, Discounts, and Other Fees 38

III. The Cost of Insulin to Patients, Medicare, and Private Payers 41

a. Insulin List and Net Price Trends: 2013 to 2019 42

b. Medicare Part D's Pre-Rebate Spending on Insulin has Risen Steadily Since 2010 46

c. Patient Out-of-Pocket Spending in Medicare Part D 48

d. A Case Study: Examining Sanofi and Novo Nordisk's Decision to Implement Aggressive List Price Increases and the Impact on the Long-acting Insulin Market 49

i. In 2014, Novo Nordisk Engaged in Shadow Pricing to Respond to Sanofi's 2013 Pricing Actions 52

ii. In 2015, Novo Nordisk Ended its Shadow Pricing Strategy to Set Up a New Basal Insulin Therapy, Tresiba 56

iii. In 2017 and 2018, Novo Nordisk Resumed Shadow Pricing to Respond to Sanofi's Pricing Actions 59

iv. In 2018, Novo Nordisk Discussed List Price Decreases after Feeling Outside Pressure 61

e. Beyond Long-Acting Insulin: Companies Used Shadow Pricing Across Multiple Product Lines 63

IV. Rebates, Administrative Fees and Other Common Contract Provisions Related to Insulin WAC and Other Therapies 65

a. Rebates for Insulins Have Increased Exponentially Since 2013 66

i. Rebates Vary Widely by Payer 69
b. PBM Contracting Practices May Contribute to High Rebates and High List Prices in the Insulin Therapeutic Class 70
i. Use of Exclusion Lists 71
ii. Administrative Fees 80
iii. Price Protection Clauses 84
V. Conclusion 88
Appendix 90

I. Introduction

On January 22, 2019, Chairman Grassley and Ranking Member Wyden sent a letter to Sanofi, Eli Lilly, and Novo Nordisk requesting information relating to the process by which they price their insulin products.[1] A few months later, on April 2, 2019, Chairman Grassley and Ranking Member Wyden sent letters to CVS Caremark, OptumRx, and Express Scripts requesting information about how their role within the insulin market impacts the cost of insulin drugs.[2] These letters began the Chairman's and Ranking Member's insulin investigation. This investigation aimed to shed light on how drug manufacturers price insulin medication, the role played by pharmacy benefit managers (PBMs), and the financial and contractual relationships between these entities.

Relatively little is publicly known about these financial relationships and the impact they have on insulin costs borne by consumers, even though PBMs play a major role in the drug supply and payment chain by negotiating drug rebates and discounts with manufacturers and managing drug benefits for health care payers, including private insurers, employers, and entities that provide coverage under Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). The Senate Finance Committee has jurisdiction over these Federal health care programs and thus has an obligation to inform other members of Congress and the public of these interactions and how they affect drug prices.

This investigation builds on work that Chairman Grassley and Ranking Member Wyden have conducted in recent years to shed light into the prescription drug supply chain, and their joint and individual efforts to bring accountability to those responsible for rising drug prices.[3] For almost two years, investigative staff reviewed more than 100,000 pages of internal company documents produced by Sanofi, Novo Nordisk, Eli Lilly, CVS Caremark, Express Scripts,

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[1] Press release, Grassley, Wyden Launch Bipartisan Investigation into Insulin Prices (Feb. 22, 2019), https://www.grassley.senate.gov/news/news-releases/grassley-wyden-launch-bipartisan-investigation-insulin-prices.

[2] Press release, Grassley, Wyden Question Role of Middlemen in Skyrocketing Insulin Prices (Apr. 2, 2019), https://www.grassley.senate.gov/news/news-releases/grassley-wyden-question-role-middlemen-skyrocketing-insulin-prices.

[3] In 2015, Ranking Member Wyden and Senator Grassley, who was then-Chairman of the Senate Judiciary Committee, released the findings of an 18-month long investigation into the pricing of Sovaldi and Harvoni, new "blockbuster" hepatitis C therapies whose price caused an international uproar. *See* Press release, Wyden-Grassley Solvaldi Investigation Finds Revenue-Driven Pricing Strategy Behind $84,000 Hepatitis Drug (Dec. 2015), https://www.finance.senate.gov/ranking-members-news/wyden-grassley-sovaldi-investigation-finds-revenue-driven-pricing-strategy-behind-84-000-hepatitis-drug. In 2018, Ranking Member Wyden released a report detailing a year-long Minority staff investigation that used public documents to explain the path that a prescription drug takes from the lab bench to the medicine cabinet or doctor's office. *See* Press Release, Wyden Releases Report on High Drug Prices in Medicare (June 2018), https://www.finance.senate.gov/ranking-members-news/wyden-releases-report-on-high-drug-prices-in-medicare. In 2019, the Senate Finance Committee held three hearings on drug pricing, bringing executives from drug companies and PBMs to testify before Congress and released the Prescription Drug Price Reduction Act (PDPRA) of 2019 in an effort to shed light on drug manufacturers pricing practices and bring down drug costs for seniors. In 2020, Chairman Grassley and Ranking Member Wyden released a bipartisan report to Finance Committee colleagues detailing how opioid manufacturers use tax-exempt organizations as extensions of their sales and marketing strategy. *See* Press release, Grassley, Wyden Call for Greater Drug Industry Transparency in Report Exposing Opioid Makers' Ties to Tax-Exempt Groups (Dec. 2020), https://www.finance.senate.gov/chairmans-news/grassley-wyden-call-for-greater-drug-industry-transparency-in-report-exposing-opioid-makers-ties-to-tax-exempt-groups.

OptumRx as well as documents and data produced by the Centers for Medicare and Medicaid Services (CMS). Investigative staff also met with experts with knowledge of the United States' drug pricing system and interviewed individuals within OptumRx and Express Scripts who have direct knowledge of how insulin is priced within their respective companies.

Information and documents collected during the course of this investigation suggest that a combination of factors contributed to consumers facing higher costs for insulin over the last 15 years. First and foremost, pharmaceutical manufacturers have complete control over setting the list price (the Wholesale Acquisition Cost (WAC)) for their products. This investigation found that manufacturers aggressively raised the WAC of their insulin products absent significant advances in the efficacy of the drugs.[4] These price increases appear to have been driven, in part, by tactics PBMs employed in the early 2010s. At that time, PBMs began to more aggressively pit manufacturers against each other by implementing formulary exclusions in the insulin therapeutic class, which effectively stopped manufacturers from reaching large blocks of patients. While insulin manufacturers had been increasing prices for their products prior to formulary exclusions being employed, this tactic appears to have been more effective in boosting the size of rebates than suppressing the upward march of WAC prices. As a result, pharmaceutical manufacturers continued to raise WAC prices aggressively—increases that were often closely timed with price changes made by competitors (a practice that has been referred to as "shadow pricing").

The Finance Committee found that drug manufacturers increased insulins' WAC in part to give them room to offer larger rebates to PBMs and health insurers, all in the hopes that their product would receive preferred formulary placement. This pricing strategy translated into higher sales volumes and revenue for manufacturers. In some cases, manufacturers appear to have been concerned that decreasing WAC prices would be viewed negatively by PBMs, since PBMs capture a portion of rebate revenue and are also paid administrative fees based on a percentage of WAC.

This report describes how Sanofi, Novo Nordisk, and Eli Lilly set the price for their insulin drugs and how those decisions were affected not only by their competitors' pricing decisions, but also by their perceived need to offer large rebates, discounts, and other fees to PBMs such as CVS Caremark, OptumRx and Express Scripts and other payers. In addition, this report also discusses and analyzes the financial and budgetary impacts of insulin on both private and public payers, including Medicare and Medicaid. Lastly, this report discusses and analyzes rebate agreements executed between manufacturers and PBMs, and seeks to shed light on the role PBMs play in the U.S. drug pricing system.

[4] Insulin manufacturers appear to focus their R&D efforts on new insulin-related devices, equipment, and other mechanical parts which are separate from insulin's formulation. For example, in response to the Committee's request for information, Sanofi listed all patents received by the company since January 1, 2014. Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019). Most, if not all, of these are patents for pen-type injectors or drive mechanisms used in drug delivery devices. (Sanofi's patent on insulin expired in 2014, paving the way for others to utilize Sanofi's insulin glargine formulation). This suggests that manufacturers' R&D spending is primarily focused on insulin-related devices, rather than insulin itself.

II. Key Findings

1. **The WAC prices of long- and short-acting insulins have risen steeply.** Sanofi's long-acting insulin pens, Lantus SoloStar, increased from $303 in 2014 to $404 in 2019. The WAC price of Novo Nordisk's long-acting insulin pens, Levemir FlexTouch, increased from $303 in May 2014 to approximately $462 in January 2019, representing an increase of $159—or 52%— in a little more than five years. Eli Lilly's rapid-acting insulin, Humalog 50-50 Kwikpen, had a WAC of $530 in 2017 compared to $323 in 2013—an increase of $207 or 64% in four years. Sanofi's rapid-acting insulin, Apidra Solostar, also increased—from $302 in 2014 to $521 in 2019—while Novo Nordisk's rapid-acting insulin, Novolog FlexPen, rose from $324 in 2013 to $558 in 2018, representing a more than 70% WAC price hike for both companies during this time period.

2. **Spending on insulin products has increased significantly for the Medicare program and its beneficiaries.** Based on data collected from CMS, annual spending on insulin has increased by billions of dollars over the last decade. Between 2010 and 2018, Medicare Part D spent $78.4 billion on insulin, prior to rebates, the majority of which was spent on Lantus ($27.4 billion), Novolog ($16.5 billion), Humalog ($12.3 billion), and Levemir ($11 billion). The growth of CMS's pre-rebate spending on insulin also significantly outstripped the growth rate of beneficiaries utilizing insulin from 2010 to 2018. For instance, the number of Part D beneficiaries using insulin increased 51%, from over 2.1 million in 2010 to approximately 3.2 million in 2017, whereas spending on insulin prior to rebates increased more than 470%, from over $3 billion in 2010 to roughly $14.3 billion in 2018.

3. **Sanofi aggressively increased its list price between 2012 and 2014 in response to market pressure and competition.** From 2001 to 2012, Sanofi increased list price as much as 18% annually, raising its price from $34 to $131 by the end of 2012. However, in 2013 and 2014, Sanofi embarked on much more aggressive increases, nearly doubling the drug's WAC to $248 by the end of 2014. Internal documents suggest that Sanofi did this for three reasons: (1) to lock in price increases in advance of introducing a new insulin product called Toujeo and anticipated market competition from Eli Lilly, (2) to respond to aggressive rebate and discount activity from Novo Nordisk, and (3) to respond to increased pressure from PBMs and payers to offer large rebates and discounts.

4. **Novo Nordisk repeatedly tracked Sanofi's price increases in a practice known as "shadow pricing."** Rather than seeking to undercut its competitors' pricing, from 2014 on Novo Nordisk engaged in a cat-and-mouse strategy of pricing that followed Sanofi's price increases closely, sometimes mirroring them within days or even hours. In 2015, Novo Nordisk changed its pricing strategy in advance of launching Tresiba, its next generation basal insulin (also known as long-acting insulin). Instead of following Sanofi, it led with a list price increase in order to set a high basal insulin price floor from which to launch Tresiba's initial list price. However, in 2017 and

2018, Novo Nordisk resumed increasing its list price to respond to Sanofi's pricing actions. According to internal memoranda, on October 1, 2017, Sanofi increased Lantus's list price by 3% and Toujeo's list price by 5.4%. Roughly three weeks later, Novo Nordisk recommended that the company make a 4% list price increase on January 1, 2018 in response to Sanofi, which was approved as recommended on November 3, 2017. Novo Nordisk would make at least one more list price increase in response to Sanofi in 2018.

5. **Novo Nordisk's board of directors voted down a proposed insulin price decrease due to financial downsides, risk of backlash from PBMs and payers, and expected pressure to take similar action on other products.** PBMs and payer backlash appeared to be of particular concern to Novo Nordisk. The company believed that its decision to decrease list price could upset payers, and that many in the drug supply chain (e.g., wholesaler distributors, PBMs, and health insurers) would be negatively impacted financially and could retaliate against Novo Nordisk.

6. **Insulin R&D spending was a fraction of manufacturers' revenue and sales and marketing expenses.** Eli Lilly reported spending $395 million on R&D costs for Humalog, Humulin, and Basaglar between 2014 and 2018, during which time the company spent nearly $1.5 billion on sales and marketing expenses for its insulins. These three drugs generated $22.4 billion in revenue during that period. Similarly, Sanofi reported net sales of nearly €31 billion (approximately $37 billion based on current currency conversion rates)[5] between 2014 and 2018 for its five insulin products, during which time the company reported spending $902 million on insulin R&D. Novo Nordisk failed to provide requested R&D spending information to the Committee.

7. **Rebates for insulins have increased exponentially since 2013.** In July 2013, Sanofi offered rebates between 2% and 4% for preferred placement on CVS Caremark's client's commercial formulary. Five years later, in 2018, Sanofi rebates were as high as 56% for preferred formulary placement. Similarly, in 2017, Novo Nordisk offered Express Scripts up to a 47% rebate for Levemir for preferred formulary placement on their client's commercial formulary compared to 25% in 2014.

8. **Manufacturers are retaining more revenue from insulin than in the 2000s.** Data and documents produced to the Committee show that the amount of revenue pharmaceutical manufacturers are retaining from insulin has risen. The increased revenue is taking place even as the net price—the revenue after rebates and discounts—has declined in recent years, although it appears to remain significantly higher than in the first decade of the 21st Century. For example, Eli Lilly reported that the average net price for Humalog KwikPen had declined slightly from $28 per pen in 2015 to $24 per pen in 2018, despite the WAC price nearly doubling during that same period. Eli Lilly has reported a steady increase in Humalog revenue for more than a decade—from $1.5 billion in 2007 to $3 billion in 2018. An internal Sanofi presentation shows that while the average Lantus net price of $87.48 in 2016 was $32

[5] Sanofi reported net sales in Euros to the Securities and Exchange Commission.

lower than the drug's net price in 2014, it was roughly double the drug's net price of $46.92 in 2005.

9. **The three largest PBMs—CVS Caremark, Express Scripts, and OptumRx—command significant market power when negotiating rebates in comparison to smaller rivals.** PBMs and health plans with more bargaining power (i.e., those with more plan members) generally command higher rebates than those with less bargaining power (i.e., fewer members). For example, in 2014, Novo Nordisk offered WellPoint, the largest for-profit managed health care company with over 40 million members, a larger rebate (40.625%) for Novolin vials for preferred formulary placement as 1 of 2 manufacturers on their client's commercial formulary compared to North Carolina State Employees (27.625%). Similarly, Eli Lilly prepared widely divergent rebate bids within a few months of each other for Humulin and Humalog to a commercial health plan in Puerto Rico called SIS (22%), Cigna (45%-55% depending on formulary placement), a PBM in Puerto Rico called Abarca Health (up to 54%), and Optum's Part D business (68%).

10. **PBM contracting practices did little to discourage higher list prices for insulin.**

    a. **Exclusion lists.** When a drug is not included on a health plan's formulary, it is "excluded." Over the past decade, payers and PBMs have increased their use of formulary exclusion lists. Exclusion can have significant consequences for patients and manufacturers. For patients, if the drug is excluded, they are forced to either switch to a new product, which could affect adherence and health outcomes, or pay significantly more to stay on their preferred medication. For manufacturers, exclusion can result in significant financial loss and reduced market share. On the contrary, being the exclusive therapy on a formulary can also be advantageous for the manufacturer's market share and revenue, which incentivizes manufactures to offer larger discounts to maintain preferred status. This investigation found several instances where manufacturers increased their rebate offers significantly following the threat of exclusion. Furthermore, in instances when manufacturers considered decreasing the list price of their products, they ultimately decided against it in part because they believed PBMs and payers would react negatively to receiving smaller rebates and administrative fees by excluding their product.

    b. **Administrative Fees.** PBMs earn administrative fees from manufacturers each time a drug is dispensed at the pharmacy. Administrative fees vary by contract, ranging up to 5% of the WAC price for the insulin therapeutic class. These fees are a significant revenue stream for PBMs and likely act as a countervailing force against lower list prices—PBMs may be reluctant to push for lower WAC prices since it would reduce their administrative fee-based revenue. The Committee's investigation found several instances in which manufacturers decided against lowering their list price in fear of retaliation from PBMs and payers for this very reason.

c. **Price Protection.** In addition to rebates and administrative fees, PBMs negotiate contract terms in which payers receive an additional rebate when manufacturers increase their price beyond a certain percentage cap—referred to as price or inflation protection. Price protection terms vary from contract to contract. For example, they can cap the annual increase of a drug's WAC price increase (i.e. prior to rebates) or its net price (after rebates). The Committee found examples of annual price caps ranging from 0% to 12% in one contract alone. The Committee's investigation also found examples of manufacturers seeking to and succeeding in efforts to avoid paying these additional rebates by timing their WAC price increases to exploit the terms in PBM contracts.

III. Diabetes: The Disease and How It's Treated

Diabetes is among the most pervasive, deadly, and costly diseases in the United States. According to the Centers for Disease Control and Prevention (CDC), diabetes is the 7th leading cause of death in the U.S. and more than 34 million people in the country live with the disease.[6] Of these, 7.3 million adults were not even aware of, or reported, having diabetes.[7] The CDC also estimates that 88 million Americans have prediabetes, a health condition that can lead to type 2 diabetes.[8] Unfortunately, this trend does not appear to be slowing: the CDC estimates that 1.5 million Americans will be diagnosed with diabetes this year alone.[9]

The number of diabetes patients in the U.S. has grown steadily since 1958, when approximately 1.6 million people were diagnosed with the disease.[10] According to the International Diabetes Foundation, the U.S. has one of the highest per capita rates of diabetes in the world, and spends heavily on the disease in comparison to other countries.[11] Moreover, as the prevalence of diabetes continues to increase in the U.S., so does spending on the disease. According to the American Diabetes Association (ADA), the U.S. spent approximately $327 billion on diabetes in 2017, of which $237 billion represented direct health care expenditures related to the disease.[12] By comparison, the U.S. spent approximately $205 billion on diabetes in 2007 (in inflation-adjusted dollars).[13]

However, the disease burden of diabetes is not equally distributed in the United States. Diabetes has a major impact on Federal health care programs within the Finance Committee's jurisdiction, as well as the health and financial well-being of program enrollees. For instance, diabetes disproportionally impacts individuals enrolled in Federal health care programs, as the growth of diabetes is primarily among those 65 and older.[14] According to CMS, diabetes affects approximately 1 in 5 individuals enrolled in Medicare compared to about 1 in 10 in the general population.[15] Medicare beneficiaries with diabetes also "reported worse general health, more inpatient admissions, and higher out-of-pocket health care costs than those without diabetes."[16]

Diabetes prevalence also varies by geography, economic status, education level, and by ethnicity. Diabetes is significantly more prevalent in impoverished regions of the U.S. that have high rates of Medicaid enrollment such as Appalachia and the Mississippi Delta, as well as

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[6] CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL DIABETES STATISTICS REPORT (2020), https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.
[7] *Id.*
[8] *Id.*
[9] *Id. See also Statistics About Diabetes*, AMERICAN DIABETES ASSOCIATION (ADA), https://www.diabetes.org/resources/statistics/statistics-about-diabetes (last viewed Nov. 18, 2020).
[10] CENTERS FOR DISEASE CONTROL AND PREVENTION, LONG TERM TRENDS IN DIABETES (2017), https://www.cdc.gov/DIABETES/statistics/slides/long_term_trends.pdf.
[11] International Diabetes Foundation Atlas, Table 3.5, Table 3.23 (2019), https://www.diabetesatlas.org/upload/resources/material/20200302_133351_IDFATLAS9e-final-web.pdf.
[12] American Diabetes Association, *Economic Costs of Diabetes in the U.S. in 2017*, 41 DIABETES CARE 917 (May 2018), https://care.diabetesjournals.org/content/41/5/917.
[13] *Id.*
[14] *Id.*
[15] *Diabetes Occurrence, Costs, and Access to Care among Medicare Beneficiaries Aged 65 Years and Over*, CTRS. FOR MEDICARE AND MEDICAID (Sept. 2017), https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/MCBS/Downloads/Diabetes_DataBrief_2017.pdf.
[16] *Id.*

among people who are eligible for both Medicare and Medicaid (so called "dual eligible" beneficiaries).[17] Adults with less than a high school education are also more likely to be diagnosed with diabetes than those who have attained a high school education or greater.[18] Lastly, minority communities are also disproportionally affected by this disease, with American Indians, Hispanics, Black Americans, and Asian Americans representing more than 45% of those diagnosed with the disease,[19] despite these groups making up 39% of the U.S. population.[20] According to the CDC, 15.1% of American Indians, 12.7% of Hispanics, 12.1% of Black Americans, and 8% of Asian Americans have been diagnosed with diabetes.[21]

Rising insulin prices negatively impact Federal health care programs, private payers, and the health system as a whole, as payers bear the costs of inadequate treatment. (Proper glycemic control, achieved through medication use, can reduce health care costs of individual patients as well as hospital admissions.)[22] They also harm patient health by reducing access to this life-saving medication. Therefore, it is incredibly important for Congress to continue to study the root cause of diabetes and how the list price of insulin can serve as a barrier for diabetics to access the very medication that allows them to survive.

a. Diabetes: The Disease

Even though diabetes is the 7th leading cause of death in the U.S. (as of 2017), it is a treatable disease and has been for almost a century.[23] Prior to the discovery of insulin in 1921,

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[17] CTRS. FOR DISEASE CONTROL AND PREVENTION, DIABETES 2019 REPORT CARD (2019), https://www.cdc.gov/diabetes/pdfs/library/Diabetes-Report-Card-2019-508.pdf; CTRS. FOR MEDICARE AND MEDICAID SERVS., RACIAL AND ETHNIC DISPARITIES IN DIABETES PREVALENCE, SELF-MANAGEMENT, AND HEALTH OUTCOMES AMONG MEDICARE BENEFICIARIES (Mar. 2017), https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/information-products/data. *See also* Heather Landi, *Lessons Learned From the Mississippi Delta, Tackling Chronic Disease Through Remove Monitoring Technology*, HEALTHCARE INNOVATION (Oct. 3, 2016), https://www.hcinnovationgroup.com/population-health-management/.

[18] *Addressing Health Disparities in Diabetes*, CDC, https://www.cdc.gov/diabetes/disparities.html (last reviewed Apr. 15, 2019).

[19] CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL DIABETES STATISTICS REPORT (2020), https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.

[20] *Quick Facts*, U.S. CENSUS BUREAU, https://www.census.gov/quickfacts/fact/table/US/PST045219 (last viewed Nov. 16, 2020).

[21] *Addressing Health Disparities in Diabetes*, CDC, https://www.cdc.gov/diabetes/disparities.html (last reviewed Apr. 15, 2019).

[22] *Cost-effectiveness of Intensive Glycemic Control, Intensified Hypertension Control, and Serum Cholesterol Level Reduction for Type 2 Diabetes*, JAMA NETWORK (May 15, 2002), https://jamanetwork.com/journals/jama/fullarticle/194927; *Medicaid Eligibility Expansions May Address Gaps In Access To Diabetes Medications*, HEALTH AFFAIRS (Aug. 2018), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2018.0154.

[23] CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL DIABETES STATISTICS REPORT (2020), https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf. *See also The History of A Wonderful Thing We Call Insulin*, ADA (July 1, 2019), https://www.diabetes.org/blog/history-wonderful-thing-we-call-insulin. Despite being patented more than a century ago, insulin lacks a less expensive alternative in the United States that would introduce downward price pressure in the marketplace. In addition to list price and rebate dynamics discussed throughout this report, another reason for this situation is that insulin is a biologic—a product derived from living cells (e.g., plant, animal, human cells)—which makes it a complex drug molecule and difficult to manufacturer on a mass scale. For further reading, *see* Jeremy A. Greene & Kevin R. Riggs, *Why Is There No Generic Insulin? Historical Origins of a Modern Problem*, 372 N. ENG. J. MED. 1171 (2015). *See also What Are*

diabetes was difficult to manage, and was treated primarily with highly restrictive diets, which compromised immune systems, stunted growth, and could lead to death by starvation.[24] It wasn't until the late 19th and early 20th century that scientists began to understand the role that insulin and the pancreas play in diabetes.[25]

Diabetes occurs when the body cannot produce insulin (type 1) or use insulin properly (type 2), resulting in higher-than-normal levels of sugar in the bloodstream.[26] Insulin injections are the cornerstone of treatment for many people with diabetes, and patients depend on them to avoid severe health complications and death. The body uses carbohydrates, proteins and fats as sources of energy to function. Primarily, the body breaks down carbohydrates for energy, producing glucose.[27] As glucose levels rise in the bloodstream, the pancreas releases the hormone, insulin. Insulin moves glucose from the blood into the cells, where it can be used as a source of energy.[28] Without insulin, glucose accumulates in the blood stream leading to high blood sugar (or hyperglycemia).

More than 90% of people with diabetes are diagnosed with type 2.[29] Type 2 diabetes is a disease that can often be prevented and managed through diet and exercise.[30] However, if these interventions fail, medication is required for proper glycemic control. And, while this type of diabetes is often associated with older adults, children, teens, and young adults with obesity and other risk factors are also susceptible.[31] For type 2 diabetes, patients are treated with a variety of medications to manage their disease, most of which work by stimulating insulin production, improving the way the body absorbs sugar and uses insulin.[32] In contrast, Type 1 diabetes is an autoimmune endocrine disorder that can be diagnosed at any age, but more often presents in children, teens, and young adults.[33] Unlike Type 2 diabetes, Type 1 diabetes cannot be prevented

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"Biologics" Questions and Answers, FDA, https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers (last viewed Oct. 6, 2020).

[24] *The History of A Wonderful Thing We Call Insulin*, ADA (July 1, 2019), https://www.diabetes.org/blog/history-wonderful-thing-we-call-insulin.

[25] CONG. RES. SERV., INSULIN PRODUCTS AND THE COST OF DIABETES TREATMENT (Nov. 19, 2018), https://fas.org/sgp/crs/misc/IF11026.pdf. *See also* Jeremy A. Greene & Kevin R. Riggs, *Why Is There No Generic Insulin? Historical Origins of a Modern Problem*, 372 N. ENG. J. MED. 1171, 1171 (2015). *See also The History of A Wonderful Thing We Call Insulin*, ADA (July 1, 2019), https://www.diabetes.org/blog/history-wonderful-thing-we-call-insulin.

[26] *Diabetes, Symptoms & Causes*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/diabetes/symptoms-causes/syc-20371444 (last viewed Sept. 15, 2020).

[27] *Carbohydrates*, THE AMERICAN HEART ASSOCIATION https://www.heart.org/en/healthy-living/healthy-eating/eat-smart/nutrition-basics/carbohydrates (last reviewed Apr. 16, 2018).

[28] *Id.*

[29] Diabetes Fast Facts, CDC, https://www.cdc.gov/diabetes/basics/quick-facts.html (last viewed Nov. 16, 2020).

[30] *Type 2 Diabetes*, CDC, https://www.cdc.gov/diabetes/basics/type2.html (last reviewed May 30, 2019). *See also The Nutrition Source: Simple Steps to Preventing Diabetes*, HARVARD SCHOOL OF PUBLIC HEALTH, https://www.hsph.harvard.edu/nutritionsource/disease-prevention/diabetes-prevention/ (last viewed Nov. 11, 2020).

[31] *Type 2 Diabetes*, CDC, https://www.cdc.gov/diabetes/basics/type2.html (last reviewed Nov. 16, 2020).

[32] The most common of these medications is metformin, a drug that decreases the amount of sugar the liver makes and increases the body's sensitivity to insulin. Metformin is often the first medication prescribed to Type 2 diabetes patients, and is often combined with other diabetes medications. Metformin was the 4th most commonly prescribed prescription drug in 2019. Sarah Lewis, *The Top 50 Drugs Prescribed in the United States*, HEALTHGRADES (Sept. 5, 2019), https://www.healthgrades.com/right-care/patient-advocate/the-top-50-drugs-prescribed-in-the-united-states.

[33] *Type 1 Diabetes*, CDC, https://www.cdc.gov/diabetes/basics/type1.html (last reviewed Jan. 3, 2021).

and can only be treated with insulin, through multiple daily insulin injections or a continuous insulin pump.[34]

As noted above, Type 1 and Type 2 diabetic patients use a combination of short-acting, rapid-acting, intermediate-acting, and long-acting insulin analogs (e.g., Lantus, Levemir, Toujeo, Tresiba, and Basaglar) to control glucose levels.[35] Today, insulin analogs are widely prescribed by physicians and are the standard of care for people with type 1 diabetes. Insulin can also be one component of care for people with type 2 diabetes, even though insulin analogs are more expensive than other types of insulin.[36]

While type 1 and type 2 diabetes are different in some respects, these diseases share one commonality: significant health risks. If left untreated or under-treated, diabetes can lead to hyperglycemia, cardiovascular disease, kidney disease, blindness, and diabetic ketoacidosis—a build-up of acids in the blood—which may result in a coma or even death.[37] According to the CDC, in 2016, 1.7 million people with diabetes were hospitalized for major cardiovascular disease, such as heart disease or stroke, 188,000 were hospitalized for diabetic ketoacidosis, and 130,000 were hospitalized for lower-extremity amputation.[38] Recently, and as a result of the COVID-19 global pandemic, those with pre-existing conditions, like diabetes, face greater risks of disease complications than the general population.[39] Initial observations also suggest that COVID-19 may be linked to patients developing diabetes or experiencing metabolic complications related to existing diabetes.[40] In addition, diabetes deaths have also been above average in 2020, according to an analysis of estimates from the CDC.[41]

b. How the High Cost of Insulin Negatively Affects Individuals with Diabetes

Approximately 7.4 million Americans use insulin, of which about 1.4 million have type 1 diabetes.[42] However, high-list prices, health plan structures, and high out-of-pocket costs make it

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[34] *Id.*
[35] Cigna-SFC-00011177; Cigna-SFC-00011229.
[36] American Diabetes Association, *Pharmacological Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes*, 43 DIABETES CARE 98, 99 (Jan. 2020), https://care.diabetesjournals.org/content/43/Supplement_1/S98.
[37] *Hyperglycemia in diabetes*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/hyperglycemia/symptoms-causes/syc-20373631 (last viewed Nov. 16, 2020); *High blood sugar with type 1 diabetes*, UNIV. OF IOWA STEAD FAMILY CHILDREN'S HOSPITAL, https://www.uichildrens.org/health-library/high-blood-sugar-type-1-diabetes (last viewed Nov. 16, 2020).
[38] CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL DIABETES STATISTICS REPORT (2020), https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.
[39] *New-Onset Diabetes in COVID-19*, 383 N. ENG. J. MED. 789 (Aug. 2020), https://www.nejm.org/doi/10.1056/NEJMc2018688; Elizabeth Cooney, *Why people with diabetes are being hit so hard by COVID-19*, STAT NEWS (Oct. 1, 2020), https://www.statnews.com/2020/10/01/why-people-with-diabetes-are-being-hit-so-hard-by-covid-19/; Chad Terhune et al., *Why COVID-19 is killing U.S. diabetes patients at alarming rates*, Reuters (July 24, 2020), https://www.reuters.com/article/us-health-coronavirus-diabetes-insight/why-covid-19-is-killing-u-s-diabetes-patients-at-alarming-rates-idUSKCN24P1B4.
[40] *New-Onset Diabetes in COVID-19*, 383 N. ENG. J. MED. 789 (Aug. 2020), https://www.nejm.org/doi/10.1056/NEJMc2018688.
[41] Denise Lu, *2020 Was Especially Deadly. COVID Wasn't the Only Culprit*, N.Y. TIMES (Dec. 13, 2020), https://www.nytimes.com/interactive/2020/12/13/us/deaths-covid-other-causes.html.
[42] American Diabetes Association, *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, 44 DIABETES CARE 1, 2 (Jan. 2020),

more difficult for patients to adhere to their medications, resulting in avoidable complications and higher costs for the U.S. health care system overall.[43] An ADA working group recently noted that "people with high cost-sharing are less adherent to recommended dosing, which results in short- and long-term harm to their health," and further detailed issues that lead to insulin accessibility issues for diabetic patients:

> Formulary exclusions and frequent formulary changes increase financial costs for patients. In addition, patients are bearing more of the cost of medications because of high-deductible plans, increased use of coinsurance, growing number of formulary tiers, and fewer medications covered per tier . . . Since negotiated discounts or rebates are usually not passed directly to people with diabetes, their financial obligations for purchasing insulin are often based on the list price. Clearly, this varies depending on the type of insurance the person has and the type of insulin purchased . . . but specifically impacts those with a high deductible, those who have to pay coinsurance, or those who are in the Medicare Part D coverage gap. People without insurance are often required to pay list price for insulins.[44]

It has been reported that some patients even cross the border into Canada to purchase insulin at lower prices.[45] Some diabetes patients have also resorted to rationing, which can be particularly dangerous to the health of a diabetic and can lead to a variety of complications such as diabetic ketoacidosis—a complication that results in tens of thousands of hospitalizations annually—and can even lead to death.[46] A survey conducted at the Yale Diabetes Center in 2017 found that 1 in 4 people reported rationing their insulin due to financial reasons, contributing to negative health outcomes and poor glycemic control.[47] If this rate of rationing was applied on a national scale, as many as 1.6 million Americans may ration their medication because of cost—highlighting the urgent need to address insulin affordability.

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https://care.diabetesjournals.org/content/early/2018/05/03/dci18-0019. *See also* CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL DIABETES STATISTICS REPORT (2020), https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.

[43] American Diabetes Association, *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, 44 DIABETES CARE 1, 8 (Jan. 2020), https://care.diabetesjournals.org/content/early/2018/05/03/dci18-0019.

[44] *Id.*

[45] Emily Rauhala, *As the price of insulin soars, American's caravan to Canada for lifesaving medication*, WASH. POST (July 31, 2019), https://www.washingtonpost.com/world/the_americas/as-price-of-insulin-soars-americans-caravan-to-canada-for-lifesaving-medicine/.

[46] American Diabetes Association, *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, 44 DIABETES CARE 1, 8 (Jan. 2020), https://care.diabetesjournals.org/content/early/2018/05/03/dci18-0019. *See also Hyperglycemia in diabetes*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/hyperglycemia/symptoms-causes/syc-20373631 (last viewed Nov. 16, 2020). *See also* Tiffany Stanley, *Life, Death and Insulin, As the costs of lifesaving medication skyrockets, some desperate diabetics are rationing – and risking their lives. Was Alec Raeshawn Smith one of them?*, WASH. POST (Jan. 7, 2019), https://www.washingtonpost.com/news/magazine/wp/2019/01/07/feature/insulin-is-a-lifesaving-drug-but-it-has-become-intolerably-expensive-and-the-consequences-can-be-tragic/?utm_term=.7d6e15666caa&itid=lk_inline_manual_18.

[47] Darby Herkert, et al., *Cost-related Insulin Underuse Among Patients with Diabetes,* JAMA NETWORK (Jan. 2019), https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2717499.

The COVID-19 pandemic has further compounded these problems, as the loss of work and income has made it more difficult for individuals and families to afford their insulin medications.[48] Earlier this year, the ADA conducted a survey of 5,000 people with diabetes nationwide since the start of the pandemic.[49] The ADA found that about 1 in 3 people with diabetes who were employed prior to COVID-19 had lost some or all of their income—rates higher than the general population.[50] The survey also found that, "24% of people with diabetes have used savings, loans or money from stimulus checks to pay for diabetes care in the past three months."[51] A quarter of people with diabetes also reported that they turned to rationing to cut costs whereas others have resorted to underground networks of people who share extra insulin, often free of charge.[52]

While insulin is the focus of the Committee's investigation, it's important to remember that diabetics often have other comorbidities associated with their disease and take other medications to treat conditions such as heart disease, high cholesterol, and hypertension.[53] Often, a large portion of medical costs associated with diabetes is for related comorbidities. For example, in 2017, the ADA estimated that $37 billion in cardiovascular-related spending was associated with diabetes, stating that "the presence of diabetes is associated with greater use of health care services in general." [54] According to the Government Accountability Office (GAO), these services can include "periodic test for blood glucose, eye and foot exams, medical nutrition therapy, and diabetes education . . . [and] services, such as cholesterol tests, smoking cessation tests, smoking cessation services, and influenza immunizations."[55] Taken together, these drugs and preventative measures greatly increase health care costs for diabetic patients in comparison to people who live without the disease.

II. Examining the Flow of Goods and Money in the U.S. Pharmaceutical Supply Chain

The path a drug takes from the manufacturer to the patient is complex and involves multiple financial exchanges. This complexity is caused, in part, by the many different players in the drug supply chain, including drug manufacturers, wholesalers, pharmacies, health insurers, PBMs, employers, and the Federal government.[56] Each link in the supply chain affects the price

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[48] Serena Gordon, *Pandemic Means Financial Hardship for Many with Diabetes*, U.S. NEWS (Aug. 19, 2020), https://www.usnews.com/news/health-news/articles/2020-08-19/pandemic-means-financial-hardship-for-many-with-diabetes.

[49] *Diabetes and COVID-19: New Data Quantifies Extraordinary Challenges Faced by Americans with Diabetes During the Pandemic*, ADA, https://www.diabetes.org/sites/default/files/2020-07/7.29.2020_dQA-ADA%20Data%20Release.pdf.

[50] *Id.*

[51] *Id.*

[52] *Id. See also* Markian Hawryluk, *Not pandemic-proof: Insulin copay caps fall short, fueling underground exchanges*, PITTSBURGH POST-GAZETTE (Oct. 11, 2020), https://www.post-gazette.com/news/insight/2020/10/11/Not-pandemic-proof-Insulin-copay-caps-fall-short-fueling-underground-exchanges/stories/202010110029.

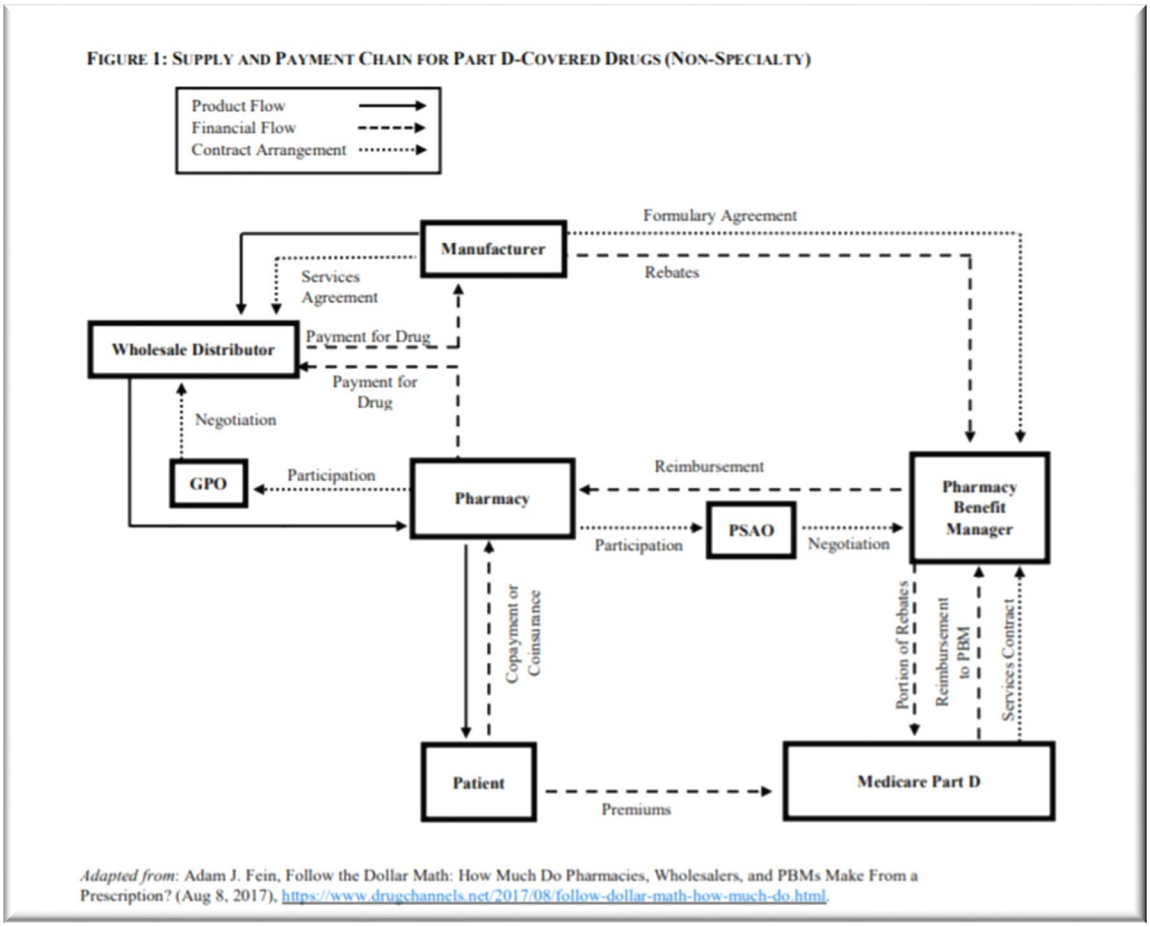
[53] American Diabetes Association, *Economic Costs of Diabetes in the U.S. in 2017*, 41 DIABETES CARE 917, 924 (May 2018), https://care.diabetesjournals.org/content/41/5/917.

[54] *Id.* at 927.

[55] GOV'T ACCOUNTABILITY OFF., MANAGING DIABETES, HEALTH PAN COVERAGE OF SERVICES AND SUPPLIES (Feb. 2005), https://www.gao.gov/new.items/d05210.pdf.

[56] Greg Brown, *The Insulin-Pricing Machine*, BEYOND TYPE 1 (June 18, 2018), https://beyondtype1.org/the-insulin-pricing-machine/.

the patient and payer eventually pays for the drug. This section will briefly explore how drugs are priced and the role of the various players in the drug supply chain.



a. Drug Manufacturers

There are two types of drug manufacturers—those that manufacture brand-name drugs and those that manufacture generic drugs.[57] While brand-name and generic manufacturers share similarities, "the branded drug business model requires very heavy investments in R&D and marketing [whereas] … the generic drug model requires particularly strong competence in manufacturing, channel management and patent litigation."[58] This report focuses on three brand-name insulin manufacturers: Sanofi, Novo Nordisk, and Eli Lilly. Therefore, it will not discuss generic manufacturers in depth. However, it's important to distinguish between these two business models because it affects the price manufacturers initially set for their product, known as the wholesale acquisition cost (WAC), which is colloquially known as the "list price."

Drug manufacturers are solely responsible for determining the WAC of their products. Internal documents produced to the Committee show that companies set their WAC price for insulin based on competitive considerations in the insulin market, maximizing revenue, and

[57] Samuel H. Kina and Marta Wosinska, *Pharmaceutical pricing*, IN HANDBOOK OF PRICING RESEARCH AND MARKETING 488, 490 (2009).
[58] *Id.*

maximizing market share. In response to the Committee, Sanofi asserted that R&D, marketing, and patent status factor into WAC.[59] However, documents produced to the Committee did not fully support the company's assertion. In fact, it appears that the only instance in which R&D costs appear to have been considered by one of the three manufacturers in relation to WAC price or rebate offers was when an Eli Lilly executive asked subordinates whether a requested bid from the Department of Veterans Affairs would result in too much of the company's manufacturing capacity being used for business that generated low margins.[60]

i. Research & Development, Sales & Marketing

1. Eli Lilly

During this investigation, the Committee requested that Sanofi, Novo Nordisk, and Eli Lilly "provide an itemized accounting of [insulin] R&D costs that breaks out costs by activity (e.g., basic research, clinical trials for marketing approval, post-marketing research and surveillance, etc.)" and "how each activity directly supports R&D for insulin products."[61] In response, Eli Lilly estimated that:

> [B]etween 2014 and 2018, it has spent approximately $244 million on research and development related to Humalog globally, $66 million on research and development related to Humulin globally, and $85 million on research and development related to Basaglar globally."[62]

However, this spending represents a fraction of the $22.4 billion in revenue Eli Lilly reported for these therapies during the same five-year period—$14.3 billion for Humalog, $6.8 billion for Humulin, and $1.3 billion for Basaglar.[63]

[59] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 29, 2019).
[60] LLY-SFCOM-UR-00003543, at LLY-SFC-UR-00003543-44.
[61] Letter from Senator Grassley and Senator Wyden to Lars Fruergaard Jorgensen, President and Chief Executive Officer, Novo Nordisk (Feb. 22, 2019).
[62] Letter from Reginald Brown, Counsel, WilmerHale, on Behalf of Eli Lilly, to Senator Grassley and Senator Wyden (Mar. 8, 2019).
[63] Revenue derived from Forms 10-K that Eli Lilly filed with the Securities and Exchange Commission for years 2014-2018. According to Eli Lilly, the company does not maintain net revenue at the NDC level on a consistent and audited basis. The company therefore produced gross revenue at the NDC level and net revenue at the consolidated product family level. *See* Letter from Reginald Brown, Counsel, WilmerHale, on Behalf of Eli Lilly, to Senator Grassley and Senator Wyden (Mar. 8, 2019). *See also* LLY-SFCOM-00000002. *Eli Lilly 10-k (2018)*, SEC, https://www.sec.gov/Archives/edgar/data/59478/000005947819000082/lly-20181231x10xk.htm; *Eli Lilly 10-k (2016)*, SEC, https://www.sec.gov/Archives/edgar/data/59478/000005947817000098/lly-20161231x10xk.htm.

Net Sales of Eli Lilly Insulin Products in Millions of Dollars (2014-2018)						
	2014	**2015**	**2016**	**2017**	**2018**	**Total**
Humalog	$2,785.2	$2,841.9	$2,768.8	$2,865.2	$2,996.5	**$14,257.6**
Humulin	$1,400.1	$1,348.3	$1,365.9	$1,335.4	$1,331.4	**$6,781.1**
Basaglar	--	$11.1	$86.1	$432.1	$801.2	**$1,330.5**
Total	**$4,185.3**	**$4,201.3**	**$4,220.8**	**$4,632.7**	**$5,129.1**	**$22,369.2**
Source: Eli Lilly Form 10-K, Securities and Exchange Commission						

Eli Lilly further explained that it could not provide a full breakdown of its R&D spending because "certain costs, such as local medical expenses and billable hours for training and administrative activities are not allocated by product."[64] R&D spending also represents a fraction of the money Eli Lilly spent on marketing the drugs. Eli Lilly reported spending nearly $1.5 billion on sales and marketing expenses on the drugs, which the company cautioned may not capture all such expenses.[65]

[64] Letter from Reginald Brown, Counsel, WilmerHale, on Behalf of Eli Lilly, to Senator Grassley and Senator Wyden (Mar. 8, 2019).

[65] LLY-SFCOM-00000045. Eli Lilly noted that "Marketing and Advertising expenses not tracked at SKU level (Pen, vial, Mixes, etc.) . . . For purposes of this report, all expenses shown at a consolidated 'Total Insulins' level . . . Certain marketing and advertising expenses incurred at Diabetes portfolio level (i.e., Requiring an allocation to the brands) are not included in this report." *Id.*

Sales Expenses for Eli Lilly Insulins (Humalog, Humulin, Basaglar), 2014-2018						
	2014	**2015**	**2016**	**2017**	**2018**	**Total**
Sales Force[1]	$136,086,445	$94,518,702	$83,835,211	$79,667,141	$87,511,840	**$481,619,340**
Market Research[2]	$8,672,584	$7,638,121	$7,147,827	$3,584,742	$2,799,660	**$29,842,934**
Samples[3]	$17,814,969	$12,817,014	$9,776,947	$8,399,706	$11,313,803	**$60,122,440**
3rd Party Vendors[4]	$61,909,679	$54,371,417	$89,351,175	$94,728,535	$82,725,285	**$383,086,091**
Medical Conference Sponsorships[5]	$227,961	$155,092	$47,512	$187,850	$37,172	**$655,587**
Other[6]	$4,874,300	$7,154,787	$6,645,130	$2,864,632	$2,514,864	**$24,053,713**
Total	**$229,585,940**	**$176,655,133**	**$196,803,802**	**$189,432,606**	**$186,902,624**	**$979,380,105**

Source: LLY-SFCOM-00000045; LLY-SFCOM-00002499.

[1] *Compensation and Benefits of Lilly Sales force for Humalog, Humulin, Basaglar. Includes meal, travel, meetings, etc.*

[2] *Includes IMS Health secondary (physician prescribing) data purchases, analytics charges.*

[3] *Includes cost of sample only, no distribution/packing costs.*

[4] *Digital Media, agency fees, patient support programs, etc.*

[5] *Exhibition fees for congress/conferences.*

[6] *Includes Compensation and Benefits of Lilly Marketing team.*

Marketing Expenses for Eli Lilly Insulins (Humalog, Humulin, Basaglar), 2014-2018						
	2014	**2015**	**2016**	**2017**	**2018**	**Total**
Consumer Marketing[1]	$22,286,002	$15,931,892	$21,679,235	$22,686,366	$23,371,480	**$105,954,975**
Prescriber Marketing[2]	$22,779,532	$15,279,295	$36,251,278	$44,687,503	$34,404,984	**$153,402,592**
Other[3]	$47,838,126	$49,391,585	$54,498,308	$38,566,312	$25,914,074	**$216,208,405**
Patient Support[4]	$595,834	$1,533,658	$539,770	$3,825,284	$15,700,246	**$22,194,793**
Total	**$93,499,494**	**$82,136,431**	**$112,968,591**	**$109,765,465**	**$99,390,784**	**$497,760,765**

Source: LLY-SFCOM-00002499.

[1] Consumer expenses reflect promotional activities designed to support patients initiating insulin treatment whom already received an insulin prescription from their Health Care Provider. Examples include branded paid search advertising and printed materials for patients. Also, included are unbranded disease state education digital content sponsored by LillyUSA, LLC. This may also include branded advertising presented alongside unbranded content. These expenses, including the unbranded content, are classified as promotional advertising by Eli Lilly & Co.

[2] Prescriber expenses reflect marketing programs designed to educate health care professionals prescribing insulin about Lilly products. These expenses include peer to peer programs (physicians educating other physicians) and Lilly's presence at medical conferences. Prescriber expenses do not include any costs for Lilly Sales force.

[3] Samples, Market Research, Analytics, Payer, Cover My Meds.

[4] Patient Support expenses reflect the operating expenses to administer insulin affordability programs. Expenses in this line do not include actual dollars spent on copay assistance (as such figures are accounted for as Gross to Net Sales adjustments in accordance with Generally Accepted Accounting Principles).

According to internal memoranda prepared for Eli Lilly's executive committee, in November 2016, the company assumed its "core insulins" would earn revenue of $3.3 billion in 2017 ($4 billion worldwide).[66] In order to achieve these results, Eli Lilly sought to improve its competitive position with respect to its key brands and planned to devote a majority of its R&D spending on clinical trials for existing Type 2 diabetes drugs—Jardiance,[67] Tranjenta,[68] and Trulicity[69]—the last of which was Eli Lilly's "largest growth driver."[70] Indeed, according to Eli Lilly, "Trulicity has been a catalyst . . . with growth driven by investments in [direct to consumer], sales force reach, and access."[71] These post-marketing clinical trials were intended to show that the therapy helped reduce incidence of cardiovascular disease which allowed Eli Lilly to seek an expansion of its FDA label indication.[72] However, even with these significant studies, the company's R&D spending for its entire diabetes franchise was budgeted to be just one-third of its sales, goods and administrative expenses, and, in fact, less than the cost of a single line item—Eli Lilly's global diabetes salesforce.[73] The following table details Eli Lilly's funded initiatives and sales force spending between 2017 and 2018.[74]

[66] LLY-SFCOM-UR-00006920; LLY-SFCOM-UR-00006921; LLY-SFCOM-UR-00006924, at LLY-SFCOM-UR-00006925.

[67] Press Release, Eli Lilly, Jardiance meets primary endpoint in reducing risk of cardiovascular death or hospitalization for heart failure in phase III clinical trial in adults with and without diabetes (July 2020), https://investor.lilly.com/news-releases/news-release-details/jardiancer-meets-primary-endpoint-reducing-risk-cardiovascular.

[68] Press Release, Eli Lilly, Boehringer Ingelheim and Lilly full results of Tradjenta's CARMELINA cardiovascular outcome trial (Oct. 4, 2018), https://investor.lilly.com/news-releases/news-release-details/boehringer-ingelheim-and-lilly-present-full-results-tradjentars.

[69] Press Release, Eli Lilly, Trulicity significantly reduced major cardiovascular events for broad range of people with type 2 diabetes (Jul. 9, 2019), https://investor.lilly.com/news-releases/news-release-details/trulicityr-dulaglutide-significantly-reduced-major.

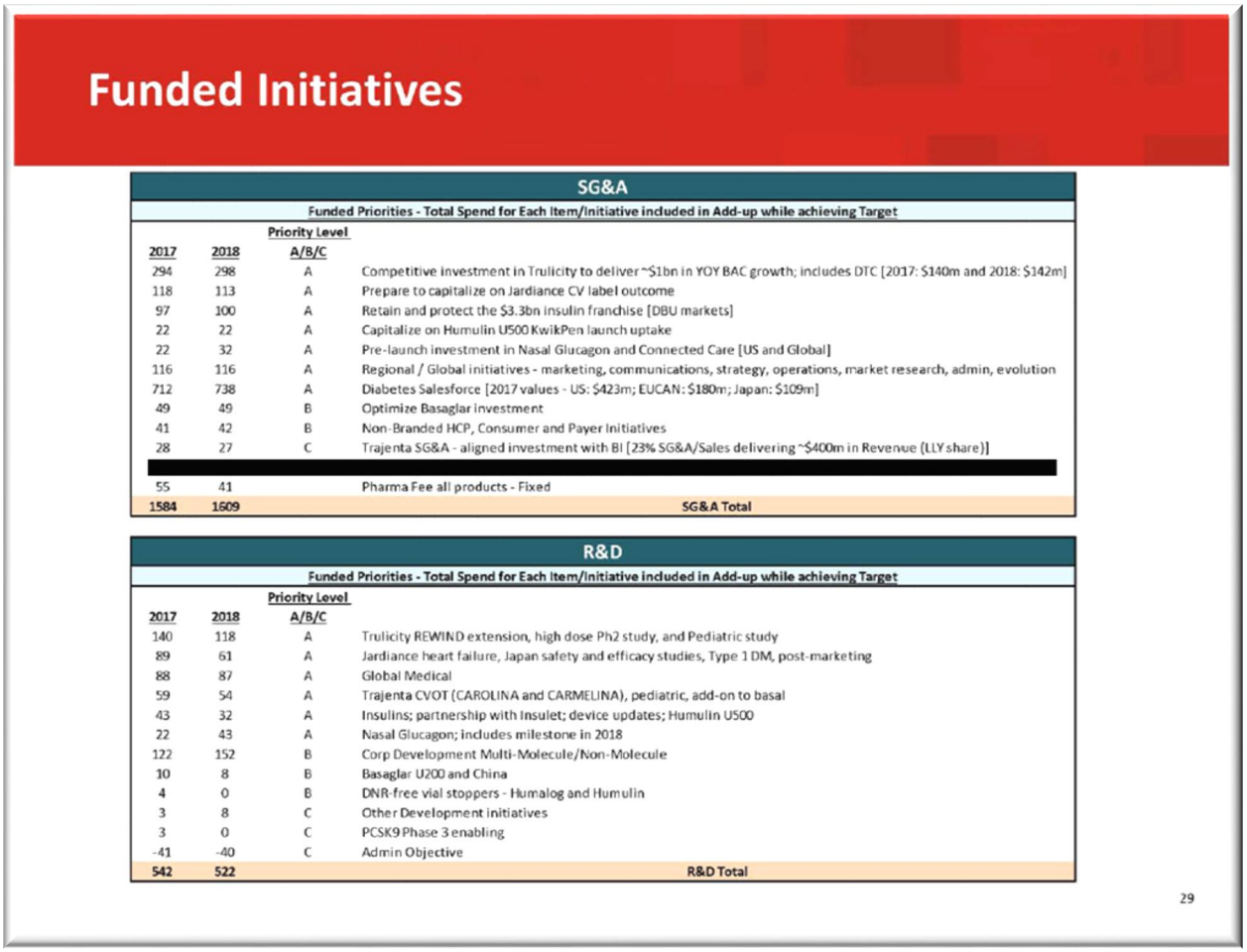
[70] LLY-SFCOM-UR-00006924, at LLY-SFCOM-UR-00006952.

[71] LLY-SFCOM-UR-00006921, at LLY-SFCOM-UR-00006922. Trulicity, Jaridance and Trajenta are marketed and manufactured in partnership with Boehringer Ingelheim.

[72] For example, in February 2020, Eli Lilly announced that the FDA approved Trulicity for the reduction of major adverse cardiovascular events in adults with type 2 diabetes. According to Eli Lilly, this new indication makes Trulicity the only type 2 medicine approved to reduce these risks. *See* Press Release, Eli Lilly, Trulicity is the first and only type 2 diabetes medicine approved to reduce cardiovascular events in adults with and without established cardiovascular disease (Feb. 21, 2020), https://investor.lilly.com/news-releases/news-release-details/trulicityr-dulaglutide-first-and-only-type-2-diabetes-medicine. LLY-SFCOM-UR-00006921; LLY-SFCOM-UR-00006924, at LLY-SFCOM-UR-00006952.

[73] LLY-SFCOM-00000045; LLY-SFCOM-00002499; LLY-SFCOM-UR-00006921; LLY-SFCOM-UR-00006924, at LLY-SFCOM-UR-00006952.

[74] LLY-SFCOM-UR-00006924, at LLY-SFCOM-UR-00006952.



Funded Initiatives

SG&A

Funded Priorities - Total Spend for Each Item/Initiative included in Add-up while achieving Target

2017	2018	Priority Level A/B/C	
294	298	A	Competitive investment in Trulicity to deliver ~$1bn in YOY BAC growth; includes DTC [2017: $140m and 2018: $142m]
118	113	A	Prepare to capitalize on Jardiance CV label outcome
97	100	A	Retain and protect the $3.3bn insulin franchise [DBU markets]
22	22	A	Capitalize on Humulin U500 KwikPen launch uptake
22	32	A	Pre-launch investment in Nasal Glucagon and Connected Care [US and Global]
116	116	A	Regional / Global initiatives - marketing, communications, strategy, operations, market research, admin, evolution
712	738	A	Diabetes Salesforce [2017 values - US: $423m; EUCAN: $180m; Japan: $109m]
49	49	B	Optimize Basaglar investment
41	42	B	Non-Branded HCP, Consumer and Payer Initiatives
28	27	C	Trajenta SG&A - aligned investment with BI [23% SG&A/Sales delivering ~$400m in Revenue (LLY share)]
[redacted]			
55	41		Pharma Fee all products - Fixed
1584	**1609**		**SG&A Total**

R&D

Funded Priorities - Total Spend for Each Item/Initiative included in Add-up while achieving Target

2017	2018	Priority Level A/B/C	
140	118	A	Trulicity REWIND extension, high dose Ph2 study, and Pediatric study
89	61	A	Jardiance heart failure, Japan safety and efficacy studies, Type 1 DM, post-marketing
88	87	A	Global Medical
59	54	A	Trajenta CVOT (CAROLINA and CARMELINA), pediatric, add-on to basal
43	32	A	Insulins; partnership with Insulet; device updates; Humulin U500
22	43	A	Nasal Glucagon; includes milestone in 2018
122	152	B	Corp Development Multi-Molecule/Non-Molecule
10	8	B	Basaglar U200 and China
4	0	B	DNR-free vial stoppers - Humalog and Humulin
3	8	C	Other Development initiatives
3	0	C	PCSK9 Phase 3 enabling
-41	-40	C	Admin Objective
542	**522**		**R&D Total**

29

2. Sanofi

In response to the Committee's request, Sanofi estimated that it had invested approximately $4.5 billion in diabetes, which includes both insulin and non-insulin products, between 2012 and 2018, noting that it spent $800 million in 2018 on diabetes alone.[75] Sanofi only provided R&D product-specific data for 2014 to 2018, and limited the data to five insulin products.[76] Therefore, the Committee was unable to confirm Sanofi's total R&D spending on its diabetes franchises. However, R&D spending (which was reported to the Committee in dollars) on these five diabetes products accounted for a fraction of the company's reported revenue from its diabetes franchise, as reported to the U.S. Securities and Exchange Commission.[77] From 2014 to 2018, the company's diabetes franchise generated nearly €31 billion in net sales

[75] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019).
[76] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 29, 2019).
[77] *Id.* Sanofi produced data regarding gross sales, net sales, and gross units by product line, which is how Sanofi tracks this information. *Id.*

(approximately $37 billion based on current currency conversion rates), [78] whereas R&D spending for these five insulin products was approximately $902 million.[79]

Net Sales of Sanofi Diabetes Products in Millions of Euros (2014-2018)						
	2014	2015	2016	2017	2018	Total
Admelog					€ 93	**€ 93**
Apidra	€ 336	€ 376	€ 367	€ 286	€ 357	**€ 1,722**
Lantus	€ 6,344	€ 6,390	€ 5,714	€ 4,761	€ 3,565	**€ 26,774**
Soliqua					€ 73	**€ 73**
Toujeo		€ 164	€ 649	€ 630	€ 840	**€ 2,283**
Total	**€ 6,680**	**€ 6,930**	**€ 6,730**	**€ 5,677**	**€ 4,928**	**€ 30,945**

Source: Securities and Exchange Commission. According to Sanofi, "[n]et sales comprise revenue from sales of pharmaceutical products, consumer healthcare products, active ingredients and vaccines, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities." (Sanofi, 20-F, 2019)

Sanofi R&D Spending by Product in Millions of Dollars (2014-2018)						
	2014	2015	2016	2017	2018	Total
Admelog	$ 24.45	$ 54.53	$ 38.25	$ 11.26	$ 6.15	**$ 134.64**
Apidra	$ 2.31	$ 5.47	$ 3.64	$ 1.36	$ 1.04	**$ 13.82**
Lantus	$ 42.79	$ 21.95	$ 20.76	$ 16.44	$ 8.24	**$ 110.18**
Soliqua	$ -	$ 1.03	$ 40.94	$ 70.76	$ 68.74	**$ 181.47**
Toujeo	$ 67.53	$ 72.45	$ 150.25	$ 117.84	$ 54.43	**$ 462.50**
Total	**$ 137.08**	**$ 155.43**	**$ 253.84**	**$ 217.66**	**$ 138.60**	**$ 902.61**

Source: Letter to Senator Grassley and Senator Wyden from Jeffrey Handwerker, Counsel, Sanofi (March 29, 2019).

3. Novo Nordisk

Novo Nordisk failed to provide a detailed accounting of its R&D expenditures to the Committee. However, on its annual report submitted to the SEC, the company reported that it spent approximately 36 million Danish krone related to diabetes and obesity R&D between 2017 and 2019.[80]

b. Wholesale Distributors and Pharmacies

Drugs are purchased directly by wholesale distributors and delivered to a variety of customers, including pharmacies, physicians, hospitals, and other medical facilities. Wholesale distributors negotiate with drug manufacturers for discounts off a drug's list price, often referred

[78] Sanofi reported net sales in Euros to the Securities and Exchange Commission.
[79] *Id.*
[80] *See Novo Nordisk Annual Report 2019*, NOVO NORDISK at 52 (2019), https://www.novonordisk.com/content/dam/nncorp/global/en/annual-report/pdfs/2019/Novo-Nordisk-Annual-Report-2019.pdf.

to as the wholesale acquisition cost (WAC).[81] Examples of discounts include volume discounts, inventory claw backs, and prompt pay discounts. The wholesale distributor then sells the product to a pharmacy, hospital, or other medical facility at WAC plus some negotiated percentage.[82]

The outcome of these negotiations is critical to a drug's success because wholesale distributors help connect pharmacies, hospitals, and other medical facilities to drug manufacturers. However, over the past 30 years, the wholesale distribution industry has become highly consolidated. In 2018, the three largest wholesale distributors—AmerisourceBergen, McKesson, and Cardinal Health—covered 95% of the market.[83] This consolidation allows wholesale distributors to use aggressive disruption techniques to secure favorable agreements, such as the refusal to stock new product, reduce service levels on certain drugs, or ordering the slowdown of drug distribution in non-U.S. countries.[84]

At the pharmacy level, payers and PBMs reimburse pharmacies for the drugs they disburse to patients. However, payments vary.[85] For example, contracts typically set pharmacy reimbursement as the lesser of (1) the over-the-counter cash price, (2) the drug cost plus a dispensing fee, (3) the contractual rate, or (4) if a generic drug, the Maximum Allowable Cost (MAC) on a MAC list.[86] Insulin drugs are not included on MAC lists because it is regulated as a biologic and has no generic alternatives.

c. Health Insurance

In the United States today, a majority of Americans receive coverage through a private health insurer. Most of these Americans—about 158 million people, or 49% of the country—receive coverage through an employer, while a smaller portion—nearly 19 million people—receive private coverage directly from an insurer, including through the Affordable Care Act's (ACA) marketplaces.[87] The remaining insured population is generally divided between Medicaid and Medicare, which covered approximately 20% and 14% of the country, respectively, in 2019.[88] That same year, nearly 29 million nonelderly Americans were uninsured.[89] Notably, the COVID-19 pandemic has altered this coverage landscape as job losses and lost income led many Americans to seek coverage through Medicaid and the marketplace.[90] For the purposes of this

[81] Samuel H. Kina and Marta Wosinska, *Pharmaceutical pricing*, IN HANDBOOK OF PRICING RESEARCH AND MARKETING 488, 500 (2009).
[82] *Id.* at 500-01.
[83] Adam Fein, *The Big Three Wholesalers: Revenues and Channel Share Up, Profits Down*, DRUG CHANNELS (Oct. 2, 2019), https://www.drugchannels.net/2019/10/the-big-three-wholesalers-revenues-and.html.
[84] SANOFI_SFC_00013920.
[85] Samuel H. Kina and Marta Wosinska, *Pharmaceutical pricing*, IN HANDBOOK OF PRICING RESEARCH AND MARKETING 488, 502 (2009).
[86] ORX_Sen_Fin_0009800. *See also* Samuel H. Kina and Marta Wosinska, *Pharmaceutical pricing*, IN HANDBOOK OF PRICING RESEARCH AND MARKETING 488, 502 (2009).
[87] *Health Insurance Coverage of Total Population*, KFF https://www.kff.org/other/state-indicator/total-population/ (last viewed July 7, 2020).
[88] *Id.*
[89] Jennifer Tolbert and Kendal Orgera, *Key Facts About the Uninsured Population*, KFF (Nov. 6, 2020), https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/.
[90] M. Karpman and S. Zuckerman, *ACA Offers Protection as the COVID-19 Pandemic Erodes Employer Health Insurance Coverage*, URBAN INSTITUTE (Nov. 6, 2020), https://www.rwjf.org/en/library/research/2020/11/aca-offers-protection-as-the-covid-19-pandemic-erodes-employer-health-insurance-coverage.html.

discussion, we will provide a brief overview of how Medicare, Medicaid, and employer-sponsored insurance generally pays for insulin products.

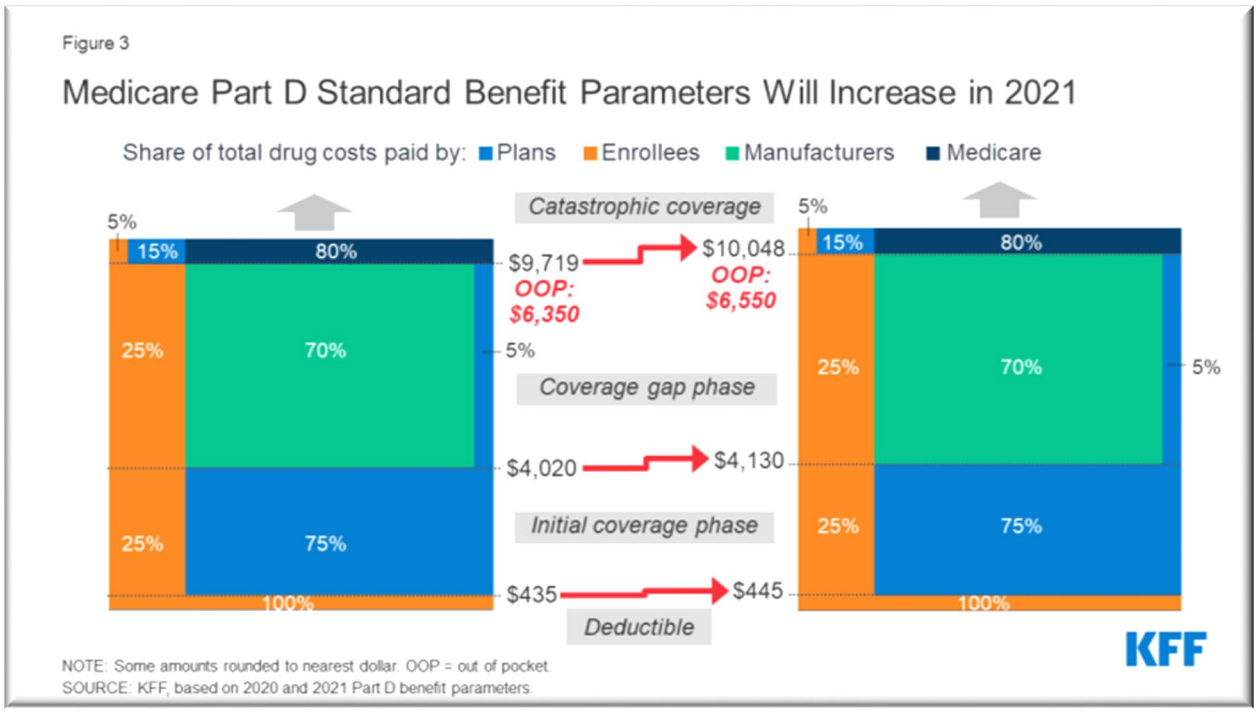
i. Medicare Part D

Medicare provides optional prescription drug coverage through its Part D benefit, which is provided through private plans that are approved by the Federal government.[91] Beneficiaries can choose Medicare Part D stand-alone prescription drug plans (PDPs) or enroll in Medicare Advantage (MA-PD) plans that offer drug coverage in addition to all other Medicare benefits.[92] In 2020, over 75% of Medicare beneficiaries were enrolled in Part D plans.[93] PDPs and MA-PD plans must offer enrollees the *standard drug benefit* or alternative coverage that is the *actuarially equivalent* in value. Part D plan formularies must include a minimum of two chemically distinct drugs in each drug class and are required to cover all drugs in the six protected classes: immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics.[94]

The Part D standard drug benefit provides different levels of coverage and cost-sharing at different phases of the benefit. These phases include a deductible, an initial coverage phase, a coverage gap, and catastrophic coverage.[95] For 2020, the standard drug benefit included a $435 deductible and a 25% coinsurance until the enrollee and plan reached $4,020 in total drug spending.[96] After this point, the enrollee enters the coverage gap phase (also referred to as the *doughnut hole*) and continues to pay a 25% coinsurance for both brand-name and generic drugs. For brand-name drugs, manufacturers pay a 70% discount on the drug while the plan pays 5%.[97] Whereas, for generic drugs, the plan pays 75%.[98] Once the enrollee's out-of-pocket costs exceeded $6,350 (an estimated $9,719 in total spending by the plan and enrollee), they reach what is known as the catastrophic phase of the Medicare Part D benefit. In this phase, Medicare pays 80%, plans pay 15%, and the enrollee must pay the greater of 5% in coinsurance or $3.60 for a generic drug and $8.95 for a brand-name drug.[99] Updated coverage parameters for 2021 are reflected in the figure below.[100]

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[91] CONG. RES. SERV., MEDICARE PRIMER, at 23 (May 21, 2020), https://fas.org/sgp/crs/misc/R40425.pdf.
[92] *An Overview of the Medicare Part D Prescription Drug Benefit,* KFF (Oct. 14, 2020), https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/.
[93] *Id.*
[94] *Id.*
[95] *Id.*
[96] CONG. RES. SERV., MEDICARE PRIMER, at 23 (May 21, 2020), https://fas.org/sgp/crs/misc/R40425.pdf.
[97] *Id.* at 23-24.
[98] *Id.*
[99] *Id.* at 24. *See An Overview of the Medicare Part D Prescription Drug Benefit*, KFF (Oct. 14, 2020), https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/.
[100] *An Overview of the Medicare Part D Prescription Drug Benefit*, KFF (Oct. 14, 2020), https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/.



In addition to paying nearly all drug costs above the catastrophic threshold of the standard drug benefit (*reinsurance*), Medicare also pays plans monthly *direct subsidies* to Part D plans for each enrollee. Every year, Part D plan sponsors submit bids to CMS estimating the cost to provide drug coverage to beneficiaries. The Federal government then pays Part D sponsors a risk-adjusted amount based on the nationwide average of all plan bids (*direct subsidies*).[101] In addition, Medicare also pays Part D plan sponsors an additional subsidy for providing drug benefits to low-income beneficiaries. For example, if a beneficiary is dual-eligible (meaning they qualify for both Medicare and Medicaid) or if they meet certain income benchmarks, Medicare pays additional subsidies to help cover the beneficiary's out-of-pocket costs, including premiums, deductibles, and lowered cost-sharing for prescriptions.[102] Dual-eligible beneficiaries and certain other low-income beneficiaries are also automatically enrolled in a PDP if they do not choose a plan on their own.[103]

According to the Congressional Budget Office (CBO), Medicare Part D spending will total $96 billion in 2021, or approximately 13% of total Medicare spending.[104] CBO further estimates that Part D spending will total $192 billion by 2030.[105] This dramatic rise in spending is due in part to the availability of more expensive drugs—many of which cost more than $7,500

[101] *Part D Payment System,* MedPAC (Oct. 2016), http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_16_partd_final.pdf?sfvrsn=0.
[102] CONG. RES. SERV., MEDICARE PRIMER, at 25 (May 21, 2020), https://fas.org/sgp/crs/misc/R40425.pdf
[103] *An Overview of the Medicare Part D Prescription Drug Benefit*, KFF (Oct. 14, 2020), https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/.
[104] *Id.*
[105] CONG. BUDGET. OFF., MEDICARE—CBO'S MAY 2020 BASELINE (Mar. 2020), https://www.cbo.gov/system/files/2020-03/51302-2020-03-medicare.pdf.

annually—causing the Federal government to pay higher reinsurance subsidies to plans.[106] Additionally, for Medicare beneficiaries, there is no cap on individual out-of-pocket spending, so individual costs can be quite high.[107] High costs can be especially problematic for people with diabetes who tend to have comorbidities, such as hypertension, obesity, or hyperlipidemia (or excess fat in the blood), and must use several drugs to stay healthy.[108]

ii. Medicaid Drug Rebate Program

Medicaid is a joint Federal-state program that provides health insurance coverage for low-income individuals and families. Though states are not required to cover prescription drugs, all state Medicaid programs currently provide this benefit.[109] Medicaid spending for prescription drugs is largely shaped by the Medicaid Drug Rebate Program (MDRP), which requires drug manufacturers to enter into rebate agreements with the Federal government in exchange for having nearly all of their drugs covered by the Medicaid program. Under the MDRP, for each drug administered to a Medicaid beneficiary, a manufacturer must provide a rebate to the state, which shares a portion of the drug rebate with the Federal government.[110] The formula for these rebates is set by statute and differs for generic and brand name drugs. For generic drugs, the rebate is 13% of the Average Manufacturer Price (AMP), which is the average price paid to drug manufacturers by wholesalers and pharmacies.[111] For brand name drugs, manufacturers pay 23.1% of the AMP or the difference between AMP and the "best price," whichever is greater.[112] The "best price" is defined as the lowest price at which the manufacturer sold a drug to any wholesaler, retailer, provider, or other entity within or outside of Medicaid, excluding certain government programs.[113] In this way, the best price requirement ensures that Medicaid receives the lowest price available *to any purchaser in any state* for a brand name drug.[114]

The MDRP plays a key role in reducing Federal and state spending on prescription drugs. In 2017, Medicaid spent approximately $64 billion on prescription drugs and collected more than half of that in rebates (nearly $35 billion), reducing net spending to just over $29 billion.[115] However, the MDRP also places some limits on states' ability to negotiate lower prices directly with manufacturers, which can increase Medicaid's exposure to new high-cost blockbuster drugs. For example, in the case of Sovaldi, Medicaid programs found themselves unable to extract additional, supplemental rebates from Gilead Sciences until the company was forced to offer more generous rebates in response to market competition in the therapeutic class. The high

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[106] Mike McCaughan, *Medicare Part D*, HEALTH AFFAIRS (Aug. 10, 2017), https://www.healthaffairs.org/do/10.1377/hpb20171008.000172/full/.
[107] *Id.*
[108] Helena Rodboard, et al., *Impact of type 2 diabetes mellitus on prescription medication burden and out-of-pocket healthcare expenses*, DIABETES RES. CLIN. PRACT. (Mar. 2010), https://pubmed.ncbi.nlm.nih.gov/20047768/.
[109] *Prescription Drugs*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/prescription-drugs/index.html (last viewed Dec. 29, 2020).
[110] *Understanding the Medicaid Prescription Drug Rebate Program,* KFF (Nov. 12, 2019), https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/.
[111] *Id.*
[112] *Id.*
[113] 42 U.S.C. § 1396r-8(c)(1)(C)(i).
[114] *Medicaid Payment for Outpatient Prescription Drugs*, MACPAC (May 2018), https://www.macpac.gov/wp-content/uploads/2015/09/Medicaid-Payment-for-Outpatient-Prescription-Drugs.pdf.
[115] *Medicaid Drug Spending Trends*, MACPAC (Feb. 2019), https://www.macpac.gov/wp-content/uploads/2019/02/Medicaid-Drug-Spending-Trends.pdf.

cost of Sovaldi initially led some states to restrict access to the drug to the sickest patients, reducing access to program beneficiaries.[116] Furthermore, as will be discussed below, the MDRP may influence drug spending outside of Medicaid by leading some drug manufacturers to inflate their launch prices and avoid setting new and lower "best prices" for their products.[117]

iii. Employer-sponsored health insurance

Collectively, employers are another major payer of prescription drugs. Employer-sponsored health insurance is health coverage offered by employers to employees, and sometimes their dependents, as a benefit of employment. Nearly all covered workers have prescription drug coverage through their plans.[118] However, many enrollees can still face significant cost-sharing in the form of high deductibles or coinsurance.[119] Approximately 30% of adults with employer-sponsored plans are enrolled in high-deductible-health-plans (HDHP).[120] In 2021, HDHPs (as defined by the Internal Revenue Service) require a deductible of at least $1,400 for an individual and $2,800 for a family.[121] HDHPs are often touted as a way to mitigate rising premiums, but for individuals with lifelong illnesses like diabetes, the financial exposure fundamental to HDHPs may contribute to their decision to delay medical treatment.

For example, several studies have found that diabetics who enroll in HDHPs often do not refill branded medications or delay treatment altogether, contributing to problems with adherence.[122] Delaying treatment can be disastrous to one's health or even deadly, and from an economic perspective, delayed treatment leads to increased health care costs for patients and payers in the long-term. The Internal Revenue Service sought to address this issue in July 2019 when it released guidance that expanded the list of preventative services that a HDHP can cover below the deductible to include insulin.[123]

d. The PBM Industry

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[116] *See* Press release, Wyden-Grassley Solvaldi Investigation Finds Revenue-Driven Pricing Strategy Behind $84,000 Hepatitis Drug (Dec. 2015), https://www.finance.senate.gov/ranking-members-news/wyden-grassley-sovaldi-investigation-finds-revenue-driven-pricing-strategy-behind-84-000-hepatitis-drug.
[117] Rachel Dolan, *Understanding the Medicaid Prescription Drug Rebate Program*, KFF (Nov. 12, 2019), https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/.
[118] Adam Fein, *Employer Pharmacy Benefits in 2019: High Deductibles and Greater Coinsurance Expose Even More Patients to Prescription List Prices*, DRUG CHANNELS (Nov. 13, 2019), https://www.drugchannels.net/2019/11/employer-pharmacy-benefits-in-2019-high.html.
[119] *Id.*
[120] *2019 Employer Health Benefits Survey*, KFF (Sept. 25, 2019), https://www.kff.org/report-section/ehbs-2019-section-8-high-deductible-health-plans-with-savings-option/#figure85.
[121] INTERNAL REVENUE PROCEDURE 2020-32, https://www.irs.gov/pub/irs-drop/rp-20-32.pdf (Total out-of-pocket expenses for the year are capped at $7,000 for individuals and $14,000 for families). *See also* A. Mark Fendrick et al*., Association between Switching to a high-deductible health plan and discontinuation of Type 2 diabetes treatment*, JAMA Network (Nov. 1, 2019), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2753788.
[122] A. Mark Fendrick et al*., Association between Switching to a high-deductible health plan and discontinuation of Type 2 diabetes treatment*, JAMA Network (Nov. 1, 2019), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2753788; J. Frank Wharam, *et al*., *High-Deductible Insurance and Delay in Care for the Microvascular Complications of Diabetes*, ANNALS OF INTERNAL MEDICINE (Dec. 18, 2018), https://www.acpjournals.org/doi/10.7326/M17-3365.
[123] Press release, IRS expands list of preventive care for HSA participants to include certain care for chronic conditions (July 17, 2019), https://www.irs.gov/newsroom/irs-expands-list-of-preventive-care-for-hsa-participants-to-include-certain-care-for-chronic-conditions.

PBMs administer prescription drug benefits on behalf of health insurers and payers, including employers, state Medicaid agencies, and commercial insurers that provide employer-sponsored insurance and coverage through Medicare, Medicaid, or CHIP.[124] The largest PBMs administer drug benefits for health plans that insure tens of millions of people (often referred to as "covered lives"), giving these PBMs tremendous bargaining power in negotiations with pharmaceutical manufacturers seeking access to, and favorable placement on, health insurers' formularies. PBMs use this power to negotiate with drug manufacturers, ostensibly to lower drug costs for their clients.

Manufacturers have a strong financial incentive to gain access to a plan sponsor's formulary, particularly national formularies administered by the three largest PBMs on behalf of hundreds or thousands of health plan clients. PBMs also negotiate formularies on behalf of individual clients. As Eli Lilly explained to its investors in 2019, failing to secure formulary placement can "lead to reduced usage of a drug for the relevant patient population due to coverage restrictions, such as prior authorizations and formulary exclusions, or due to reimbursement limitations which result in higher consumer out-of-pocket cost, such as non-preferred co-pay tiers, increased co-insurance levels, and higher deductibles."[125] This is why pharmaceutical manufacturers compete fiercely for formulary placement, particularly in therapeutic areas such as diabetes where there are multiple branded products with similar clinical attributes. They also seek to balance drug price increases and price concessions—primarily rebates and price protection clauses—to compete against each other for favorable formulary placement with health plans represented by PBMs and health plans that choose to negotiate with manufacturers directly.[126]

The PBM industry has grown and consolidated rapidly in recent decades. As an example, in 1989, roughly 60 million people had their prescription drug coverage administered by PBMs.[127] A few years later, just five companies controlled roughly 80% of a 100 million person market[128] and, by 2014, health care experts estimated three companies—CVS Caremark, Express Scripts, and OptumRx—served over 180 million people, representing roughly 80% of people whose pharmacy benefits were administered by PBMs (as of 2014).[129] However, PBMs have only continued to grow and expand their operations.

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[124] *See Pharmacy Benefit Managers: Practices, Controversies, and What Lies Ahead*, COMMONWEALTH FUND (Mar. 2019), https://www.commonwealthfund.org/sites/default/files/2019-03/Seeley_pharmacy_benefit_managers_ib_v2.pdf; Kathleen Gifford et al., *How State Medicaid Programs are Managing Prescription Drug Costs: Resulting from a State Medicaid Pharmacy Survey for State Fiscal Years 2019 and 2020*, KFF (Apr. 29, 2020), https://www.kff.org/report-section/how-state-medicaid-programs-are-managing-prescription-drug-costs-pharmacy-benefit-administration/.

[125] *Eli Lilly Form 10-K*, SEC at 35, https://www.sec.gov/ix?doc=/Archives/edgar/data/59478/000005947820000057/lly-20191231x10xk.htm.

[126] For example, Eli Lilly boosted its rebate offer to one PBM after it learned of a competitor offering a 54% rebate, 6% annual price protection, and "covering the cost of 'transitioning lives away from Lilly products.'" LLY-SFCOM-UR-00003520, at LLY-SFCOM-UR-00003521; LLY-SFCOM-UR-00003532. *See also* LLY-SFCOM-UR-00002612; LLY-SFCOM-UR-00002644; LLY-SFCOM-UR-00003325.

[127] *Pharmacy Benefit Managers, Early Results on Ventures with Drug Manufacturers*, GAO at 3 (Nov. 1995), https://www.gao.gov/assets/230/221921.pdf.

[128] *Id* at 3.

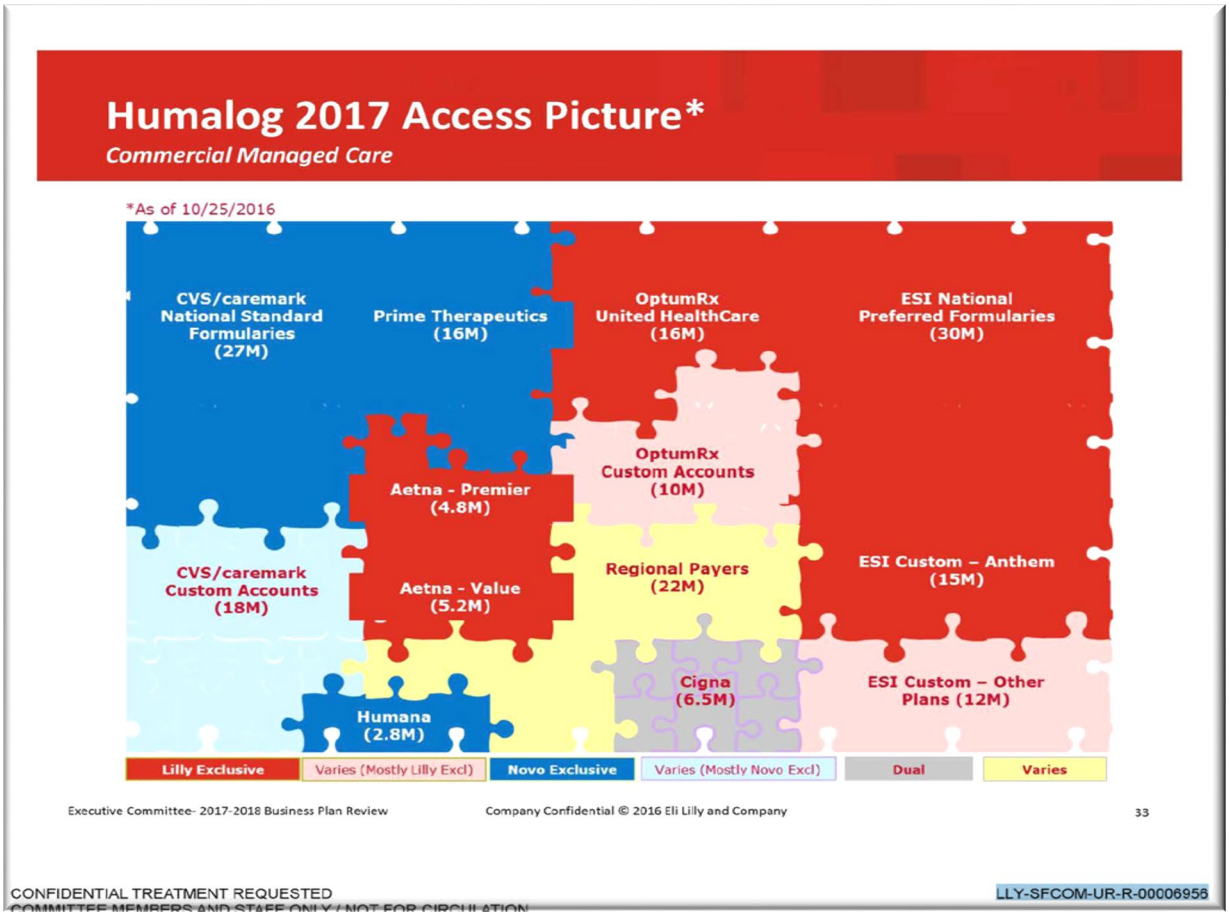
[129] Cole Werble, *Pharmacy Benefit Managers*, HEALTH AFFAIRS (Sept. 14, 2017), https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/full/.

Company	History and Market Position	Proposed Mergers and Partnerships	Total Lives Covered (as of 2019)
CVS Caremark	CVS Health acquires Aetna in November 2018 in a deal worth nearly $70 billion.[130]		105 million.[131]
Express Scripts	In 2018, Cigna acquired Express Scripts in a deal worth approximately $67 billion.[132] In 2012, Express Scripts acquired rival Medco Health Solutions for $29 billion.[133]	In December 2019, Express Scripts announced a partnership with Prime Therapeutics, a PBM collectively owned and operated by 18 Blue Cross Blue Shield health plans, to enhance "pharmacy networks" and "pharmaceutical manufacturer value"—essentially meaning that the PBM will handle negotiations between the health insurer and drug manufacturers.[134]	More than 80 million.[135]
OptumRx	A subsidiary of UnitedHealth Group. In 2015, UnitedHealth Group acquired PBM Catamaran Corp. for		More than 65 million.[137]

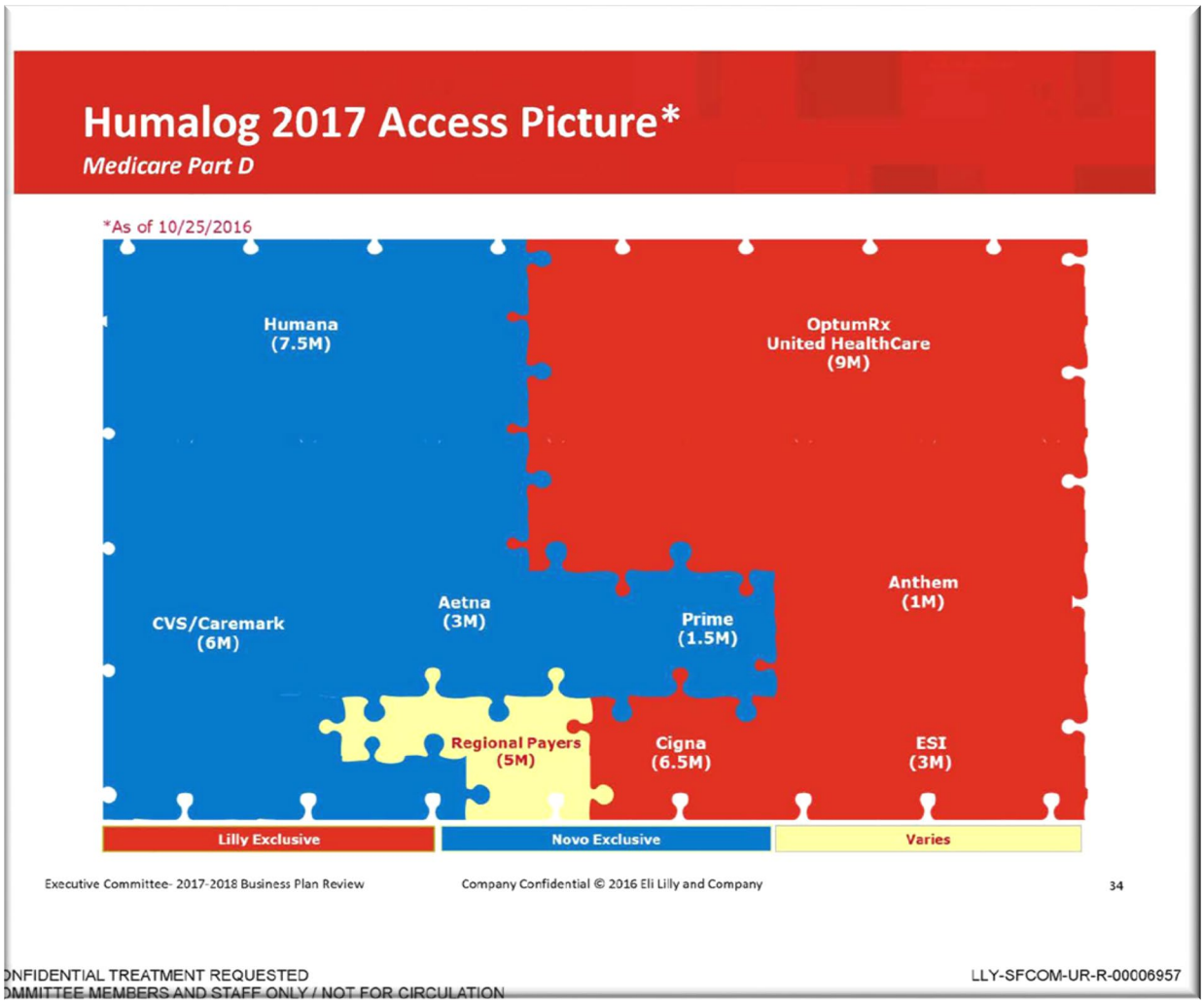
[130] Anna Wilde Mathews and Aisha Al-Muslim, *CVS Completes $70 Billion Acquisition of Aetna*, WALL ST. J. (Nov. 28, 2018), https://www.wsj.com/articles/cvs-completes-70-billion-acquisition-of-aetna-1543423322.
[131] *2019 Annual Report*, CVS HEALTH at 58, https://www.annualreports.com/HostedData/AnnualReports/PDF/NYSE_CVS_2019.pdf.
[132] Press Release, Cigna, Cigna to Acquire Express Scripts for $67 Billion (Mar. 8, 2018), https://www.cigna.com/about-us/newsroom/news-and-views/press-releases/2018/cigna-to-acquire-express-scripts-for-67-billion.
[133] Jaimy Lee, *Express Scripts Buys Medco for $29 Billion*, MODERN HEALTH CARE (Apr. 2, 2012), https://www.modernhealth care.com/article/20120402/NEWS/304029961/express-scripts-buys-medco-for-29-billion.
[134] Press Release, Prime Therapeutics, Express Scripts and Prime Therapeutics Collaborate to Deliver More Affordable Care to More Than 100 Million Americans (Dec. 19, 2019), https://www.primetherapeutics.com/en/news/pressreleases/2019/release-prime-express-scripts-collaboration.html.
[135] Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Apr. 16, 2019).
[137] *How Did UnitedHealth's OptumRx Revenues Increase in Q3 Despite A Drop in Retail Prescriptions*, FORBES (Nov. 28, 2019), https://www.forbes.com/sites/greatspeculations/2019/11/28/how-did-unitedhealths-optumrx-revenues-increase-in-q3-despite-a-drop-in-retail-prescriptions/?sh=751ad7c42547.

	approximately $13 billion.[136]		

In addition to being the largest PBMs in the country, these companies are also vertically integrated with health insurance companies and operate specialty pharmacies through acquisitions and mergers. For example, OptumRx is a subsidiary of UnitedHealth Group, CVS Caremark is a subsidiary of CVS Health, which acquired the health insurer Aetna in a $69 billion deal in 2018, and Express Scripts merged with health insurer Cigna in 2018.[138] An Eli Lilly presentation prior to the Cigna-Express Scripts and CVS-Aetna mergers suggested that the companies, once combined, would represent 172 million or about 75% of the nearly 228 million people in Part D and commercial markets, alone.[139] Adding the Express Scripts-Prime Therapeutics partnership brings the number to 189.5 million or roughly 83% of those markets.[140] Excerpts from this presentation are shown below.[141]



[136] Anna Wilde Mathews and Joseph Walker, *UnitedHealth to Buy Catamaran for $12.8 Billion in Cash*, WALL ST. J. (Mar. 30, 2015), https://www.wsj.com/articles/unitedhealth-to-buy-catamaran-for-12-8-billion-in-cash-1427709601.
[138] Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Apr. 16, 2019).
[139] LLY-SFCOM-UR-R-00006924, at LLY-SFCOM-UR-R-00006956-57.
[140] LLY-SFCOM-UR-R-00006924, at LLY-SFCOM-UR-R-00006956-57.
[141] LLY-SFCOM-UR-R-00006924, at LLY-SFCOM-UR-R-00006956-57.



As PBMs have grown, they have faced significant legal scrutiny, including paying millions of dollars in damages, settlements, and fines connected to kickback schemes, fraud allegations, and false claims.[142] Members of Congress and industry groups have expressed

[142] Nate Raymond, *Ohio accuses UnitedHealth's OptumRx of drug overcharges in lawsuit*, REUTERS (Mar. 18, 2019) (emphasizing the significance of current legal scrutiny), https://www.reuters.com/article/us-ohio-drugprices-lawsuit/ohio-accuses-unitedhealths-optumrx-of-drug-overcharges-in-lawsuit-idUSKCN1QZ1UH. *See also 2017 Annual Report*, CVS HEALTH, https://s2.q4cdn.com/447711729/files/doc_financials/annual/annual-report-2017.pdf (last visited Mar. 29, 2019) (noting that CVS reported receiving a civil investigative demand in 2017 from the Attorney General for Washington. The state informed the company that information provided in response to the demand would be shared with California, Florida, Minnesota, New Mexico, and the District of Columbia.); *Express Scripts Form 10-K*, SEC at 32 (Feb. 27, 2018), https://www.sec.gov/Archives/edgar/data/1532063/000153206318000004/esrx-12312017x10k.htm (noting "[Express Scripts] has received inquiries from various state Attorneys General offices in connection with pending investigations into potential unfair and deceptive acts or practices related to the pricing, reimbursement and rebates for insulin and epinephrine products and possible contracts, combinations or conspiracies in restraint of trade in the setting of prices for insulin and epinephrine products" and "[o]n March 29, 2017, the Company received a Civil Investigative Demand from the Office of the Attorney General of Washington related to insulin products."). *Id. See also The State of Competition in the Pharmacy Benefits Manager and Pharmacy Marketplaces, Hearing Before the House Judiciary Comm., Subcomm. on Regulator Reform, Commercial and Antitrust Law*, 114th Cong.

concern that consolidation in the health care sector harms patients and discourages competition. During the Committee's April 9, 2019 hearing titled *Drug Pricing in America: A Prescription for Change, Part III*, Senator Grassley and Senator Wyden questioned CVS Caremark, Express Scripts, and OptumRx executives on anti-competitive behavior and asked that they respond to their concerns that vertical integration may actually harm patients and consumers.[143] In response to Senator Grassley's question, the witnesses pointed to the highly competitive nature of their industry and alluded that vertical integration was required to keep costs low for patients and insurers.[144]

Information collected during this investigation demonstrates that smaller PBMs and rival health insurers with less bargaining power (generally those with fewer patients or "covered lives" served by the company) are offered less generous rebates, discounts, and other fees by drug manufacturers when compared to larger competitors.[145] An example of this dynamic is on display in an internal Sanofi memo regarding its rebate negotiations with a small company, WellDyneRx, LLC, as the company considered offering lower rebates for Lantus and Toujeo, which represented an "opportunity to retain glargine business at WellDyneRx at a lower rebate rate than the national PBM rates."[146] A September 27, 2017 email further elaborated on the company's view:[147]

(2015)(statement of David A. Balto), https://docs.house.gov/meetings/JU/JU05/20151117/104193/HHRG-114-JU05-Wstate-BaltoD-20151117.pdf; Press Release, U.S. Dep't of Justice, Medco to Pay $7.9 Million to Resolve Kickback Allegations, (May 20, 2015), https://www.justice.gov/opa/pr/medco-pay-79-million-resolve-kickback-allegations; Press Release, U.S. Dep't of Justice, U.S. Attorney's Office, Southern District of New York, Manhattan U.S. Attorney Announces $60 Million Civil Fraud Settlement With Accredo Health Group Over Kickback Scheme Involving Prescription Drug (May 1, 2015), https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-60-million-civil-fraud-settlement-accredo-health-group; Press Release, Attorney General McKenna Announces Caremark To Pay $41 Million To Resolve Multistate Consumer Protection Claims (Feb. 14, 2008), https://www.atg.wa.gov/news/news-releases/attorney-general-mckenna-announces-caremark-pay-41-million-resolve-multistate; Press Release, U.S. Dep't of Justice, Medco to Pay U.S. $155 Million to Settle False Claims Act Cases (Oct. 23, 2006), https://www.justice.gov/archive/opa/pr/2006/October/06_civ_722.html; Press Release, U.S. Dep't of Justice, Justice Department Recovers $1.4 Billion in Fraud & False Claims in Fiscal Year 2005; More Than $15 Billion Since 1986 (Nov. 7, 2005), https://www.justice.gov/archive/opa/pr/2005/November/05_civ_595.html.

[143] *Drug Pricing in America: A Prescription for Change, Part III: Hearing Before S. Comm. on Finance*, 116th Cong. (Apr. 2019) (Question for the record of Sen. Charles E. Grassley, Chairman, S. Comm. Finance).

[144] *Id.*

[145] *See* Press Release, American Medical Association, AMA urges DOJ to challenge CVS-Aetna merger (Aug. 8, 2018), https://www.ama-assn.org/press-center/press-releases/ama-urges-doj-challenge-cvs-aetna-merger.

[146] SANOFI_SFC_00010641.

[147] SANOFI_SFC_00010655.

From: Fondaco, Michael /US
Sent: Wednesday, September 27, 2017 9:32 PM
To: Borys, Margaret /US; Halenar, Lori /US
Subject: RE: Preliminary PRB Agenda 9/28/17

Margaret,

In a nutshell, WellDyneRx is a PBM with ~1M lives. They currently use Gateway as their claims aggregator under ESI. WellDyne believes they can better negotiate rebates on their own instead of getting their rates nipped by both Gateway and ESI. Much more information to be presented tomorrow but the bottom line is the proposed rates are less than the ESI rate so it's a savings to the brand.

Feel free to call me if you have any questions.

Thanks.

Mike

Little more than a month after this email was sent, Sanofi considered offering WellDyneRx rebates between 42% and 50% off WAC for Lantus, and between 40% and 48% off WAC for Toujeo.[148] In comparison, Sanofi prepared a much better offer for CVS's Part D portfolio, which covered 12.8 million lives at the time and was preparing to merge with Aetna, adding another 3.1 million lives. According to internal pricing review board memoranda, on November 30, 2017, Sanofi sought approval to offer rebates up to 72% for Lantus and 67% for Toujeo in addition to administrative fees and deferred payments.[149] A "bid tracker" with rebates Sanofi offered to different payers similarly shows that companies with more "lives" typically received larger discounts than smaller competitors.[150]

What follows is a brief overview of PBM operations based on information collected during the course of the investigation.

i. Formulary Development Process

One of the primary functions that PBMs perform is developing lists of covered drugs for plan sponsors, known as formularies. A formulary is "[a] list of prescription drugs covered by a prescription drug plan or another insurance plan offering prescription drug benefits."[151] Drugs listed on a formulary are typically less expensive for a plan beneficiary to purchase, since they are subject to the plan's drug benefit. In turn, a manufacturer typically provides a rebate to a health plan when a drug is placed on a formulary, saving the plan money on the cost of the medication. A product's formulary placement can also affect a patient's out-of-pocket spending, as demonstrated by an internal Sanofi analysis of Part D formularies operated by CVS Caremark that found co-pays for Lantus could "range . . . from $236 (34% co-ins) to as high as $348 (50% co-ins)" depending on its formulary tier.[152]

[148] SANOFI_SFC_00010641.
[149] SANOFI_SFC_00009950, at SANOFI_SFC_00009954.
[150] SANOFI_SFC_00010668, at SANOFI_SFC_00010671.
[151] *Formulary*, HEALTHCARE.GOV, https://www.healthcare.gov/glossary/formulary/ (last viewed Dec. 29, 2020).
[152] SANOFI_SFC_00009811, at SANOFI_SFC_00009815.

There are many different types of formularies with different cost-sharing tiers.[153] While each PBM has different names and particular practices for each of its formularies, they all offer their clients a range of options that vary in the amount of restrictions placed on patients (such as step-therapy and prior authorizations), the number of therapies available, and the cost. However, the development of a health plan's formulary is relatively similar across PBMs in that it follows a multi-step process involving several distinct committees within the respective PBMs.

Pharmacy & Therapeutics Committee. The Pharmacy & Therapeutics Committee (P&T Committee) is an independent advisory committee comprised of actively practicing physicians, pharmacists, and other experts who are responsible for evaluating clinical evidence to assess a medication's clinical value.[154] In determining a medication's clinical value, the P&T Committee reviews scientific evidence, medical literature, and standards of practice to assess a medication's safety and efficacy.[155] It then assigns a clinical designation for the drug and makes formulary recommendations for the PBM's "national" formularies (a type of formulary that is designed by the PBM and offered to multiple, sometimes thousands of, plan sponsors) or for an individual client's custom formulary.[156] According to CVS Caremark, Express Scripts, and OptumRx, the P&T Committee neither has access to, nor does it consider, financial factors such

[153] For example, CVS Caremark has several different formularies it offers clients. One such formulary, the "Standard Opt-Out" is the least restrictive, and includes the greatest number of products, with the CVS website noting that it does "not include formulary removals." Troy Brennen, *2018 Formulary Strategy*, CVS CAREMARK (Aug. 1, 2017), https://payorsolutions.cvshealth.com/insights/2018-formulary-strategy. Meanwhile, the "Standard Control" formulary "offers the broadest coverage of generic, brand and specialty medications of [CVS Caremark's] formularies. Updates are made at the beginning of the year with potential quarterly exclusions for hyperinflation and specialty products. It offers savings of 1 to 2 percent on pharmacy spending." *Formulary Management*, CVS CAREMARK, https://payorsolutions.cvshealth.com/programs-and-services/cost-management/formulary-management (last viewed Dec. 29, 2020). The "Value" formulary purports to include only the lowest-cost medications, with CVS Caremark noting it "covers most generics, and select brands, including specialty medications, with tier exceptions or higher copays for non-formulary brands. Drug list and management strategies are updated quarterly. Value Formulary can deliver pharmacy spend savings of up to 8 percent and an increase in generic dispensing of up to 5 percent or more." *Id.* As formularies have become more restrictive, they cost clients less money. CVS Caremark estimated costs for clients with a custom formulary who opted-out of exclusions to be $113.62 per-member per-month (PMPM) whereas the "Value" formulary, which had the highest generic dispensing rate of CVS's various formularies, had the lowest baseline cost at $81.86 per-member-per-month. Jon Roberts, *Trend Drops to the Lowest Level in 4 years, Despite the Headlines, Prescription Spending Growth Slowed for Our Clients*, CVS CAREMARK (Mar. 15, 2017), https://payorsolutions.cvshealth.com/insights/trend-drops-lowest-level-4-years.

[154] *See* Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Apr.16, 2019); Letter from Michael Bopp, Counsel, Gibson Dunn ,Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (June 21, 2020); Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Sept. 25, 2019); Letter from Enu Mainigi, Counsel, Williams & Connolly, on Behalf of CVS Health Corp., to Senator Grassley and Senator Wyden (Apr. 26, 2019); Letter from Enu Mainigi, Counsel, Williams & Connolly, on Behalf of CVS Health Corp., to Senator Grassley and Senator Wyden (Aug. 27, 2019); Cigna-SFC-0008830; ORX_Sen_Fin_00001935.

[155] Based on information collected during the Committee's interview with Andy Behm, Vice President of the Office of Clinical Evaluation and Policy, Express Scripts (Nov. 7, 2019). *See also* ORX_Sen_Fin_0005329. (This document, produced by OptumRx, is an example of the type of evidence reviewed by the P&T Committee in making their determination.)

[156] ORX_Sen_Fin_00001935.

as rebates, discounts, or net costs.[157] However, with regard to insulin, the P&T Committee, from a clinical perspective, considers these drugs to be mostly interchangeable.[158]

The P&T Committee also meets annually to review final formulary recommendations.[159] This is often an opportunity to ensure that formularies include products for a wide-range of therapeutic classes and, if necessary, to make final adjustments to plan formularies.[160]

Formulary Development. PBMs also maintain internal committees that determine which therapies are placed on formularies. The development of drug formularies has a major financial impact not only on pharmaceutical companies, but on health insurers and the PBMs. Formulary development committees appear to be at the center of developing these lists. These committees are comprised of company personnel, which may include representatives from formulary management, product management, trade relations, human resources, and clinical account management.[161] PBMs differ in what they call this committee. For example, Express Scripts refers to this committee as the *Value Assessment Committee*, CVS Caremark refers to this Committee as the *Formulary Review Committee*, and OptumRx refers to this committee as the *Formulary Management Committee*.[162] Regardless, their purpose and composition remains similar. What follows is a summary of the operations of OptumRx's Formulary Management Committee (FMC).

OptumRx's FMC meets on a monthly basis and is responsible for reviewing evidence transmitted by the P&T Committee to make formulary placement decisions.[163] The FMC also reviews the "P&T Committee Drug Classification Designations" to make decisions or recommendations about the formulary structure."[164] The P&T Committee can assign one of seven different drug designations, including "essential drug," "essential class," and "optional inclusion" based on clinical evidence.[165] Subject to the clinical designations and recommendations of the P&T Committee, the formulary development committee makes

[157] Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (June 21, 2019); Letter to Senator Grassley and Senator Wyden from Enu Mainigi, Counsel, CVS Caremark (Aug. 27, 2019); ORX_Sen_Fin_00001935, at ORX_Sen_Fin_00001936.
[158] *See* Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Sept. 25, 2019).
[159] *See* Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (June 21, 2019).
[160] Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (June 21, 2019).
[161] Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Sept. 25, 2019); Letter from Enu Mainigi, Counsel, Williams & Connolly, on Behalf of CVS Health Corp., to Senator Grassley and Senator Wyden (Apr. 26, 2019); ORX_Sen_Fin_0005387.
[162] Letter from Enu Mainigi, Counsel, Williams & Connolly, on Behalf of CVS Health Corp., to Senator Grassley and Senator Wyden (Apr. 26, 2019); Cigna-SFC-00008830; ORX_Sen_Fin_0005377.
[163] ORX_Sen_Fin_0005377, at ORX_Sen_Fin_0005379.
[164] ORX_Sen_Fin_0005377, at ORX_Sen_Fin_0005378, ORX_Sen_Fin_0005383.
[165] ORX_Sen_Fin_0005377, at ORX_Sen_Fin_0005378, ORX_Sen_Fin_0005383.

formulary recommendations for drugs that are deemed interchangeable[166] by evaluating net cost, rebates, discounts, plan sponsor costs, utilization trends, and business benefit considerations.[167]

Several presentations collected during this investigation demonstrate how the FMC considers the financial impact to OptumRx's business. For example, a FMC presentation dated April 25, 2018, refers to the financial evaluation of different insulin products, such as the net cost and per-member-per-month impact of Humalog;[168] the annual impact on rebates by moving Tresiba to a different formulary tier;[169] the net cost and incremental cost of every insulin product in the long-acting class,[170] and the net WAC of multiple insulin products.[171] This presentation also refers to an FMC vote that was conducted by email,[172] states that "[t]he basal insulin class was evaluated as part of 2019 recontracting (sic) effort to leverage competition and reduce the overall cost of the category,"[173] stresses the need for a "[r]eevaluation of the Humalog brand … to address market dynamics … [and mentions with respect to Humalog that] [a]dditional rebate opportunities [are] available for the various benefit designs."[174]

The materials used for these meetings are provided to, and maintained by, FMC members.[175] The FMC's policies also suggest that the FMC engages in several other types of communications that would have been responsive to the Committee's April 2nd request for information, but that the company failed to produce. For example, OptumRx's FMC policy states:[176]

[166] Some PBMs assign designations to drugs that are clinically similar to other available drug alternatives. For example, Express Scripts' P&T Committee designates insulins as *optional* and forwards this information to the Value Assessment Committee, which evaluates net cost, market share, and drug utilization trends of clinically similar medications. *See* Cigna-SFC-00008330, at Cigna-SFC-00008831. Express Scripts' P&T Committee considers insulins interchangeable. Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Sept. 25, 2019).

[167] *See* Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (June 21, 2020)(stating that Cigna's Value Assessment Committee considers the value of the drug by evaluating net cost, market share, and drug utilization trends of clinically similar medications); Letter from Enu Mainigi, Counsel, Williams & Connolly, on Behalf of CVS Health Corp., to Senator Grassley and Senator Wyden (Apr. 26, 2019)(stating that CVS Caremark's Formulary Review Committee considers net-cost, clinical guidance, marketplace dynamics, and the potential for patient disruption); ORX_Sen_Fin_0005387 (stating that OptumRx's Formulary Management Committee considers net-cost, economic, pharmacoeconomic, and business/benefit considerations as well as factors that are "attractive to current and potential clients, particularly by providing clients with the lowest possible net cost of drugs.")

[168] ORX_Sen_Fin_0007468, at ORX_Sen_Fin_0007489.

[169] ORX_Sen_Fin_0007468, at ORX_Sen_Fin_0007479.

[170] ORX_Sen_Fin_0007468, at ORX_Sen_Fin_0007480

[171] ORX_Sen_Fin_0007468, at ORX_Sen_Fin_0007490.

[172] ORX_Sen_Fin_0007468, at ORX_Sen_Fin_0007490.

[173] ORX_Sen_Fin_0007468, at ORX_Sen_Fin_0007479.

[174] ORX_Sen_Fin_0007468, at ORX_Sen_Fin_0007489.

[175] ORX_Sen_Fin_0005377, at ORX_Sen_Fin_0005378.

[176] ORX_Sen_Fin_0005377, at ORX_Sen_Fin_0005380.

COMMUNICATION
FMC will deliver all approved decisions to SVP of Clinical, and SVP of Industry Relations, for their reference.

FMC will deliver final decisions to the Benefit Implementation Committee ("BIC") for implementation and communication to internal and external stakeholders. Refer to BIC Charter.

PBM clients can also receive documentation concerning formulary recommendations from OptumRx, if their agreement allows for it. (The Finance Committee did not attempt to determine if plans are in fact allowed to review these agreements. However, the Office of Inspector General for the Department of Health and Human Services found that, while some Part D plans have certain contractual rights to audit agreements between their PBMs and manufacturers, they are not always allowed to do so.)[177] The FMC also provides its clients with guidance about how to structure their formularies:[178]

- Clinical Program Strategy: FMC also provides economic guidance into the type of utilization management tools ("UM") for use with particular drugs or a particular Formulary, including, but not limited to, prior authorizations, quantity limits, step therapies, and provider education. FMC makes these decisions by considering clinical, economic and pharmacoeconomic evidence (as available) provided by the P&T Committee, OptumRx staff, and other supporting financial, business and benefit strategy analyses. FMC reviews and considers recommendations and other information, including, but not limited to:

Trade Relations Group. The Trade Relations Group is an internal committee comprised of PBM personnel who are responsible for negotiating or approving rebate agreements with drug manufacturers.[179] PBMs differ in what they call this committee. For example, OptumRx refers to this committee as the Industry Relations Group whereas CVS Caremark and Express Scripts refer to this committee as the Trade Relations Group.[180] For the purposes of this discussion, "Trade Relations Group" will be used. The Trade Relations Group utilizes the PBM's purchasing power and other market forces to negotiate rebates, discounts, and other fees with drug manufacturers.[181] The Trade Relations Group also seeks to obtain the lowest net cost for its clients—regardless of the list price set by manufacturers—and uses certain tactics (e.g., formulary exclusions) to meet its goal.[182]

ii. Rebates, Discounts, and Other Fees

[177] DEP'T HEALTH AND HUMAN SERVS., OFF. OF INSPEC. GEN., CONCERNS WITH REBATES IN THE MEDICARE PART D PROGRAM at 22 (Mar. 11, 2011), https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf.
[178] ORX_Sen_Fin_0005387.
[179] *See* Letter from Enu Mainigi, Counsel, Williams & Connolly, on Behalf of CVS Health Corp., to Senator Grassley and Senator Wyden (Aug. 27, 2019).
[180] Letter from Enu Mainigi, Counsel, Williams & Connolly, on Behalf of CVS Health Corp., to Senator Grassley and Senator Wyden (Apr. 26, 2019); ORX_Sen_Fin_0004991.
[181] *See* ORX_Sen_Fin_0004991.
[182] ORX_Sen_Fin_0057558.

Rebates are payments made by drug manufacturers to PBMs after the point of sale,[183] and are calculated as a percentage of WAC. Drug manufacturers negotiate rebates with PBMs and health insurers to secure preferred formulary placement for their products.[184] These negotiations can be of such great financial importance to pharmaceutical companies that senior executives up to and including the chief executive officer are often personally involved in the process.[185] Typically, PBMs pass on the majority of these rebates to health insurers,[186] who use rebates to lower premiums, lower cost-sharing, or fund wellness programs for beneficiaries.[187] However, plan sponsors have not always been sufficiently transparent as to how they use rebates, discounts, and other fees they receive from their contracted PBM or from drug manufacturers.[188]

There is limited publicly available information about the contractual arrangements between manufacturers and PBMs. The lack of public understanding stems from the commercial sensitivity of these contracts, and the broad confidentiality clauses that limit their disclosure.[189] The lack of transparency even extends to health plans. While some health plans have certain contractual rights to conduct audits of agreements between their contracted PBM and manufacturers, HHS OIG found that manufacturers can and do refuse such audits.[190]

Moreover, Federal law restricts the dissemination of price and rebate information that companies disclose to the Federal government for Medicaid and Part D plans. Until recently, such information could only be reviewed by the Secretary of the Department of Health and Human Services (HHS), the Comptroller General, Congressional Budget Office, and States (in regards to Medicaid). However, the Consolidated Appropriations Act of 2021 expanded the dissemination of price and rebate information to the Executive Directors of the Medicare Payment Advisory Commission and Medicaid and CHIP Payment and Access Commission—an

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[183] *See* Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Apr. 16, 2019). CVS Caremark, Express Scripts, and OptumRx all have rebate contracts with the three major insulin manufacturers—Eli Lilly, Novo Nordisk, and Sanofi. Letter Wyden from Michael Bopp, Counsel, Cigna to Senator Grassley and Senator (June 21, 2019); Letter Wyden from Enu Mainigi, Counsel, CVS Caremark to Senator Grassley and Senator (May 24, 2019); ORX_Sen_00001935; ORX_Sen_Fin_0005305.

[184] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (May 24, 2019); ORX_Sen_Fin_0005389. For an example of a rebate agreement, *see* Cigna-SFC-00009847.

[185] e.g., LLY-SFCOM-UR-00005146; LLY-SFCOM-UR-00003868; LLY-SFCOM-UR-00003699; LLY-SFCOM-UR-00003445, LLY-SFCOM-UR-00003449. For example, Eli Lilly's chief executive officer and chief financial officer were personally involved in the approval of multiple rebate offers. At one point, the company's chief financial officer "requested LillyUSA implement a more structured process for executive review of material payer deals (requiring CFO and CEO approval)." *See* LLY-SFCOM-UR-00003445. In another instance, diabetes unit employees were chastised for providing management insufficient time to review rebate deals. *See* LLY-SFCOM-UR-00005146.

[186] In 2019, GAO reported that "PBMs passed nearly all rebates received from manufacturers through to Part D plan sponsors in 2016. Part D plan sponsors reported to CMS that, of the approximately $18 billion in rebates that PBMs negotiated with pharmaceutical manufacturers that year, PBMs retained $74.3 million, or about 0.4%, and passed through the remaining 99.6% to plan sponsors." GOV. ACCT. OFFICE, MEDICARE PART D, USE OF PHARMACY BENEFIT MANAGERS AND EFFORTS TO MANAGE DRUG EXPENDITURES AND UTILIZATION, at 16 (July 2019), https://www.gao.gov/assets/710/700259.pdf .

[187] Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Apr. 16, 2019); ORX_Sen_Fin_00001935.

[188] *See generally* DEP'T HEALTH AND HUMAN SERVS., OFF. OF INSPEC. GEN., CONCERNS WITH REBATES IN THE MEDICARE PART D PROGRAM (Mar. 11, 2011), https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf.

[189] SANOFI_SFC_00007985, at SANOFI_SFC_00007994.

[190] DEP'T HEALTH AND HUMAN SERVS., OFF. OF INSPEC. GEN., CONCERNS WITH REBATES IN THE MEDICARE PART D PROGRAM (Mar. 11, 2011), https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf.

expansion proposed in the Prescription Drug Pricing Reduction Act of 2019 that was introduced by Chairman Grassley and Ranking Member Wyden. And, with regard to public disclosure, the Secretary of HHS is allowed to "disclose (through a website accessible to the public) the weighted average of the most recently reported monthly average manufacturer prices and the average retail survey price determined for each multiple source drug."[191]

The Committee's investigation found that manufacturers negotiate contracts directly with health plans or their PBM representatives. These contracts contain terms for drug-specific rebates, price protection clauses (designed to dissuade manufacturers from implementing large year-over-year WAC increases), and administrative fees charged by PBMs, among other items. The investigation also found that these contracts and subsequent amendments can stretch over hundreds of pages and cover multiple therapies offered by a manufacturer. The base contracts and subsequent amendments are updated frequently—sometimes multiple times a year—often over the course of a decade or more.

Contracts between PBMs and manufacturers provide a menu of options from which their health plans clients can choose certain terms and conditions. Rebates can vary significantly based on utilization and the plan's benefit design. Manufacturers will also typically make multiple rebate offers for each drug, with the size of each offer typically tied to formulary access and competition within a therapeutic class. Often, a higher rebate is offered for preferred formulary placement which may include few, if any, utilization restrictions (i.e., lower cost-sharing for patients or plans agreeing not to implement prior authorization). Manufacturers will also pay higher rebates, and sometimes even an additional rebate, if the health plan agrees to make their drugs the only therapy on a given formulary tier. As this investigation has shown, the size of rebates for the insulin therapeutic class has risen rapidly, with some PBMs securing rebates as high as 70% in recent years. However, it's the PBM or health plan who ultimately decide a drug's formulary placement and the patient's cost-sharing responsibility. (PBMs generate revenue from these negotiations. For example, Cigna retains approximately 5% of these negotiated discounts, since it reported passing on "approximately 95% of rebates, discounts, and price reductions back to our clients.")[192]

In addition to rebates, PBMs negotiate with drug manufacturers for other discounts and fees. One such example is the use of inflationary protection fees (often referred to as price protection). If drug manufacturers raise the WAC beyond a certain agreed upon percentage, price protection is triggered, and manufacturers must pay additional rebates to plan sponsors in addition to rebates and other discounts.[193] As stated previously, plan sponsors use these fees to lower premiums, lower cost-sharing, or fund wellness programs for beneficiaries.[194] (This investigation did not examine the financial relationships between PBMs and plan sponsors.) However, in 2011, HHS OIG raised concerns that Part D sponsors "commonly had complex

[191] *See* 42 U.S.C. 1396r-8(b)(3)(D)(cross-referenced at 42 U.S.C. 1395w-102(d)(2) and 42 U.S.C. 1396r-8(b)(3)(D)).
[192] Letter from Kristin Julason Damato, Vice President, Global Public Policy & Government Affairs, Cigna Corporation, to Senator Grassley and Senator Wyden (Dec. 7, 2020).
[193] Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Apr. 20, 2019); Letter from Enu Mainigi, Counsel, Williams & Connolly, on Behalf of CVS Health Corp., to Senator Grassley and Senator Wyden (May 24, 2019); ORX_Sen_Fin_00001935; ORX_Sen_Fin_0005389.
[194] Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Apr. 16, 2019); ORX_Sen_Fin_00001935.

relationships with their PBMs, and in some cases, these relationships lacked transparency," which "raises concerns that sponsors may not always have enough information to oversee the services and information provided by PBMs."[195] HHS OIG added:

> Five sponsors had limited information about the rebate contracts and the rebate amounts negotiated by their PBMs. One PBM reported that it does not share the manufacturer rebate contracts with its sponsors because they contain confidential information and there is a chance that the sponsor may one day become a PBM itself. Another PBM specifically stated that the sponsor would 'not be permitted to copy or retain' any portion of the contract. As a result of these practices, most of the selected sponsors were unaware of all of the contract terms that determine the rebates they receive from drug manufacturers.[196]

The following information details the Committee's findings based on internal documents and memoranda collected from manufacturers (Sanofi, Novo Nordisk, and Eli Lilly) and PBMs (CVS Caremark, Express Scripts, and OptumRx), and seeks to shed further light on these contractual relationships, the negotiations that take place between these two groups, and how rebates, discounts, and fees contribute to insulin's rising list price.

III. The Cost of Insulin to Patients, Medicare, and Private Payers

Increases in insulin's list price have dramatically exceeded rates of inflation and health care inflation,[197] leading to concerns about affordability and access for patients. Indeed, during the Committee's hearing titled: *Drug Pricing in America: A Prescription for Change Part I*, the Committee heard from Kathy Sego, a resident of Indiana and a mother whose son has Type 1 diabetes.[198] Ms. Sego told the Committee how, unbeknownst to her, her son rationed his insulin so that their family could afford the $1,700 price tag of his monthly insulin medication. It wasn't until he stopped eating, lost 20 pounds, and seemed depressed that she realized that something was wrong. Unfortunately, Ms. Sego's family is not alone in this struggle. Therefore, as Congress considers common sense policy solutions to address this growing crisis, it is critically important to understand how insulin's list price has evolved over time, and the various factors and players that have caused it to increase exponentially in the past decade.[199]

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[195] DEP'T HEALTH AND HUMAN SERVS., OFF. OF INSPEC. GEN., CONCERNS WITH REBATES IN THE MEDICARE PART D PROGRAM, at 17 (Mar. 11, 2011), https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf.
[196] Id. AT 17-18.
[197] *National Health Expenditure Projections, 2019-2028*, CTRS. MEDICARE AND MEDICAID SERVS., https://www.cms.gov/files/document/nhe-projections-2019-2028-forecast-summary.pdf (last viewed Dec. 28, 2020) (The rate of personal health care inflation is projected to grow 1.9% in 2020 up from 1.5% in 2019). According to the Keiser Family Foundation: "Among the 22 insulin therapies that have been on the market since 2013, 16 products had average annual increases of more than 10% between 2014 and 2018 . . . which far exceeded the 1.5% rate of inflation over the same time period." *Insulin Costs and Coverage in Medicare Part D*, KFF (June 2020), https://www.kff.org/report-section/insulin-costs-and-coverage-in-medicare-part-d-issue-brief/.
[198] *Drug Pricing in America: A Prescription For Change Part I, Hearing Before the S. Fin. Comm*., 116th Cong. (2019) (statement of Kathy Sego), https://www.finance.senate.gov/imo/media/doc/29JAN2019SEGOSTMNT.pdf.
[199] The *Prescription Drug Price Reduction Act of 2020* (co-authored by Senator Grassley and Senator Wyden) is one such piece of legislation that would reduce prescription drug costs for Americans. *See* Press Release, Grassley, Colleagues Introduce Updated Bipartisan Prescription Drug Pricing Bill (July 2, 2020), https://www.grassley.senate.gov/news/news-releases/grassley-colleagues-introduce-updated-bipartisan-prescription-drug-pricing-bill.

a. Insulin List and Net Price Trends: 2013 to 2019

Drug manufacturers independently set the price for their medications—referred to as wholesale acquisition cost, WAC, or list price—based on a number of factors.[200] Documents reviewed during this investigation show that the primary factors considered by companies were the competitive environment, the need to provide rebates, discounts, and other fees to health insurers and their PBMs, and the importance of maintaining market access to preserve sales volume and revenue. When manufacturers set the WAC price for a given product, it is applicable to all payer contracts in its book of business. However, the WAC price is not the amount the manufacturer receives, nor is it the amount paid by the Federal government, health insurers, or employers. The WAC price is the starting point that manufacturers use to negotiate with wholesale distributers, who resell the medication to pharmacies.[201] Instead, manufacturers receive what is known as "net price," which is the amount of money remaining after the manufacturer pays for rebates, discounts, and other fees to health insurers or PBMs, Federal and state health care programs, employers, and other entities.[202]

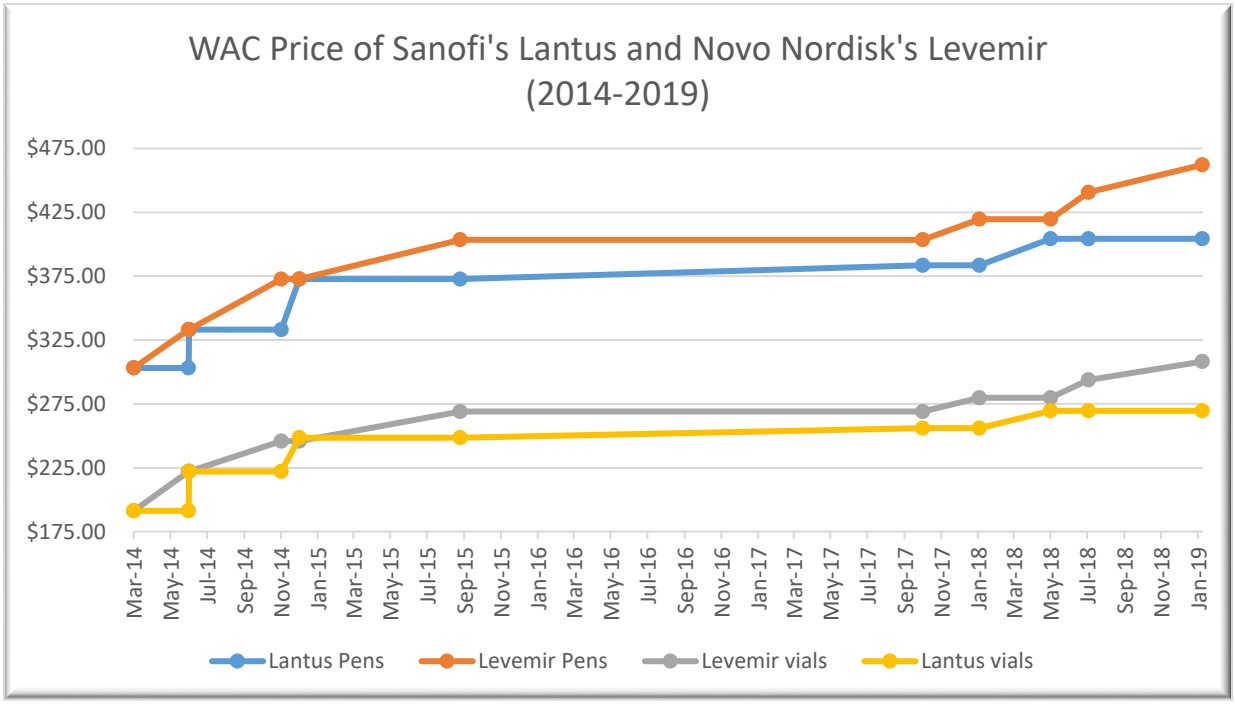
The following tables refects the WAC price of Sanofi's Lantus and Novo Nordisk's Levemir between 2014 and 2019.[203]

[200] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019); Letter from Raphael Prober, Counsel, Akin Gump, on Behalf of Novo Nordisk, to Senator Grassley and Senator Wyden (Mar. 8, 2019); Letter from Joseph B. Kelley, Vice President, Global Government Affairs, Eli Lilly, to Senator Grassley and Senator Wyden (Mar. 8, 2019).

[201] Letter from Joseph B. Kelley, Vice President, Global Government Affairs, Eli Lilly, to Senator Grassley and Senator Wyden (Mar. 8, 2019).

[202] *Id.* The practical effect of rebates is substantial. For example, Novo Nordisk reported net sales of DKK 122 billion (Danish krone) in 2019, noting in its annual report, "the provision for sales rebates and discounts amounted to DKK 30,878 million as of December 31, 2019, *of which a significant portion relates to the US business*." *2019 Annual Report*, NOVO NORDISK, https://www.novonordisk.com/content/dam/nncorp/global/en/annual-report/pdfs/2019/Novo-Nordisk-Form-20-f-2019.pdf (last viewed Dec. 29, 2020).

[203] Calculated using WAC data produced by Sanofi and Novo Nordisk. Sanofi produced WAC data for insulin products per milliliter. In order to calculate the WAC total, Committee staff multiplied price per milliliter by the amount of mL in the vial or in the box. *See* Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019) (attachment 1(a) and (b)). NNI-FINANCE-0002-03.



This investigation primarily focused on the change in WAC price between three long-acting insulins[204]—Lantus, Levemir, and Basaglar—that are in direct competition with each other. Sanofi and Novo Nordisk have steadily increased Lantus' and Levemir's WAC since 2005.[205] Based on WAC data tracked in internal documents, between 2013 and 2019, Lantus' and Levemir's WAC prices increased rapidly.[206] For example:

- Sanofi's Lantus SoloStar (pens) increased from a WAC of $303 in January 2014 to approximately $404 in January 2019—an increase of over 33% in 5 years.[207]

- Novo Nordisk's Levemir Flextouch (pens) increased from a WAC of $303 in May 2014 to approximately $462 in January 2019—an increase of over 52% in 5 years.[208]

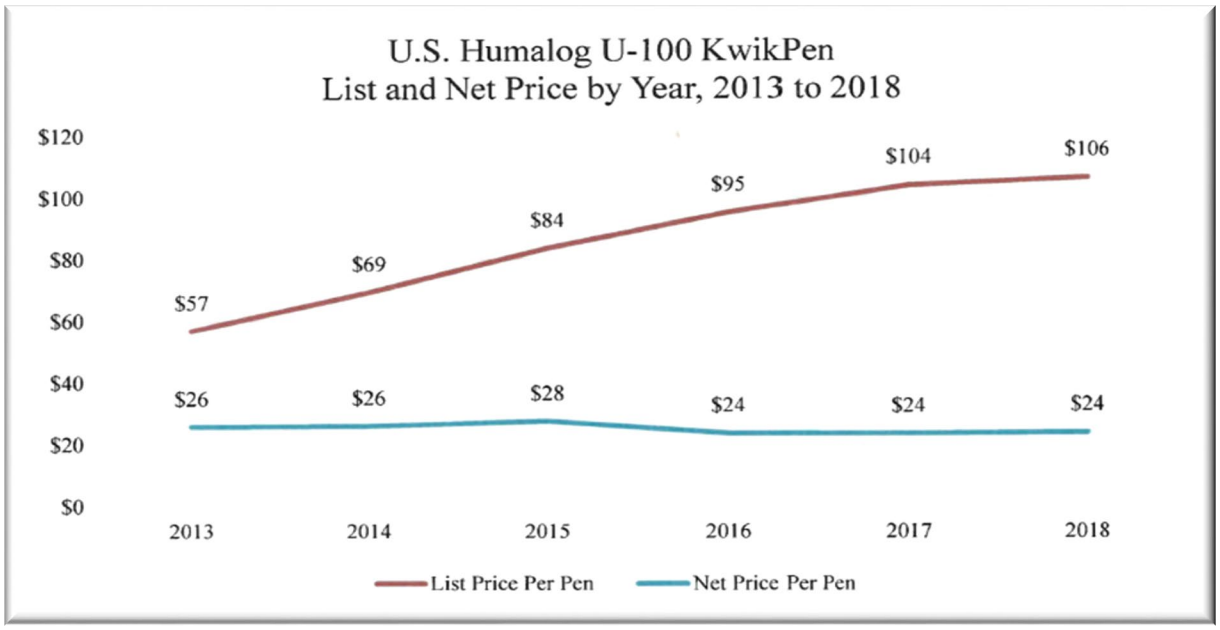
[204] According to the ADA, "long-acting insulin reaches the blood stream several hours after injection" and keeps glucose levels stable in the body for up to 24 hours. *See Insulin Basics*, ADA, https://www.diabetes.org/diabetes/medication-management/insulin-other-injectables/insulin-basics (last visited Dec. 29, 2020).
[205] E.g., Sanofi increased Lantus's WAC by almost 250% from 2005 to 2015, while retaining higher average net prices. *See* SANOFI_SFC_00009556. (On file with Committee). *See also* SANOFI_SFC_00009527.
[206] *See* Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019) (attachment 1(a) and (b)). NNI-FINANCE-0002-03.
[207] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019) (attachment 1(a) and (b)).
[208] NNI-FINANCE-0002-03.

- Eli Lilly's Basaglar launched in November 2016 with a WAC price 23% lower than Lantus at $316.85.[209] However, Basaglar's WAC price increased to $326.36 the following year.[210]

List prices for short-acting and rapid-acting insulins have also risen dramatically during this time period.[211] For example, in 2017, Eli Lilly's Humalog 50-50 Kwikpen[212] had a WAC of $530.40 compared to $323.95 in 2013—representing an increase of approximately 64% in 4 years.[213] Sanofi's rapid-acting insulin, Apidra, increased from $302 in 2014 to $521 in 2019, and Novo Nordisk's rapid acting insulin, Novolog Mix 70/30 FlexPen, increased from $324 in 2013 to $558 in 2018, over a 70% WAC increase for both companies during this time.[214]

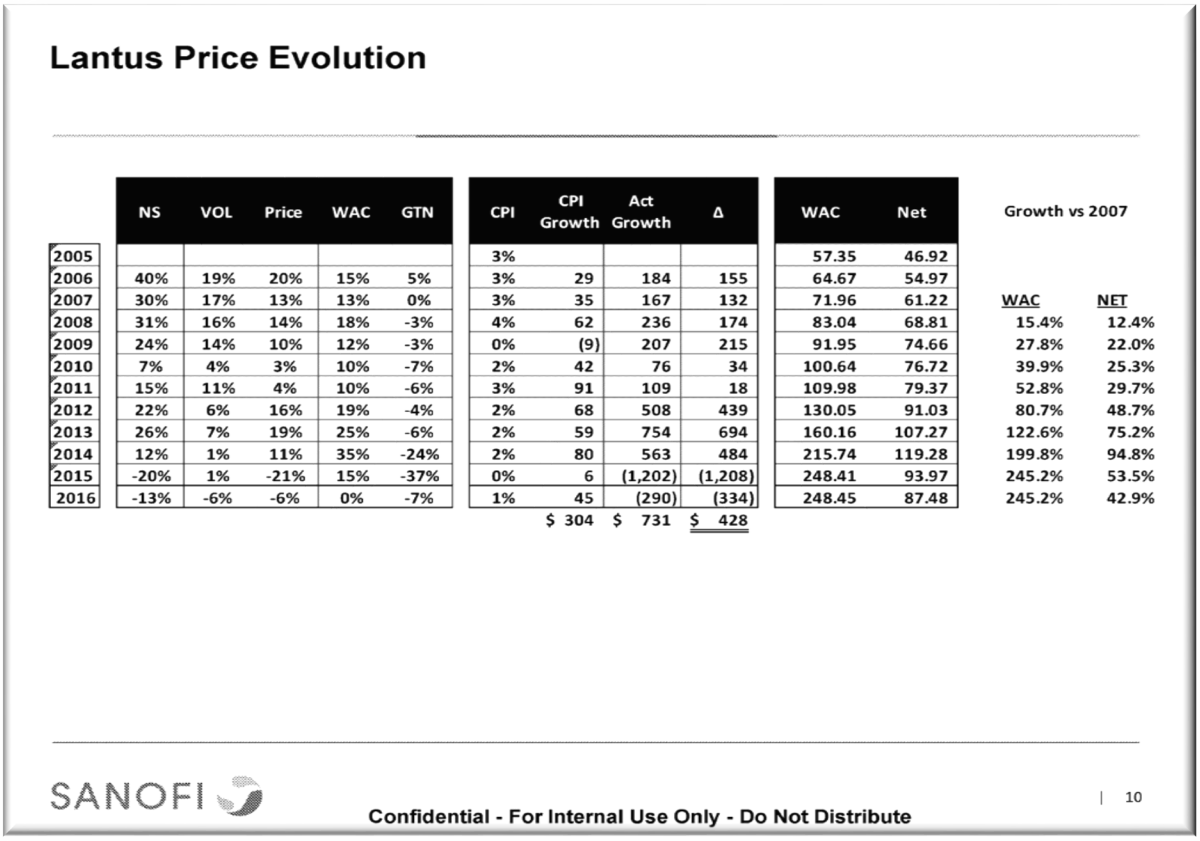
While insulin manufacturers set a single WAC price for each product across their entire book of business, it is important to note that there is no "single" net price for insulin.[215] As discussed above, manufacturers negotiate contracts with PBMs that provide participating health plans with a range of rebates and other discounts based on, and subtracted from, the product's WAC price. The contracts stipulate terms the plans must follow regarding factors such as formulary placement and competition from other drugs in the therapeutic class. As such, a manufacturer can actually receive multiple net prices from a single payer if the payer operates multiple plans that, in turn, place the product in different formulary positions.[216]

[209] LLY-SFCCOM-00000001. *See also* Letter from Joseph B. Kelley, Vice President, Global Government Affairs, Eli Lilly, to Senator Grassley and Senator Wyden (Mar. 8, 2019).
[210] LLY-SFCCOM-00000001.
[211] As discussed above, there are several different kinds of insulin products. According to the ADA, rapid-acting insulins begin to work about 15 minutes after injection (e.g., Fiasp, NovoLog, Apidra, Admelog, and Humalog). Short-acting insulins on the other hand reach the bloodstream within 30 minutes after injection (e.g., Humulin R, Novolin R). *See Insulin Basics*, ADA, https://www.diabetes.org/diabetes/medication-management/insulin-other-injectables/insulin-basics (last viewed Dec. 29, 2020).
[212] Specifically, Humalog Kwikipen U-100.
[213] LLY-SFCCOM-00000001.
[214] *See* Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019) (attachment 1(a) and (b)). NNI-FINANCE-0002-03.
[215] *See* Letter from Reginald Brown, Counsel, WilmerHale, on Behalf of Eli Lilly, to Senator Grassley and Senator Wyden (Mar. 8, 2019).
[216] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019); Letter from Raphael Prober, Counsel, Akin Gump, on Behalf of Novo Nordisk, to Senator Grassley and Senator Wyden (Mar. 8, 2019); Letter from Joseph B. Kelly, Vice President, Global Government Affairs, Eli Lilly, to Senator Grassley and Senator Wyden (Mar. 8, 2019).



Data and documents produced to the Committee suggest that the net prices of insulin manufacturers' products has declined in recent years, but remained significantly higher than they were in the first decade of the 21st Century. For example, in a letter to the Committee, Eli Lilly provided data showing that its average net price for Humalog KwikPen had declined slightly from $28 per pen in 2015 to $24 per pen in 2018, despite the WAC price nearly doubling during that same period (see figure above).[217] On the other hand, an internal Sanofi presentation shows that while the average Lantus net price of $87.48 in 2016 was $32 lower than the drug's net price in 2014, it was roughly double the drug's net price of $46.92 in 2005.[218] Net price growth was also significantly greater than the Consumer Price Index growth the company tracked.[219] An excerpt of Sanofi's internal presentation is shown below.[220]

[217] Letter from Joseph B. Kelly, Vice President, Global Government Affairs, Eli Lilly, to Senator Grassley and Senator Wyden (Mar. 8, 2019).
[218] SANOFI_SFC_00011407, at SANOFI_SFC_00011416.
[219] SANOFI_SFC_00011407, at SANOFI_SFC_00011416.
[220] SANOFI_SFC_00011407, at SANOFI_SFC_00011416.



Lantus Price Evolution

	NS	VOL	Price	WAC	GTN	CPI	CPI Growth	Act Growth	Δ	WAC	Net	Growth vs 2007	
												WAC	NET
2005						3%				57.35	46.92		
2006	40%	19%	20%	15%	5%	3%	29	184	155	64.67	54.97		
2007	30%	17%	13%	13%	0%	3%	35	167	132	71.96	61.22		
2008	31%	16%	14%	18%	-3%	4%	62	236	174	83.04	68.81	15.4%	12.4%
2009	24%	14%	10%	12%	-3%	0%	(9)	207	215	91.95	74.66	27.8%	22.0%
2010	7%	4%	3%	10%	-7%	2%	42	76	34	100.64	76.72	39.9%	25.3%
2011	15%	11%	4%	10%	-6%	3%	91	109	18	109.98	79.37	52.8%	29.7%
2012	22%	6%	16%	19%	-4%	2%	68	508	439	130.05	91.03	80.7%	48.7%
2013	26%	7%	19%	25%	-6%	2%	59	754	694	160.16	107.27	122.6%	75.2%
2014	12%	1%	11%	35%	-24%	2%	80	563	484	215.74	119.28	199.8%	94.8%
2015	-20%	1%	-21%	15%	-37%	0%	6	(1,202)	(1,208)	248.41	93.97	245.2%	53.5%
2016	-13%	-6%	-6%	0%	-7%	1%	45	(290)	(334)	248.45	87.48	245.2%	42.9%
							$ 304	$ 731	$ 428				

SANOFI

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| 10

It is clear that WAC prices have not kept up with the growing size of rebates, discounts, and other fees, putting pressure on pharmaceutical manufacturers' margins. The Committee found examples of manufacturers recognizing this market dynamic and seeking to make up for lost revenue elsewhere. For example, in 2014, senior officials in Eli Lilly's diabetes business unit were preparing to warn company executives "that the ability to pull the US price lever for Humalog to cover a gap in the overall corporate plan does not exist."[221] Another employee in the exchange observed, "[t]his is an interesting picture –list prices going way up and so are rebates– after these major changes … our net prices are flat."[222] His colleague responded, "Exactly. And to expect it to grow again in a meaningful way would be a huge planning risk."[223]

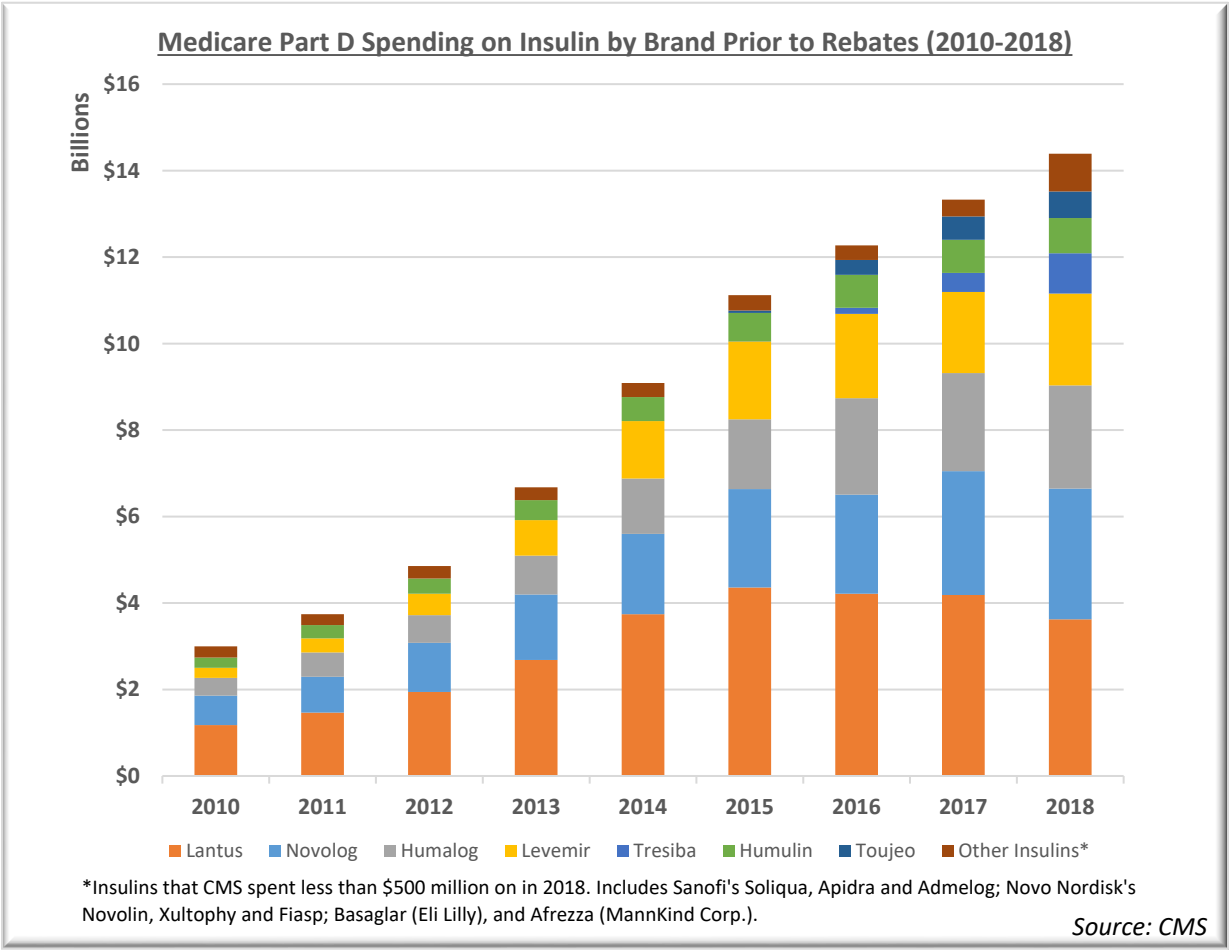
b. Medicare Part D's Pre-Rebate Spending on Insulin has Risen Steadily Since 2010

CMS provided the Finance Committee with data that show the growing amount of money that Medicare Part D plans have paid for insulin, prior to rebates and other discounts, since 2010. Rebates negotiated by Part D plans are treated as confidential information by Federal law,

[221] LLY-SFCOM-UR-00003170.
[222] LLY-SFCOM-UR-00003170.
[223] LLY-SFCOM-UR-00003170.

therefore, this analysis examines spending before rebates.[224] Spending before rebates is an important data point to consider, as patients' out-of-pocket costs are affected in part by a drug's WAC price before rebates, discounts, and other fees are included.

Based on data provided by CMS, annual spending on insulin has increased by billions of dollars over the last decade. Between 2010 and 2018, Medicare Part D spent $78.4 billion on insulin prior to rebates, the majority of which was spent on Lantus ($27.4 billion), Novolog ($16.5 billion), Humalog ($12.3 billion), and Levemir ($11 billion).[225]



The growth of CMS's pre-rebate spending on insulin also significantly outstripped the growth rate of beneficiaries utilizing insulin from 2010 to 2018. For instance, the number of Part

[224] According to Medicare actuaries, the average rebate negotiated by Medicare Part D plan sponsors for all drugs has increased substantially in recent years. 2020 ANNUAL REPORT OF THE BOARDS OF TRUSTEES OF THE FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUNDS (2020), https://www.cms.gov/files/document/2020-medicare-trustees-report.pdf.

[225] During this investigation, the Committee received data from CMS on insulin spending on Medicare Part B and D. Spending for Medicare Part B drugs also increased between 2010 and 2018. For example, in 2010, the Federal government spent $14 million prior to rebates on insulin drugs administered by a physician and covered by Medicare Part B. By 2018, the Federal government reported spending over $96 million prior to rebates on Medicare Part B insulin payments—representing an increase of approximately 585% in less than 8 years.

D beneficiaries using insulin increased 51%, from over 2.1 million in 2010 to approximately 3.2 million in 2017, whereas spending on insulin prior to rebates increased more than 470%, from over $3 billion in 2010 to roughly $14.3 billion in 2018. To put this into perspective, the $11 billion increase in pre-rebate annual spending on insulin over those eight years is roughly equal to the total proposed budget of the Federal Transit Administration for Fiscal Year 2021.[226]

c. Patient Out-of-Pocket Spending in Medicare Part D

As noted above, rising WAC prices can increase a patient's out-of-pocket costs. However, out-of-pocket costs vary widely due to multiple factors, including WAC price, dosage quantity, days' supply, formulary and utilization management decisions made by the health plan, and the relevant coverage phase of the Part D benefit.[227] A recent study published in *The New England Journal of Medicine* breaks down the considerable costs faced by Part D beneficiaries using insulin:

> When examining strategies for making insulin more affordable for older adults, it is important to consider how Part D plans currently cover insulin. Of the 3649 outpatient prescription-drug plans that were available to Medicare beneficiaries (Part D plans) in 2019, we found that nearly 90% offered long-acting insulin products (the most commonly used insulin in Part D) with copayments ranging from $45 to $47 per fill in the initial coverage phase (up to $4,020 in total drug spending in 2020) of the Part D benefit. We expect benefit designs to be similar for 2020 plans. Thus, for beneficiaries with less than $4,020 in total drug spending in 2020, copayments would be used for every insulin fill. For beneficiaries with more than $4,020 in total drug spending (average monthly drug costs of more than $335), nearly all plans required 25% coinsurance in the Part D coverage gap, with median out-of-pocket costs ranging from $72 to $236 per fill in this benefit phase. Considering average list prices, patients with typical Part D plans who use long-acting insulin and have no other drug expenditures would spend $1,140.68 out of pocket on 12 fills of insulin ($46.00 per fill for about 6.5 fills in the initial coverage phase and $153.75 per fill for the remaining fills in the coverage gap).[228]

However, a patient's out-of-pocket costs are likely higher, as a majority of diabetics also utilize short-acting, rapid-acting, and/or intermediate-acting insulins, buy test-strips and other medical devices, and take medications for other comorbidities (e.g., hypertension or renal disease).[229] Indeed, based on Part D gross drug cost data collected from CMS, in 2018, more than a quarter of patients enrolled in Medicare Part D spent upwards of $5,000 a year on their

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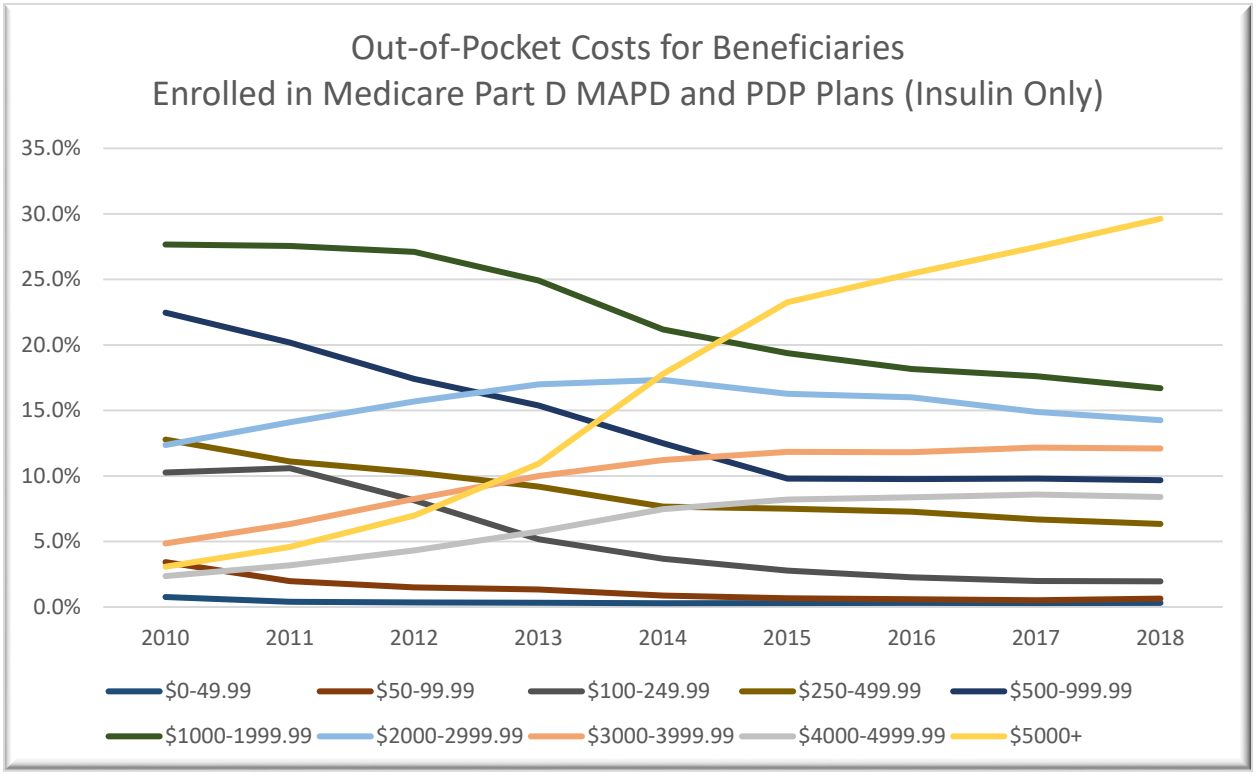
[226] *See* PRESIDENT DONALD J. TRUMP'S FY 2021 BUDGET TITLED: A BUDGET FOR AMERICA'S FUTURE, https://www.whitehouse.gov/wp-content/uploads/2020/02/budget_fy21.pdf.

[227] Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Apr. 20, 2019).

[228] Stacie B. Dusetzina et al., *Medicare Part D and Insulin Affordability—The Devil is in the Details*, N. ENG. J. MED. 1878, 1878 (Apr. 1, 2020).

[229] *Type 1 diabetes*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/type-1-diabetes/diagnosis-treatment/drc-20353017(last viewed Jan. 4, 2021); *Type 2 diabetes*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/type-2-diabetes/diagnosis-treatment/drc-20351199 (last viewed Jan. 1, 2021).

insulin medications.[230] This represents a dramatic increase in out-of-pocket spending compared to 2010 where a majority of Medicare Part D patients spent $2,000 or less.



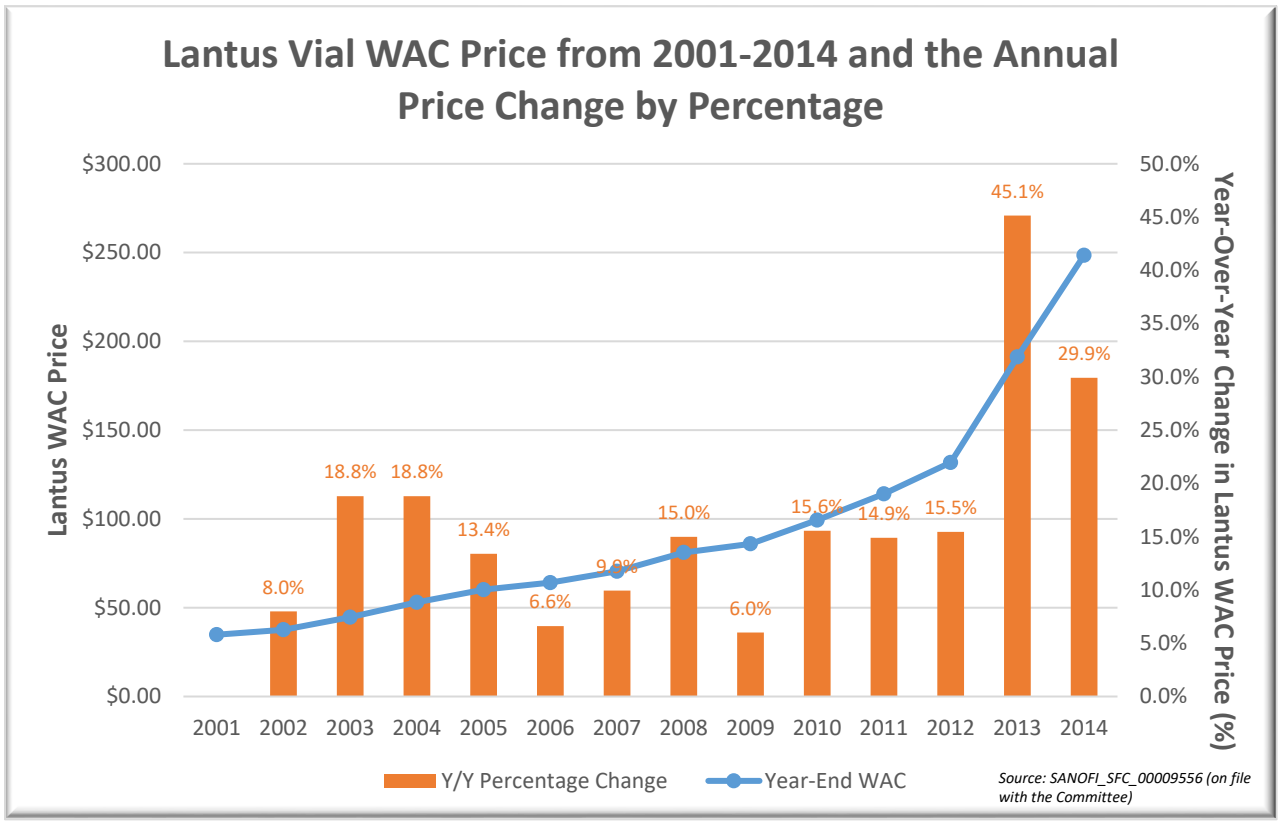
Documents produced to the Committee show that rebates, administrative fees and other price concessions are significant factors affecting how manufacturers determine WAC prices. In the insulin therapeutic class, PBMs consider insulins to be interchangeable in their safety, efficacy, and kinetics.[231] It has also become increasingly common for PBMs and health insurers to offer only one line of insulin products on their formularies while excluding the rest.[232]

d. A Case Study: Examining Sanofi and Novo Nordisk's Decision to Implement Aggressive List Price Increases and the Impact on the Long-acting Insulin Market

Sanofi's decision to significantly increase Lantus's list price between 2001 and 2014 contributed to the dramatically increasing cost of long-acting insulins over the past decade. Sanofi manufactures two long-acting insulins under the trade names Lantus and Toujeo,[233] in

[230] During this investigation, we collected data from CMS on insulin spending on Medicare Part C and D gross drug costs by coverage type. Medicare Part D prescription drug events contain prescription drug costs and payment data that enable CMS to make payments to plans. Using this data, CMS was able to calculate gross drug costs for insulin drugs from 2012 through 2018.
[231] *See* Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Apr. 16, 2019).
[232] Letter from Joseph B. Kelly, Vice President, Global Government Affairs, Eli Lilly, to Senator Grassley and Senator Wyden (Mar. 8, 2019).
[233] Sanofi manufactures insulin glargine, a type of long-acting insulin that mimics the flat profile of insulin released from a healthy pancreas. *See* Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, to Senator Grassley and Senator Wyden (Mar. 8, 2019).

addition to rapid-acting insulins Apidra and Admelog (a biosimilar of the mealtime insulin Humalog).[234] According to internal documents and correspondence acquired by the Committee, Sanofi's intent behind Lantus's price increase centered on its objective to maximize profits, ensure the overall long-term success of its diabetes franchise, and respond to aggressive rebate and discount activity from Novo Nordisk and PBMs.[235]



According to internal data, Lantus's WAC price was $34.81 in 2001.[236] See graph above. From 2005 to 2011, internal memoranda show Sanofi increased Lantus's list price as much as 18% annually.[237] However, between 2012 and 2014, Sanofi increased Lantus's list price at a rate significantly higher than it had done previously. For example, Sanofi increased Lantus's list price three times in 2013 alone—on April 26, 2013, August 2, 2013, and December 13, 2013—resulting in a total increase of approximately 39.7% for Lantus vials and 29.7% for Lantus pens.[238] Data provided to the Committee by Sanofi show the company increased Lantus's price two more times in 2014 and, by December 1, 2014, Lantus cost $248.51 per vial, and Lantus pens cost $372.76 per package.[239] However, Sanofi's decision to increase Lantus's list price was

[234] *See* Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, to Senator Grassley and Senator Wyden (Mar. 8, 2019).
[235] SANOFI_SFC_00009132, at SANOFI_SFC_00009135.
[236] SANOFI_SFC_00009556.
[237] This figure represents Lantus's average WAC increase between 2005 and 2011 on a percentage basis. *See* SANOFI_SFC_0011407, at SANOFI_SFC_00011416.
[238] SANOFI_SFC_00014580, at SANOFI_SFC_00014582; NNI-FINANCE-001699, at NNI-FINANCE-001701.
[239] *See* Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, to Senator Grassley and Senator Wyden (Mar. 8, 2019) (attachment 1(a) and (b)).

not without consequences. In the run-up to rebate negotiations with Express Scripts in 2015, Sanofi noted that "Lantus price increases over the past two years have positioned Sanofi as a cost driver that has triggered significant attention from [Express Scripts]."[240]

According to an internal memo created by Sanofi in 2013/2014, the company took aggressive pricing actions for several reasons. First, Sanofi sought to retain as many diabetes patients as possible in advance of future pipeline expansion and product competition and, in 2013, decided to close the price differential between Lantus vials and Lantus pens on a per unit basis.[241] By setting a single price point for Lantus, and by launching Toujeo—its next-generation concentration of insulin glargine—at WAC parity to Lantus, Sanofi believed that it would remove cost as a barrier for switching patients to Toujeo to become the preferred basal insulin.[242] The diabetes franchise was—and remains—extremely important to the company, with Sanofi describing Lantus as a "flagship product" of its diabetes division, accounting for revenue of €4.9 billion in 2013, equal to 14.2% of the company's revenue that year.[243] According to Sanofi, if Lantus were to encounter product challenges, such as pressure from existing competitive products or a reduction in sales, the adverse impact to Sanofi's business "could be significant."[244]

Second, Sanofi raised Lantus's list price to respond to rebate and discount competition from Novo Nordisk. Novo Nordisk manufactures two long-acting insulins under the trade names Levemir and Tresiba as well as two rapid-acting insulins NovoLog and Fiasp.[245] In the long-acting insulin category, Lantus and Levemir often compete to win the same accounts. According to internal memoranda, in 2013, Sanofi believed that Novo Nordisk was attempting to minimize the clinical difference between Lantus and Levemir and was offering "increased rebates and/or portfolio offers for the sole purpose of removing Lantus from favorable formulary access."[246] According to an internal Sanofi memo, "the strategy to close the price differential between the Lantus vial and pen before the LOE [loss of exclusivity] period was believed to be critical to the overall long-term success of the franchise."[247]

Third, Sanofi also faced increased pressure from its payer and PBM clients to offer more generous rebates and price protection terms or face exclusion from formularies, developments that were described as "high risk for our business" that had "quickly become a reality."[248] These insurance market changes were partly driven by the implementation of the ACA, which put pressure on plan margins, and a willingness by plans to exclude drugs from their formularies as a negotiating tool.[249] This market environment created an enormous challenge for Lantus and, in order to protect its flagship diabetes franchise, Sanofi appears to have increased Lantus's list

[240] SANOFI_SFC_00014648, at SANOFI_SFC_00014653.
[241] SANOFI_SFC_00009132, at SANOFI_SFC_00009135.
[242] SANOFI_SFC_00009377, at SANOFI_SFC_00009378, SANOFI_SFC_00009388-89.
[243] Sanofi 20-F, page 8 (2013). Sanofi reported revenue to the Securities and Exchange Commission in Euros. €4.9 billion is approximately $5.96 billion in today's dollars.
[244] Sanofi 20-F, page 8 (2019); Sanofi 20-F, page 8 (2013).
[245] *See* Letter from Raphael Prober, Counsel, Akin Gump, on Behalf of Novo Nordisk, to Senator Grassley and Senator Wyden (June 28, 2019).
[246] *See* SANOFI_SFC_00009211, at SANOFI_SFC_00009217. Sanofi believed that Novo Nordisk was offering rebates as high as 53% on Levemir during this time. SANOFI_SFC_00009132, at SANOFI_SFC_00009140.
[247] SANOFI_SFC_00009132, at SANOFI_SFC_00009135.
[248] SANOFI_SFC_00009132, at SANOFI_SFC_00009135.
[249] SANOFI_SFC_00009132, at SANOFI_SFC_00009132-33.

price so that it could improve its rebate and discount offering to payers while maintaining net sales.

Sanofi understood the risk of its decision and "went into 2013 with eyes wide open that the significant price increases planned would inflame [its] customers," and that its aggressive pricing actions would cause an immediate reaction from Novo Nordisk.[250] However, it was seeking to make up for "shortfalls with Lantus demand generation and global profit shortfalls" which it said "put pressure on the US to continue with the price increases to cover gaps."[251] The company conceded that it was "difficult to determine whether we would face these risks anyway if we hadn't taken the price increases."[252]

Internal documents and correspondence show that immediately following Sanofi's 2013 pricing actions, Novo Nordisk increased Levemir's list price in lockstep with Lantus in its continued effort to offer increased rebates and discounts to payers and displace Lantus from preferred formulary placement.

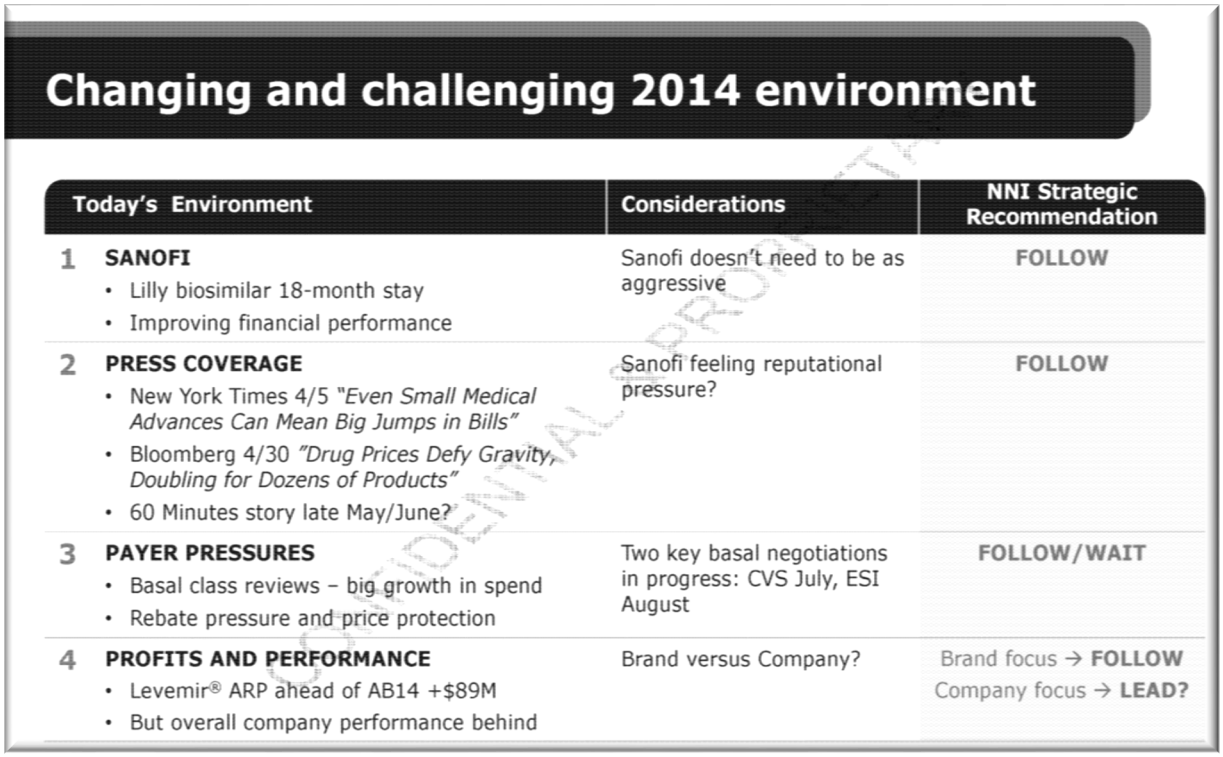
i. In 2014, Novo Nordisk Engaged in Shadow Pricing to Respond to Sanofi's 2013 Pricing Actions

The cornerstone of Novo Nordisk's pricing strategy was to follow Sanofi's actions—a practice that has been referred to as "shadow pricing."[253] Industry observers have described shadow pricing as a phenomenon of "price increases on related brands of aging products from competing companies that often seem to move in synchronized fashion," that "are not tied to the health care inflation rate or cost of goods, but seemingly to the ability of insurance payers and consumers to pay."[254] The practical effect eliminates any meaningful or sustained price variation between Sanofi and Novo Nordisk's basal insulins, which at the time were the only basal insulins available to patients.

Internal documents show that Novo Nordisk's U.S. Pricing Committee (USPC), which makes pricing recommendations for insulin and other drugs, repeatedly suggested matching competitors' pricing for insulin and other products. For example, on May 19, 2014, Novo Nordisk's USPC discussed how to price Levemir in response to Sanofi's 2013 pricing actions.[255] Based on an internal presentation created for this meeting, Novo Nordisk's USPC discussed

[250] SANOFI_SFC_00009132, at SANOFI_SFC_00009135.
[251] SANOFI_SFC_00009132, at SANOFI_SFC_00009135.
[252] SANOFI_SFC_00009132, at SANOFI_SFC_00009135.
[253] An internal presentation revealed that Novo Nordisk amended its pricing strategy on October 21, 2013, to follow Sanofi's marketing, access and profits movements" to "Maximize Brand Value." NNI-FINANCE-001699, at NNI-FINANCE-001701.
[254] Anurag Rathore & Faheem Shereef, *Shadow pricing and the art of profiteering from outdated therapies*, NATURE BIOTECHNOLOGY (2019), https://www.nature.com/articles/s41587-019-0049-7. *See* also Lydia Ramsey Pflanzer, *There's something off about the way insulin prices change*, BUSINESS INSIDER (Sept. 17, 2016), https://www.businessinsider.com/rising-insulin-prices-track-competitors-closely-2016-9.
[255] NNI-FINANCE-0001699. Pricing decisions for drugs marketed and sold by Novo Nordisk in the U.S. are made by its USPC. Between 2014 and 2019, Novo Nordisk's USPC was comprised of 17 members with 4 voting members responsible for insulin pricing. The four voting members responsible for insulin pricing are: Doug Langa, Executive Vice President, North America Operations, and President of Novo Nordisk; Steve Albers, Corporate Vice President, Market Access and Public Affairs; David Moore, Senior Vice President, Commercial; and, Ulrich Ottee, Senior Vice President, Finance and Operations. *See* Letter from Raphael Prober, Counsel, Akin Gump, on Behalf of Novo Nordisk, to Senator Chuck Grassley and Senator Wyden (Mar. 8, 2019); Letter from Raphael Prober, Counsel, Akin Gump, on Behalf of Novo Nordisk, to Senator Chuck Grassley and Senator Wyden (June 28, 2019).

whether it should be a follower in the market, in relation to Sanofi, and considered external factors like press coverage, payer reactions, profits, and performance.[256] In each case, the company's strategic recommendation was to follow Sanofi's pricing moves, rather than lead.[257] Of note, the presentation shows that the USPC considered Levemir's performance, which was ahead of 2014's annual budgeting by $89 million, but that "overall company performance [is] behind."[258] The presentation appears to recommend following Sanofi's pricing actions if the brand's performance is the priority, and to lead if the company's performance is the priority.[259] An excerpt of Novo Nordisk's presentation is shown below.[260]



Changing and challenging 2014 environment

Today's Environment	Considerations	NNI Strategic Recommendation
1 **SANOFI** • Lilly biosimilar 18-month stay • Improving financial performance	Sanofi doesn't need to be as aggressive	**FOLLOW**
2 **PRESS COVERAGE** • New York Times 4/5 *"Even Small Medical Advances Can Mean Big Jumps in Bills"* • Bloomberg 4/30 *"Drug Prices Defy Gravity, Doubling for Dozens of Products"* • 60 Minutes story late May/June?	Sanofi feeling reputational pressure?	**FOLLOW**
3 **PAYER PRESSURES** • Basal class reviews – big growth in spend • Rebate pressure and price protection	Two key basal negotiations in progress: CVS July, ESI August	**FOLLOW/WAIT**
4 **PROFITS AND PERFORMANCE** • Levemir® ARP ahead of AB14 +$89M • But overall company performance behind	Brand versus Company?	Brand focus → **FOLLOW** Company focus → **LEAD?**

In alignment with this strategy, Novo Nordisk's USPC debated potential pricing scenarios based on Sanofi's actions, which they projected with a great deal of specificity. The presentation provided options regarding whether the company should follow Sanofi—and increase list price in July—or lead with a 9.9% increase in August which it considered "optically less aggressive."[261] Based on internal memoranda, it appears that Novo Nordisk's USPC decided to revisit the issue with specific recommendations once Sanofi took action.[262]

Less than two weeks later, on May 30, 2014, Farruq Jafery, Vice President of Pricing, Contract Operations and Reimbursement, emailed Novo Nordisk's USPC to inform them that

[256] NNI-FINANCE-001699, at NNI-FINANCE-001702.
[257] NNI-FINANCE-001699, at NNI-FINANCE-001702.
[258] NNI-FINANCE-001699, at NNI-FINANCE-001702.
[259] NNI-FINANCE-001699, at NNI-FINANCE-001702.
[260] NNI-FINANCE-001699, at NNI-FINANCE-001702.
[261] NNI-FINANCE-001699, at NNI-FINANCE-001703.
[262] NNI-FINANCE-001699, at NNI-FINANCE-001703.

"Sanofi took a price increase on Lantus effective today: 16.1% vial and 9.9% pen."[263] He further wrote that the USPC had "agreed that the best strategy for Levemir is to observe the market and maintain list price parity to competitors."[264] Mr. Jafery then requested that Novo Nordisk's USPC vote "ASAP" to raise the list price of Levemir effective May 31, 2014 (the next day) from $191.28 to $222.08 for vials and from $303.12 to $333.12 for pens.[265] Only a few hours after Sanofi took its list price increase, members of the USPC approved Mr. Jafery's request and Novo Nordisk moved forward with a 16.1% increase on Levemir vial, and a 9.9% increase on Levemir FlexPen and FlexTouch.[266] An excerpt of Mr. Jafery's email is shown below.[267]

Dear Pricing Committee:

Sanofi took a price increase on Lantus effective today: 16.1% vial and 9.9% pen.

Based on our PC discussion on 5/19/2014, we agreed that the best strategy for Levemir® is to observe the market and maintain list price parity to competitors**.

As such, we will be moving forward with a 16.1% increase on Levemir® vial and a 9.9% increase on Levemir® FlexPen® and FlexTouch® effective tomorrow 5/31/2014. This is the approach which minimizes Price Protection impact in 2015 (avoids $13M in incremental PP rebates vs. taking after 6/1/14).

As we need to move immediately to ensure the increase is operationalized in time, please reply back ASAP. We have discussed the impact with Brand and Trade on FlexTouch launch and with Market Access on impact on ongoing negotiations. Although this will generate some pushback from customers, it is believed that this can be managed to mitigate negative impact.

Note that the RE2 forecast assumed 14.9% vial and 9.9% pen, so the ARP upside from this increase is +$32.3M vs RE2 and +$125.9M vs AB14.

List prices resulting from the proposed increase are shown in the table below:

NDC#	Product Name	Current WAC/pkg	Pct Change	WAC/pkg	Effective Date*
00169-3687-12	Levemir®	$191.28	**16.1%**	**$222.08**	5/31/2014
00169-6438-10	Levemir® FlexTouch®	$303.12	**9.9%**	**$333.12**	5/31/2014
00169-6439-10	Levemir® FlexPen®	$303.12	**9.9%**	**$333.12**	5/31/2014

** or as soon as operationally feasible upon approval.*

*** Prior to taking any price increase, Novo Nordisk undertakes a review of all factors relevant to the price increase to ensure that the increase remains consistent with brand pricing strategy.*

Kind regards,
Farruq

By following Sanofi's actions, Novo Nordisk stood to make an additional $125 million in revenue above its baseline estimates for the year.[268] Mr. Jafery noted that the company's second quarter forecast assumed only a 14.9% price increase for vials. Therefore, by following Sanofi's 16.1% increase, the "ARP [annual revenue projection] upside … is +$32.3M in RE2 and

[263] NNI-FINANCE-001713, at NNI-FINANCE-001714. Based on internal memoranda, Sanofi increased Lantus's list price because Lantus was at WAC parity with Levemir. Sanofi believed that the increase would provide a financial upside and bring vial and pen to WAC parity. SANOFI_SFC_00014580.
[264] NNI-FINANCE-001713, at NNI-FINANCE-001714.
[265] NNI-FINANCE-001713, at NNI-FINANCE-001714.
[266] NNI-FINANCE-001713, at NNI-FINANCE-001714.
[267] NNI-FINANCE-001713, at NNI-FINANCE-001714.
[268] NNI-FINANCE-001713, at NNI-FINANCE-001714.

+$125.9M vs AB14."[269] In the same email chain, one USPC member asks whether Novo Nordisk would "pass on" the price increase to CVS's commercial book of business.[270] Mr. Jafery again signaled that the company would follow Sanofi's lead:

> Since we have heard that Sanofi is not passing this through to CVS Commercial, the recommendation is to follow course and not pass on to their commercial book so as not to disadvantage us in the current negotiations. For their Part D business, we have not heard anything yet to indicate that Sanofi is not passing on. In the event of major pushback on the Part D side, we would need to assess implications and decide whether to pass on or not. By taking this by 6/1, this at least provides us this option.[271]

The back-and-forth between Novo Nordisk officials underscores how closely it was monitoring Sanofi's actions, and appears to mirror the approach laid out in a January 27, 2014 presentation regarding the company's bidding strategy that hinged on CVS's Part D business.[272] Novo Nordisk described its bids for the Part D business as "pivotal," and laid out a game of cat-and-mouse across different accounts in which company officials sought to have Levemir be the only therapeutic option on different PBM formularies.[273] Novo Nordisk recognized that offering "attractive exclusive rebates to large, receptive customers" [274] would "encourage a stronger response from Sanofi."[275] However, Novo Nordisk was willing to take this risk because it would result in "immediate volume and value" for the company and could lead to an exclusive deal for CVS's commercial formulary.[276]

Another series of emails show that Novo Nordisk again shadowed Sanofi's price increase in November 2014, increasing Levemir's list price immediately after Sanofi increased Lantus vials and pens by 11.9%. [277] On the morning of November 7, 2014, Novo Nordisk's USPC learned that Sanofi increased Lantus's list price overnight.[278] (An excerpt of this email is shown below.)[279] And, by the afternoon they were asked to approve the same exact price increase for Levemir, which was approved hours later.[280]

[269] NNI-FINANCE-001713, at NNI-FINANCE-001714.
[270] NNI-FINANCE-001713.
[271] NNI-FINANCE-001713. Emphasis included in the original.
[272] NNI-FINANCE-001939.
[273] NNI-FINANCE-001939.
[274] NNI-FINANCE-001939, at NNI-FINANCE-001941.
[275] NNI-FINANCE-001939, at NNI-FINANCE-001945.
[276] NNI-FINANCE-001939, at NNI-FINANCE-001945.
[277] NNI-FINANCE-001719-20.
[278] NNI-FINANCE-001719-20.
[279] NNI-FINANCE-001719-20.
[280] NNI-FINANCE-001719-20.

From: RDZI (Rich DeNunzio)
Sent: Friday, November 07, 2014 4:03 PM
To: LAG (Lars Green); JESH (Jesper Hoiland); CLEE (Camille Lee); ANAJ (Andy Ajello); CUOT (Curt Oltmans); PFO (Phil Fornecker)
Cc: SEAP (Sean Phillips); DUGL (Doug Langa); FAJA (Farruq Jafery); KAYE (Karen Yee); BKNO (Bill Knott); BBRT (Bill Breitenbach)
Subject: Approval Requested: Levemir Price increase

Dear Pricing Committee,

As stated earlier this morning, we found out, via Trade, that Lantus has taken an 11.9% increase on both their vial and device and we would follow up with a vote post analysis on the optimal time of the increase.

After analyzing the additional cost of rebates and price protection, based on specific contracting terms, it was determined that it makes better financial sense **(~+$10M benefit)** to wait until after the 45th day of the quarter (11/18 is the first feasible date for the increase) vs increasing price today (effective 11/8). **Therefore, we are asking for your approval to follow their 11.9%** on November 18th** (first feasible increase date post the 15th). Approving this request will have a **benefit to 2014 of ~$25M.**

Please respond with your approval prior to November 13th. Please reach out if you have any questions.

Have a nice weekend,
Rich

*** Prior to taking any price increase, Novo Nordisk undertakes a review of all factors relevant to the price increase to ensure that the increase remains consistent with brand pricing strategy.*

NDC#	Product Name	Current WAC/pkg	Pct Change	WAC/pkg	Effective Date
00169-3687-12	Levemir® 10mL vial	$222.08	11.9%	$248.56	11/18/2014*
00169-6438-10	Levemir® FlexTouch® - 5x3mL	$333.12	11.9%	$372.76	11/18/2014*

** or when operationally feasible upon approval.*

The speed with which Novo Nordisk reacted to Sanofi's price changes is notable. Within 25 minutes after learning of Sanofi's price increase, Rich DeNunzio, Senior Director of Novo Nordisk's Strategic Pricing, emailed Novo Nordisk's USPC to alert them of the change and promise a recommendation the same afternoon after reviewing the financial impact of any move.[281] By late afternoon, Mr. DeNunzio had requested Novo Nordisk's USPC "follow [Sanofi's] 11.9% [list price increase] on November 18th" and vote to increase Levemir's list price, which was promptly approved by Novo Nordisk's chief financial officer for U.S. operations, Lars Green. [282]

ii. In 2015, Novo Nordisk Ended its Shadow Pricing Strategy to Set Up a New Basal Insulin Therapy, Tresiba

After more than a year and a half shadowing Sanofi's insulin pricing, Novo Nordisk adopted a new pricing strategy. According to a series of emails sent in 2015, Novo Nordisk's leadership changed their basal insulin strategy in anticipation of launching Tresiba—Novo Nordisk's second generation basal insulin that was a follow-on product to Levemir. The company wanted to ensure that they set a high basal insulin price floor from which to launch

[281] NNI-FINANCE-001719-20.
[282] NNI-FINANCE-001719. Emphasis included in the original.

Tresiba's initial list price.[283] In order to do so, Novo Nordisk broke with its shadow pricing strategy and increased the price of Levemir, independent of a Lantus increase.

In June 2015, Novo Nordisk officials debated increasing Levemir's price increase in July, to set up Tresiba during negotiations with Express Scripts and CVS Caremark for the 2016 contract year.[284] Doing so would be a departure from following Sanofi. Bill Breitenbach, Vice President of Basal Portfolio Marketing, wrote:[285]

> Good morning,
>
> I spoke with Doug last night about the CVS and ESI 2016 negotiations and it appears they should be completed by the end of June. With that in mind, I recommend we pull forward the Levemir price increase to July 1st. Taking an increase in July 1st will be 7 months since our last and given the timing we can take a leadership position. The sooner we take the increase the better positioned we'll be in the market place and for the potential launch of Tresiba. I see more downsides by waiting until September vs moving now.
>
> Thoughts?
>
> BR,
>
> Bill

Mr. DeNunzio, pushed back, arguing there was little upside "outside of the few months of added revenue."[286] He further added that, by allowing Lantus to lead, Novo Nordisk would be better positioned as they launched Tresiba with "payers still on our side in basal and not fighting Tresiba."[287] An excerpt of this exchange is shown below.[288]

> On Jun 2, 2015, at 8:20 PM, RDZI (Rich DeNunzio) <rdzi@novonordisk.com> wrote:
>
> Thanks Bill.
>
> I'm sure I'm swimming upstream on this one, as it sounds like JESH okay moving, but I would hold until September. Assuming we gain tresiba approval, I think we'll launch at the same price if we take increase in July vs September, so because of that and this isn't aligned to strategy (follow lantus and no sooner than 9 months), i don't see the upside outside of the few months of added revenue. I feel we could be better positioned allowing lantus to lead, let them be the bad guys again, and as we launch tresiba we do so into what could be good situation - open environment and payers still on our side in basal and not fighting tresiba. So potentially short term upside of a few months could hinder longer term opportunity and I think fast access/uptake with tresiba could outweigh '15 gain.

In August 2015, as contract negotiations with CVS Caremark came to a close, the question of leading or following on insulin prices came up again. On August 6, 2015, Mr. DeNunzio—who earlier in the year had advocated for Novo Nordisk getting out ahead of Sanofi on insulin pricing—sent an email to Novo Nordisk's USPC asking if there was any appetite to delay Levemir's next scheduled price increase on August 18, 2015.[289] He further noted that

[283] *See* NNI-FINANCE-001732.
[284] NNI-FINANCE-001771.
[285] NNI-FINANCE-001771.
[286] NNI-FINANCE-001771.
[287] NNI-FINANCE-001771.
[288] NNI-FINANCE-001771.
[289] NNI-FINANCE-001792, at NNI-FINANCE-001793-94.

"LRS said he would recommend waiting due to [the public relations] risk of leading."[290] ("LRS" appears to stand for Lars Rebien Sorensen, Novo Nordisk's former CEO). Mr. Sorensen's view deviated from other senior executives, including "LAG" (Lars Green, SVP and CFO of Novo Nordisk U.S.) and "JESH" (Jesper Hoiland, President and Executive Vice President U.S.), who were "aligned to take [the price increase] now." [291]

In response to Mr. DeNunzio's email, some Novo Nordisk officials raised concerns that CVS, a major account, would push back on the pricing increase.[292] After several back-and-forth emails—and apparently additional behind-the-scenes discussion—the company struck a compromise on the timing of the price increase that would ultimately move Novo Nordisk to get ahead of Sanofi on insulin pricing. Mr. DeNunzio elaborated:[293]

> Lars informed me today that him and Jesper were having a conversation on Levemir and that they have to "manage their stakeholders", which I'm interpreting as ExecMan. ExecMan agreed to take a Levemir a price increase to set up Tresiba, however they have concerns this far ahead of launch/approval (and they want us to be confident of approval before moving/leading with Levemir).
>
> With this said, Jesper and Lars suggested we take an increase with an 8 in front of it, to appease our internal stakeholders (justification is us showing the market we're not going to take double digit increases here anymore), but still moving on the 18th to hit what's in RE2 and 3. I then informed Lars of CVS issue and PrePC thoughts (minus Doug's).

One senior vice president went along with the decision, but expressed his reservations about moving away from the shadow pricing strategy:[294]

> In the end as I have stated all along, I don't believe that we should be leading with price increases. Again, I understand the rationale (certainly as it impacts next generation products) but I think that it hurts the message that we have been sending to the market and a bit of our credibility with payers.

However, any question about the motivation of moving away from shadow pricing are erased in the final approval request to the USPC. On August 14, 2015—just a few days after requesting their input—Mr. Jafery sent an email to the USPC requesting their final approval to execute an 8.2% price increase on Levemir, effective August 25, 2016. According to Mr. Jafery, "the proposed timing and magnitude is slightly later and lower than what we had previously agreed too, but it balances the concerns of ExecMan while also meeting our strategic objectives which are outlined below."[295] ("ExecMan" refers to Novo Nordisk's "Executive Management" team, which is made up of the company's CEO and his direct reports, which are typically executive vice presidents.) An excerpt of this email is shown below.[296] The USPC agreed to Mr. Jafery's proposal that same day.[297]

[290] NNI-FINANCE-001792, at NNI-FINANCE-001793-94.
[291] NNI-FINANCE-001792, at NNI-FINANCE-001793-94.
[292] *See* NNI-FINANCE-001792-94.
[293] NNI-FINANCE-001792.
[294] NNI-FINANCE-001792.
[295] NNI-FINANCE-001801-02.
[296] NNI-FINANCE-001801-02.
[297] NNI-FINANCE-001801-02.

Rationale:

Timing is important for executing our Tresiba® premium strategy. With FDA approval anticipated late September (or early October) and "soft launch" in mid-November, we want to ensure a Levemir® price increase sooner rather than later to allow enough time for competition to assess and potentially respond in advance of Tresiba® launch.

- HQ asked us to consider delaying the price increase to as close as possible to Tresiba® launch, however, they ultimately agreed that we should use our best judgment to set up Tresiba® for success.
- From a Levemir® access perspective, we have confirmation that Levemir® will remain on formulary in 2016 at CVS and ESI.
- The price increase is still timed to minimize rebate and price protection impact (many of our contracts have language whereby the rebate and price protection are based on our WAC as of mid-point of the quarter). Note that CVS has pushed back on the timing of our list price increases and demanded changes in contract language which will take effect 1/1/16 to address this. We're finalizing the amendment language which is expected to be signed before 8/25.

Magnitude is within industry norms and is lower than recent history in the basal market.

- It sends a signal to stakeholders that we're cognizant of the public discourse around manufacturer price increases.
- The financial impact to 2015 is negligible given that we have CPP of 8%; downside impact to 2016 is ~$11M (vs. RE2 assumption).

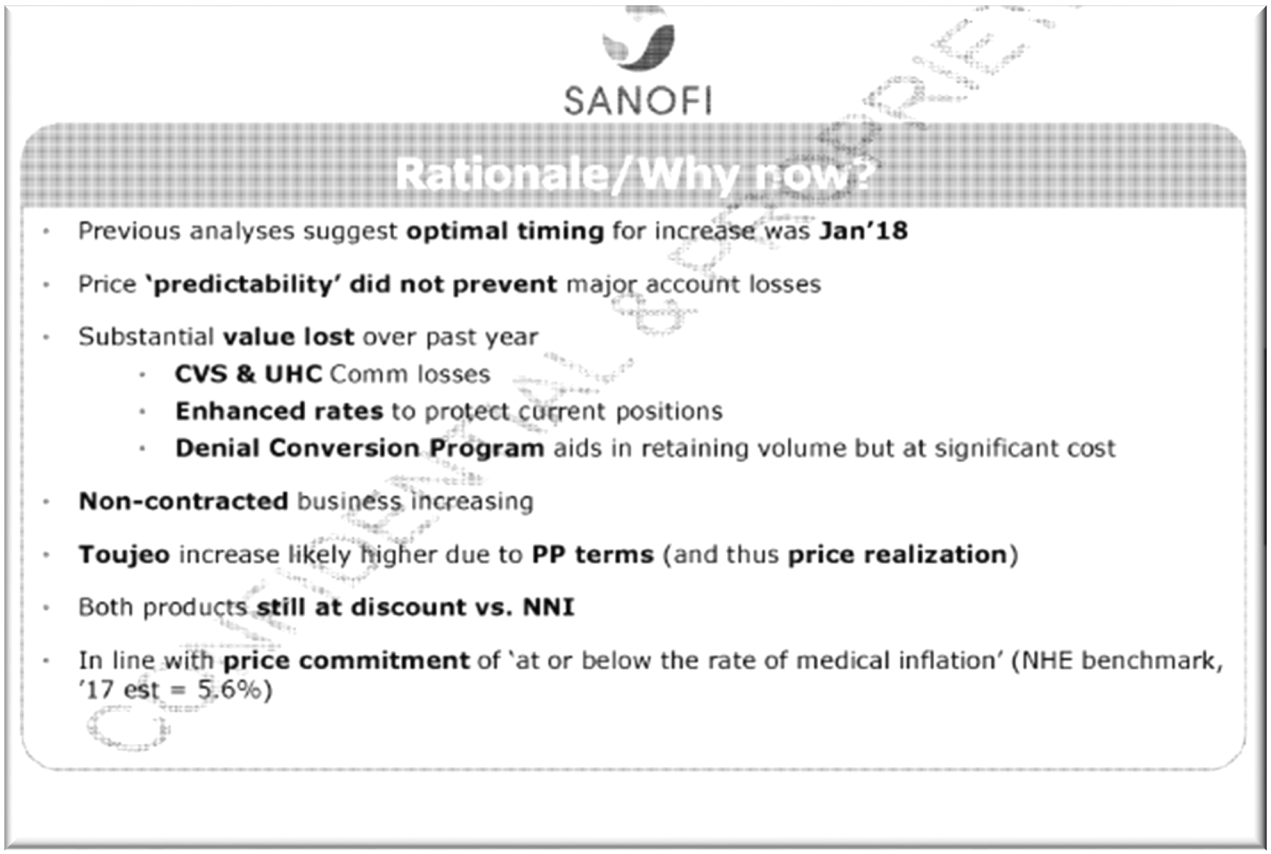
Internal correspondence and memoranda show that Novo Nordisk did not increase Levemir's list price for at least two years following its August 2015 pricing actions and remained the basal pricing leader over Sanofi until 2017. However, Novo Nordisk resumed its strategy of following, rather than leading, Sanofi's pricing actions in 2017 when Sanofi began to increase the price of Lantus.[298]

iii. In 2017 and 2018, Novo Nordisk Resumed Shadow Pricing to Respond to Sanofi's Pricing Actions

Based on data collected for this investigation, Novo Nordisk continued to increase list prices in response to Sanofi's pricing actions. On October 1, 2017, Sanofi increased Lantus's list price by 3% to $256 for vials and $384 for pens, respectively, and Toujeo's list price by 5.4% to $354.[299] Roughly three weeks later, on October 26, 2017, Novo Nordisk's USPC called a "special" USPC meeting to discuss Sanofi's pricing action.[300] During this meeting, Novo Nordisk's USPC debated why Sanofi took a list price increase in October when their "previous analysis suggest optimal timing for increase was Jan'18 [sic]."[301] (An excerpt of the presentation used during this meeting is shown below.)[302] Novo Nordisk believed that Sanofi was forced to pay enhanced rebates and price protection terms to its payer and PBM clients over the past year to protect its current formulary position.[303] In alignment with the list price approach endorsed by its USPC, Novo Nordisk recommended that the company follow Sanofi and take a 4% list price

[298] Internal WAC data shows that Sanofi did not take another list price increase on its long-acting insulins until October 1, 2017. *See* Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, to Senator Grassley and Senator Wyden (Mar. 8, 2019) (attachment 1(a) and (b)).
[299] NNI-FINANCE-003621; NNI-FINANCE-003624, at NNI-FINANCE-003626. *See* Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, to Senator Grassley and Senator Wyden (Mar. 8, 2019) (attachment 1(a) and (b)).
[300] NNI-FINANCE-003621.
[301] NNI-FINANCE-003621; NNI-FINANCE-003624, at NNI-FINANCE-003626.
[302] NNI-FINANCE-003624, at NNI-FINANCE-003626.
[303] NNI-FINANCE-003624.

increase to $279.76 for vials and $419.64 for pens, respectively, in January 2018, which was "approved as recommended on November 3, 2017."[304]

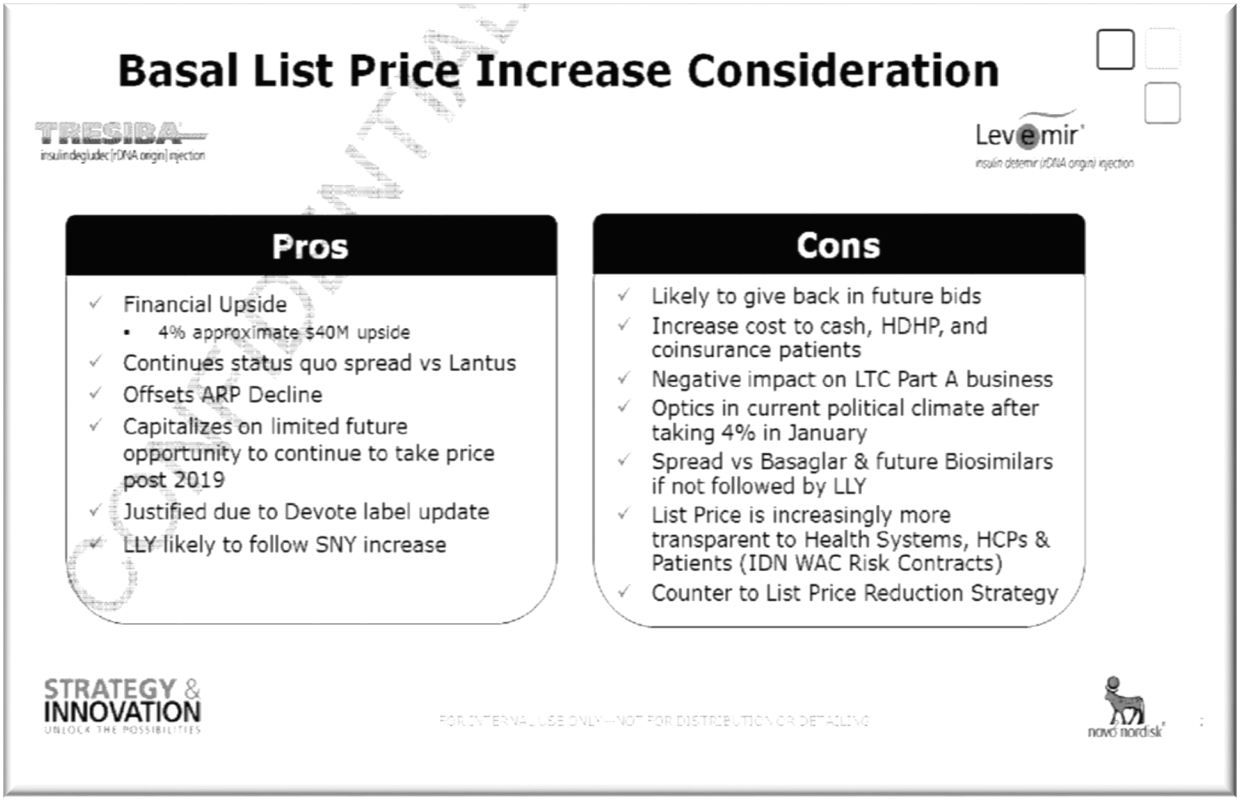


On April 13, 2018, Sanofi again increased the list price of its long-acting insulins by 5.3%, effective May 1, 2018.[305] At this point, the list price of Lantus vials was $269.54 and the price of Lantus pens was $404.29.[306] Based on internal memoranda, it is clear that Novo Nordisk's USPC believed that Sanofi's latest price increase put Levemir at a disadvantage in negotiations with health insurers and their PBMs. On April 19, 2018, Novo Nordisk's USPC recommended another "4% increase on both Levemir and Tresiba."[307]

According to internal memoranda prepared in advance of an April 20, 2018 executive management meeting, Novo Nordisk rationalized its decision with a pro-con list, noting that a 4% increase would result in $40 million gain in revenue and capitalize on "limited opportunities to take price [increases]" with multiple insulin glargine biosimilars on the horizon.[308] The price increase would also stay within Novo Nordisk's commitment to not raise list prices more than 9.9%.[309] This commitment was only taken after the company had spent years dramatically

[304] NNI-FINANCE-000002-03; NNI-FINANCE-003621; NNI-FINANCE-002950.
[305] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, to Senator Grassley and Senator Wyden (Mar. 8, 2019) (attachment 1(a) and (b)). *See also* NNI-FINANCE-003191, at NNI-FINANCE-003192.
[306] *See* Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, to Senator Grassley and Senator Wyden (Mar. 8, 2019) (attachment 1(a) and (b)).
[307] NNI-FINANCE-003190; NNI-FINANCE-003191-92.
[308] NNI-FINANCE-003190; NNI-FINANCE-003191-92.
[309] NNI-FINANCE-003190; NNI-FINANCE-003191-92.

raising insulin's WAC on which its percentage increases were based. However, the company also noted "cons" which included the increased "cost to cash, [high deductible health plan], and coinsurance patients," a "negative impact on [long-term care] Part A business," and "optics in the current political climate after taking a 4% increase in January."[310] An excerpt of Novo Nordisk's pro-con list is shown below.[311]

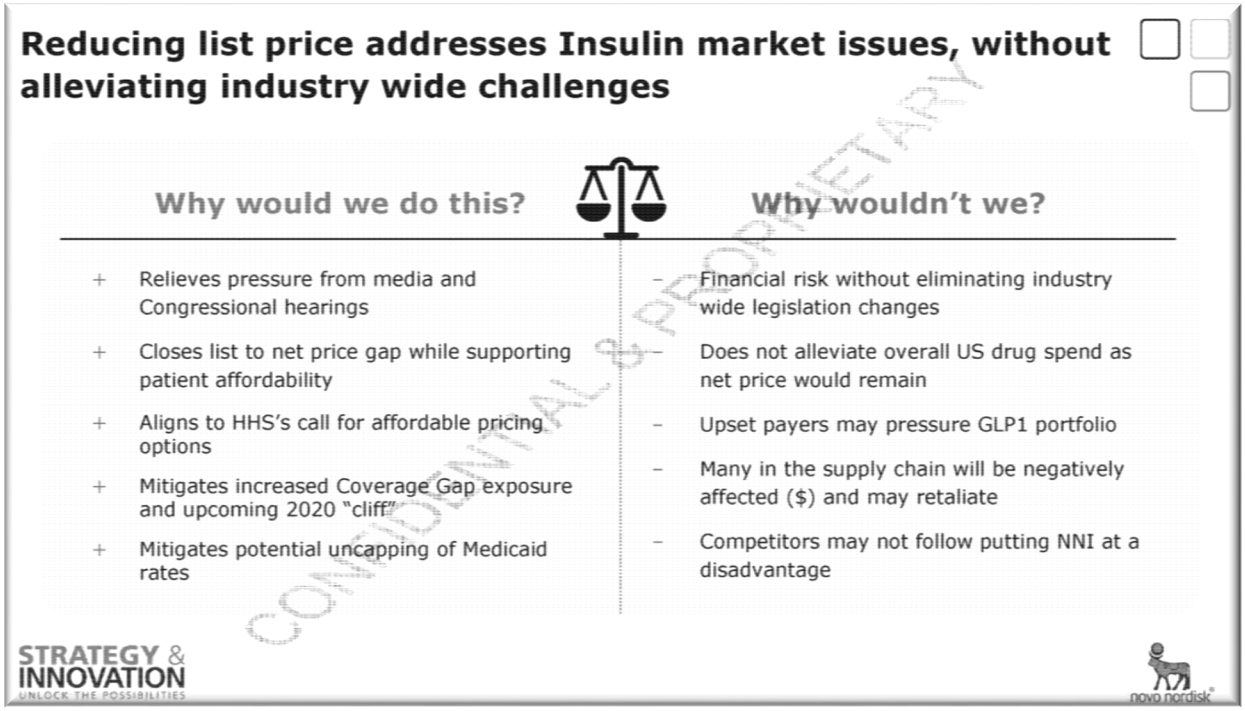


iv. In 2018, Novo Nordisk Discussed List Price Decreases after Feeling Outside Pressure

Following its April 2018 list price increase, Novo Nordisk began to face pressure from payers, the media, and Congress to reduce the price of its insulin drugs.[312] On May 29, 2018, Novo Nordisk's USPC debated whether it should reduce the list price of its insulin drugs by 50% after a string of news reports detailed how patients were struggling to afford their medications.[313] Novo Nordisk believed that a 50% cut would be a meaningful reduction to patients, significantly close the list to net gap, head off negative press attention, and reduce "pressure" from Congressional hearings.[314] However, Novo Nordisk was concerned that a list price reduction

[310] NNI-FINANCE-003190; NNI-FINANCE-003191-92.
[311] NNI-FINANCE-003191.
[312] *See* INSULIN ACCESS AND AFFORDABILITY: THE RISING COST OF TREATMENT, SENATE SPECIAL COMMITTEE ON AGING, 115TH CONG. (2018); Aimee Picchi, *The rising cost of insulin: "Horror stories every day"*, CBS News (May 9, 2018), https://www.cbsnews.com/news/the-rising-cost-of-insulin-horror-stories-every-day/; Irl Hirsh, *Paying the price for insulin*, STAT (May 17, 2018), https://www.statnews.com/2018/05/17/insulin-paying-the-price/.
[313] NNI-FINANCE-002025.
[314] NNI-FINANCE-002025, at NNI-FINANCE-002026-27.

posed significant financial risk to the company.[315] It is noteworthy that the company's primary concerns were retributive action from other entities in the pharmaceutical supply chain, many of which derive payments that are based on a percentage of a drug's WAC price.[316] An excerpt from a memo created for this meeting is show below.[317]



Despite these concerns, internal memoranda suggest that Novo Nordisk was prepared to lower its list price by 2019 or 2020 if its "must haves" were met, which included an agreement from its payer and PBM clients that they would not retaliate against them by changing their formulary placement and would accept lower rebate percentages.[318] It is unclear if Novo Nordisk eventually received an agreement from its payer and PBM clients. However, according to internal memoranda created for Novo Nordisk's USPC, its board of directors voted against this strategy in June 2018 and recommended that the company continue its reactive posture.[319] The rationale for this decision was the "$33 million downside identified (NovoLog only)," "risk of payer backlash or demand for current rebate on new NDC," and "high likelihood of immediate pressure to take similar action on other products."[320] Following the decision by its board of directors, on August 30, 2018, Novo Nordisk decided to continue its strategy to "monitor the market . . . to determine if other major pharma companies are taking list price [increases]."[321] An excerpt from this email is shown below.[322]

[315] *See* NNI-FINANCE-003737.
[316] NNI-FINANCE-002025, at NNI-FINANCE-002026.
[317] NNI-FINANCE-002025, at NNI-FINANCE-002026.
[318] NNI-FINANCE-002025, at NNI-FINANCE-002029.
[319] NNI-FINANCE-003906; NNI-FINANCE-003907-08.
[320] NNI-FINANCE-003906; NNI-FINANCE-003907-08.
[321] NNI-FINANCE-002969.
[322] NNI-FINANCE-002969.

From:	FAJA (Farruq Jafery)
To:	DUGL (Doug Langa); UCO (Ulrich Christian Otte); SALR (Steve Albers); DDME (David Moore); MPDU (Pia D'Urbano)
CC:	CBLE (Craig Bleifer); BKNO (Bill Knott); RDZI (Rich DeNunzio); FCC (Franco Cognata); EDCI (Ed Cinca); ELIV (Elena Livshina); BLMI (Blandine Lacroix); JTCX (Jack Cox)
Sent:	11/21/2018 5:56:47 PM
Subject:	PC Vote - CA Notification of Planned Price Increase for Victoza & Execution of 2019 Planned Price Increases
Attachments:	2019 List Price Alignment.pptx

Dear Pricing Committee,

Please recall that on Aug 30 PC discussion around 2019 list price, PC concluded on the following:

- Monitor the market in 4Q18 and Jan. 2019 to determine if other major pharma companies are taking list price. If the market supports it, we would continue to take a list price increase in 2019 across our portfolio (with the exception of NovoLog, NovoLog Mix and Novolin)
- Continue to stick to our pricing pledge and do not anchor to another benchmark such as NHE (Nat'l Healthcare Estimate)
- Limit any price increases to once per year per brand

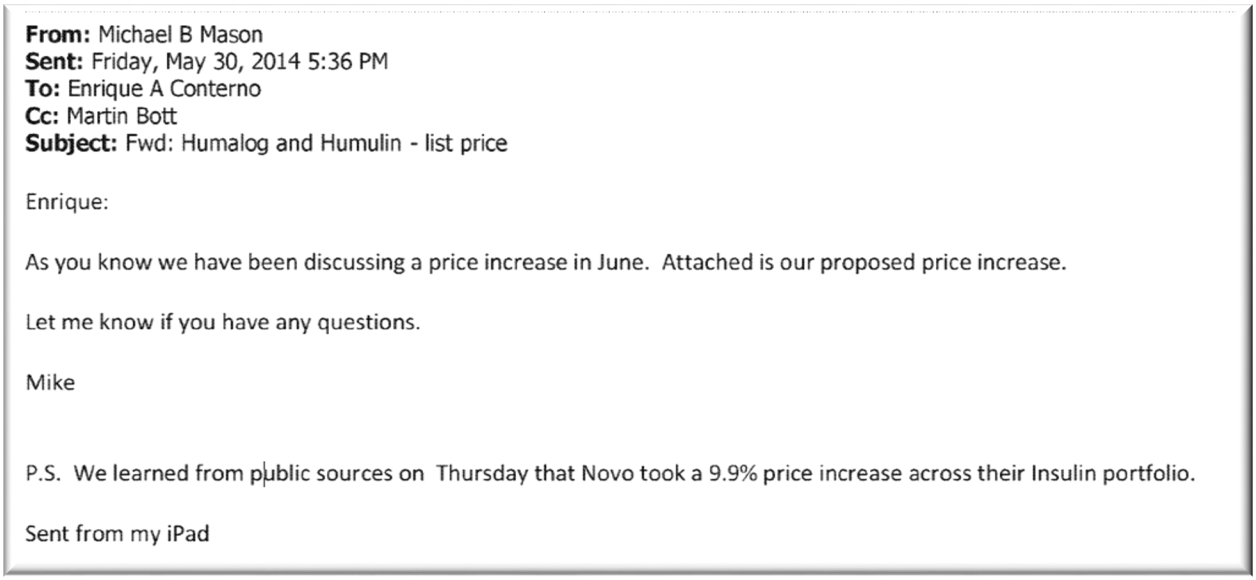
In November 2018, Novo Nordisk learned that Pfizer intended to increase the list price for 41 of its products (or 10% of its portfolio) effective January 15, 2019.[323] Novo Nordisk also discovered that Bristol Myers Squibb and Allergan would do the same in January 2019.[324] After learning of these list price increases, Mr. Jafery immediately emailed Novo Nordisk's USPC and requested a vote to move forward with all "other 2019 planned increases effective February 1 instead of June 2019."[325] Novo Nordisk would ultimately proceed with its 2019 planned list price increases and vote to increase Levemir's and Tresiba's list prices by 4.9%.[326] On January 8, 2019, Levemir cost $308.14 per vial and $462.21 for pens.[327]

e. Beyond Long-Acting Insulin: Companies Used Shadow Pricing Across Multiple Product Lines

Novo Nordisk was not the only company that mimicked its competitor's price increases, nor was the practice limited to long-acting insulins. Documents produced by Eli Lilly and Sanofi show that these companies, at a minimum, closely tracked and responded to price increases. For example, on May 30 2014, company officials at Eli Lilly proposed increasing the list prices of Humalog and Humulin by 9.9%.[328] At the time, the list prices for these drugs were $184.30 per

[323] NNI-FINANCE-002969.
[324] NNI-FINANCE-002969; NNI-FINANCE-002971.
[325] NNI-FINANCE-002969; NNI-FINANCE-002971.
[326] NNI-FINANCE-003988; NNI-FINANCE-002063. The investigation sought information from insulin manufacturers between 2013 and 2019. Therefore, the Committee cannot determine whether Novo Nordisk continued to follow Sanofi's list price increases in 2020.
[327] NNI-FINANCE-000002-03.
[328] LLY-SFCOM-UR-00003044, at LLY-SFCOM-UR-00003045.

vial for Humalog and $99.80 per vial for Humulin.[329] In asking for a price increase, a company official noted:[330]



From: Michael B Mason
Sent: Friday, May 30, 2014 5:36 PM
To: Enrique A Conterno
Cc: Martin Bott
Subject: Fwd: Humalog and Humulin - list price

Enrique:

As you know we have been discussing a price increase in June. Attached is our proposed price increase.

Let me know if you have any questions.

Mike

P.S. We learned from public sources on Thursday that Novo took a 9.9% price increase across their Insulin portfolio.

Sent from my iPad

Six months later, on November 19, 2014, when Novo Nordisk increased prices again, Eli Lilly's CEO, John Lechleiter, was notified by Enrique Conterno, the head of the company's diabetes unit, who wrote, "[t]oday Novo took a price increase of 9.9% for Novolog and 11.9% for Levemir. As you are aware, we have assumed as part of our business plan a price increase of 9.9% for Humalog before the end of the year."[331] Mr. Conterno, discussing the move with his colleagues over email a few days later, noted, "[g]iven Novo's price increase, let's compensate by taking the price increase earlier,"[332] adding later that day, "I think we should push for [a list price increase] asap given that Novo has taken a price increase already and thus, distributors will start to inventory."[333] Ultimately the company decided to move up their planned pricing increase in response to Novo Nordisk's unexpected price increase, and reiterated that their distributors would expect a price increase from Lilly.[334]

This investigation also showed that Sanofi had a shadow pricing strategy for their short-acting insulin, Apidra, which it called a "fast follower" approach. In November 2014, Sanofi's USPC recommended Sanofi approve a WAC increase of 9.9% because "Apidra has employed a fast follower strategy to Novolog/Humalog prices increases – Novolog just implemented their increase effective November 18th."[335] Along with the pricing recommendation, the USPC

[329] LLY-SFCOM-UR-00003044, at LLY-SFCOM-UR-00003045.
[330] LLY-SFCOM-UR-00003044.
[331] LLY-SFCOM-UR-00003198.
[332] LLY-SFCOM-UR-00003200.
[333] LLY-SFCOM-UR-00003202.
[334] LLY-SFCOM-UR-00003206.
[335] SANOFI_SFC_00014206. This request would result in the WAC price of Apidra vials increasing from $184.85 to $203.15 and Apidra Solostar (pens) from $357.10 to $392.45. *Id.*

included a two-line risk assessment stating matter-of-factly that "[a]ll price increases have the potential to subject the organization to public scrutiny from payers, physicians and patients."[336]

This investigation specifically examined manufacturers' business decisions related to insulin and their contracting practices with PBMs and other plans. While not discussed in this report, the Committee's investigation found that shadow pricing is not limited to the insulin product portfolio.[337]

Shadow pricing practices among pharmaceutical manufacturers are simple: leaders lead and the competitors follow. For a time, Sanofi had the higher price in the basal insulin market with Lantus, so Novo Nordisk followed its competitor's pricing signals with Levemir, deviating slightly from the prices Sanofi settled on. Similarly Novo Nordisk had the highest price in the rapid-acting market, with NovoLog, so they led while Sanofi followed with Apidra and Eli Lilly followed with Humalog.

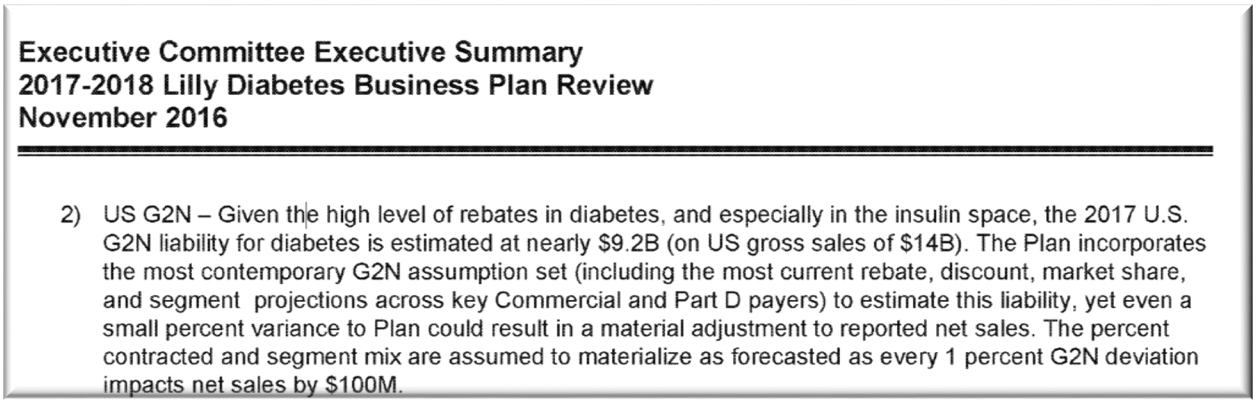
IV. Rebates, Administrative Fees and Other Common Contract Provisions Related to Insulin WAC and Other Therapies

PBMs have been subject to a great deal of scrutiny for their role in rising drug prices.[338] Although they are the centerpiece of drug pricing negotiations, their practices and business relationships remain largely opaque. As discussed above, the lack of transparency is due in large part to the confidentiality of contractual relationships PBMs have with both health insurers and drug manufacturers, as well as Federal laws barring disclosure of some information related to these negotiations.[339] While the HHS OIG found that this "lack of transparency raises concerns that sponsors may not always have enough information to oversee the services and information provided by PBMs,"[340] the industry continues to fight efforts to bring visibility to its operations.[341] Likewise, PBMs were not fully responsive to the Finance Committee's requests during this investigation, variously failing to timely produce documents, produce all of the requested documents, or produce documents that were fully un-redacted.[342]

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[336] SANOFI_SFC_00014206.
[337] For example, *see* SANOFI_SFC_00014352, at SANOFI-SFC_00014358-59.
[338] Duane Schulthess, *Insulin prices and pharmacy benefit manager rebates: pin the tail on the patient*, STAT (Mar. 19, 2020), https://www.statnews.com/2020/03/19/insulin-prices-pbm-rebates/; Oliver McPherson-Smith and Steve Pociask, *Rx middlemen cost American consumers billions each year*, THE HILL (Jan 27, 2020), https://thehill.com/blogs/congress-blog/health care/480155-rx-middlemen-cost-american-consumers-billions-each-year; Laura Entis, *Why Does Medicine Cost So Much? Here's How Drug Prices Are Set*, TIME (Apr. 19, 2019), https://time.com/5564547/drug-prices-medicine/.
[339] *See, e.g.,* 42 U.S.C. 1396r-8(b)(3)(D)(cross-referenced at 42 U.S.C. 1395w-102(d)(2) and 42 U.S.C. 1396r-8(b)(3)(D)).
[340] DEP'T HEALTH AND HUMAN SERVS., OFF. OF INSPEC. GEN., CONCERNS WITH REBATES IN THE MEDICARE PART D PROGRAM (Mar. 11, 2011), https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf.
[341] Robert Langreth et al., *The Secret System Middlemen Use to Rake in Millions*, BLOOMBERG (Sept. 11, 2018), https://www.bloomberg.com/graphics/2018-drug-spread-pricing/.
[342] On February 25, 2020, the Committee sent OptumRx and Cigna Corporation letters detailing their failure to produce information and records pertaining to their formulary management committees, and other related information. Press Release, Grassley, Wyden Warn PBM: Cooperate with Insulin Investigation or Face Subpoena (Feb. 26, 2020), https://www.grassley.senate.gov/news/news-releases/grassley-wyden-warn-pbm-cooperate-insulin-investigation-or-face-subpoena. Although CVS Caremark didn't receive a public letter, the Committee did not view the company's production to be fully responsive to the senators' requests for information.

At the same time, industry representatives from both sides have attempted to shift blame for increasing drug prices. In response to the Committee's April 2nd letter, CVS Caremark, Express Scripts, and OptumRx blamed drug manufacturers for increasing insulin prices, arguing that they unilaterally set list prices.[343] Sanofi, Novo Nordisk, and Eli Lilly, on the other hand, blamed PBMs for their demand for ever-higher rebates which has caused them to raise list prices to maintain profitability and patient access.[344] Indeed, PBMs have been accused of "play[ing] drug companies off one another"; "want[ing] juicy rebates"; and "profiting on all sides."[345] What is clear is that the money that flows through PBMs is nothing short of enormous. As discussed throughout this report, rebates have grown at a rapid pace in the insulin market in recent years, which is not true in all therapeutic markets. A 2016 memo to Eli Lilly's executive committee underscored the evolving market:[346]



Executive Committee Executive Summary
2017-2018 Lilly Diabetes Business Plan Review
November 2016

2) US G2N – Given the high level of rebates in diabetes, and especially in the insulin space, the 2017 U.S. G2N liability for diabetes is estimated at nearly $9.2B (on US gross sales of $14B). The Plan incorporates the most contemporary G2N assumption set (including the most current rebate, discount, market share, and segment projections across key Commercial and Part D payers) to estimate this liability, yet even a small percent variance to Plan could result in a material adjustment to reported net sales. The percent contracted and segment mix are assumed to materialize as forecasted as every 1 percent G2N deviation impacts net sales by $100M.

As Congress considers policy solutions to address prescription drug costs, it is important to understand how rebates and other PBM contracting practices contribute to list price increases, especially in the insulin therapeutic class. The following section provides insight into the PBMs' business practices and their role in the insulin market.

a. Rebates for Insulins Have Increased Exponentially Since 2013

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[343] Letter from Enu Mainigi, Counsel, Williams & Connolly, on Behalf of CVS Health Corp., to Senator Grassley and Senator Wyden (Apr. 26, 2019); Letter from Enu Mainigi, Counsel, Williams & Connolly, on Behalf of CVS Health Corp., to Senator Grassley and Senator Wyden (May 24, 2019); Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, Corporation, to Senator Grassley and Senator Wyden (Apr. 16, 2019); ORX_Sen_Fin_00001935.

[344] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019); Letter from Raphael Prober, Counsel, Akin Gump, on Behalf of Novo Nordisk, to Senator Grassley and Senator Wyden (Mar. 8, 2019); Letter from Joseph Kelly, Vice President, Global Affairs, Eli Lilly, to Senator Grassley and Senator Wyden (Mar. 8, 2019).

[345] Duane Schulthess, *Insulin prices and pharmacy benefit manager rebates: pin the tail on the patient*, STAT (Mar. 19, 2020), https://www.statnews.com/2020/03/19/insulin-prices-pbm-rebates/; Oliver McPherson-Smith and Steve Pociask, *Rx middlemen costs American consumers billions each year*, THE HILL (Jan 27, 2020), https://thehill.com/blogs/congress-blog/health care/480155-rx-middlemen-cost-american-consumers-billions-each-year; Laura Entis, *Why Does Medicine Cost So Much? Here's How Drug Prices Are Set*, TIME (Apr. 19, 2019), https://time.com/5564547/drug-prices-medicine/.

[346] LLY-SFCOM-UR-00006921.

Based on internal memoranda and correspondence collected for this investigation, the practice of offering rebates in the insulin therapeutic class appears to be contributing to both increasing insulin WAC prices and limited uptake of lower-priced products. Drug manufacturers—typically on an annual, but sometimes more frequent, basis—submit bids to PBMs which reflect a variety of different rebate offers that manufacturers are willing to pay depending on where the drug is placed on a health plan's formulary.[347] However, it's important to note that the final agreement does not guarantee a product's placement. Instead, health insurers make the final decision with regard to formulary placement and the patient's cost-sharing responsibility for the product.

This investigation found that manufacturers offer substantial rebates to PBMs and their clients for the purposes of securing preferred formulary placement for their products, and to ensure strong market access by securing formulary positions that minimize cost-sharing for patients.[348] Low cost-sharing is an important consideration for manufacturers when developing their rebate offers because patients often gravitate towards the cheapest drug to save on their out-of-pocket expenses. A patient's cost-sharing responsibility can affect a manufacturer's market share and profitability.

As noted above, rebates for insulins have increased steadily as manufacturers attempted to secure preferred placement. Rebate offers made by Sanofi and Novo Nordisk to CVS Caremark have increased exponentially between 2013 and 2019. For example, in July 2013, Sanofi offered rebates between 2% and 4% for preferred placement on CVS Caremark's client's commercial formulary.[349] Five years later, in 2018, Sanofi rebates were as high as 56% for preferred formulary placement.[350] Similarly, rebates to Express Scripts and OptumRx increased dramatically between 2013 and 2019 for long-acting insulins. For example, in 2019, Sanofi offered OptumRx rebates up to 79.75%[351] for Lantus for preferred formulary placement on their client's commercial formulary, compared to just 42%[352] in 2015. Similarly, in 2017, Novo Nordisk offered Express Scripts rebates up to 47%[353] for Levemir for preferred formulary placement on their client's commercial formulary, compared to 25%[354] in 2014.

This investigation also found that rebate offers for Medicare Part D, and other high-control formularies, appear to be just as high (if not higher) than those offered for placement on PBMs' commercial formularies. For example, in 2019, Novo Nordisk offered rebates as high as 71% for preferred formulary placement on CVS Caremark's Medicare Part D formulary.[355]

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[347] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019); Letter from Eni Mainigi, Counsel, CVS Caremark, to Senator Grassley and Senator Wyden (Apr. 26, 2019). Rebates are often calculated on a per unit basis and are billed to the drug manufacturer monthly after the drug is dispensed at the pharmacy. *See* Cigna-SFC-00009847. PBMs also reserve the right to solicit new bids or new offers based on changes in the marketplace, and often do so each year. *Id.*

[348] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (May 24, 2019).

[349] CVSCM_SFC_0003979, at CVSCM_SFC_0004000.

[350] CVSCM_SFC_0004331, at CVSCM_SFC_0004334.

[351] ORX_Sen_Fin_0009384, at ORX_Sen_Fin_0009413.

[352] ORX_Sen_Fin_0009066, at ORX_Sen_Fin_0009078.

[353] Cigna-SFC-00009578, at Cigna-SFC-00009582.

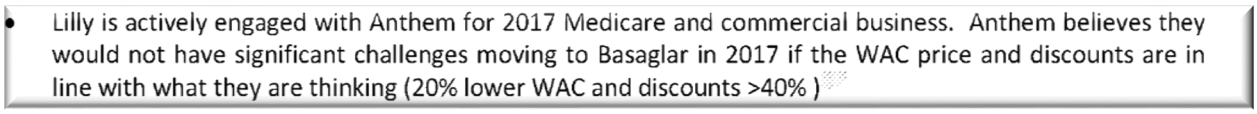
[354] Cigna-SFC-00009535, at Cigna-SFC-00009544.

[355] CVSCM_SFC_0004991, at CVSCM_SFC_0004993-94.

Similarly, in 2019, Eli Lilly also offered rebates as high as 74%[356] for preferred formulary placement.

Rebates have increased for several reasons. Just three PBMs (CVS Caremark, Express Scripts, and OptumRx) now manage 80% of drug benefits for more than 220 million Americans, resulting in manufacturers facing high stakes when negotiating for formulary placement.[357] Pharmaceutical companies are sensitive to the sheer size of PBMs and the resulting product volumes they can affect, which allows the middlemen to extract higher rebates from manufacturers through the use of formulary exclusion tactics. Internal memoranda and correspondence collected for this investigation suggest that manufacturers seek to avoid triggering Medicaid "best price" when developing their bids for commercial plans.[358] As discussed in more detail in this report's background section, under Medicaid "best price," drug manufacturers must give Medicaid the lowest price they offer private plans, wholesalers, providers, and other purchasers, with rebates taken into account.[359] However, rebates offered to Part D plans are excluded from the Medicaid best price calculation, allowing manufacturers to offer higher rebates under Medicare Part D without triggering best price.

Manufacturers have increased their rebates in order to win preferred formulary placement and block competitors. In 2016, Sanofi and Novo Nordisk enhanced their rebate offers around the same time Eli Lilly introduced Basaglar, a follow-on biologic to Lantus. Basaglar is a long-acting insulin and is "[c]linically . . . very similar" to Lantus.[360] Because of its near clinical equivalence, Basaglar introduced additional competition in the long-acting insulin market. Payers used the competition to threaten to switch to Basaglar because it was priced lower and they expected Eli Lilly to offer larger discounts. (This investigation confirmed Eli Lilly offered rebates between 60% and 70% off WAC).[361] A 2016 Sanofi memo describes the market dynamic:[362]



[356] CVSCM_SFC_0004838, at CVSCM_SFC_0004843.
[357] Letter from Raphael Prober, Counsel, Akin Gump, on Behalf of Novo Nordisk, to Senator Grassley and Senator Wyden (June 28, 2019).
[358] *See* SANOFI_SFC_00014281, at SANOFI_SFC_00014285. In developing its OptumRx Medicare Part D bid for Lantus, Sanofi discusses how its pricing strategy for Toujeo could set a high "best price" and thus a high Medicaid rebate "from day one and for the lifecycle of Toujeo." *Id.*
[359] 42 U.S.C. 1396r-8(c)(1)(C)(i).

> The term 'best price' means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal, Food, Drug, and Cosmetic Act), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity . . . *excluding* . . . any prices charged . . . [to] part D."

Id.
[360] SANOFI_SFC_00011791.
[361] CVSCM_SFC_0004784, at CVSCM_SFC0004805.
[362] SANOFI_SFC_00012618, at SANOFI_SFC_00012619.

In an attempt to avoid payers switching to Basaglar, Sanofi and Novo Nordisk increased their rebate bids to respond to Eli Lilly. For example, according to internal memoranda collected from Sanofi, sometime around April 2016, Express Scripts requested bids for its 2017 national commercial formulary and indicated its desire to only add one insulin glargine product to its basal insulin category.[363] Express Scripts communicated to Sanofi that "with the right competitive price, [it] would not have significant challenges moving [from Lantus and Toujeo] to Basaglar"[364] and that Sanofi must enhance its current rebate rate of 42% to maintain current access for their basal insulins.[365] An internal Sanofi memo describes this dynamic:[366]

Likely Competitive Approach and Response:

- Lilly is actively engaged with ESI for 2017 commercial business. Pricing has not been confirmed however ESI has informed that the following assumptions pose a threat to Sanofi's glargine franchise:
  - Discounts for Basaglar in the mid 60's have been communicated by ESI to Sanofi. This is likely a starter for ESI to consider excluding Lantus and Toujeo. Modeling assumed 70%.
  - Basaglar WAC will be 15% to 25% less than the WAC price of Lantus. Sanofi modeling assumed 15%.
- ESI has signaled, with the right competitive price, they would not have significant challenges moving to Basaglar in 2017 despite a follow-on biologic (Basaglar) approval.
- In addition ESI has indicated that Novo must also enhance its current rate to maintain current access for their basal insulin(s). Novo is likely to enhance its current rebates given recent Tresiba addition to part D formulary.

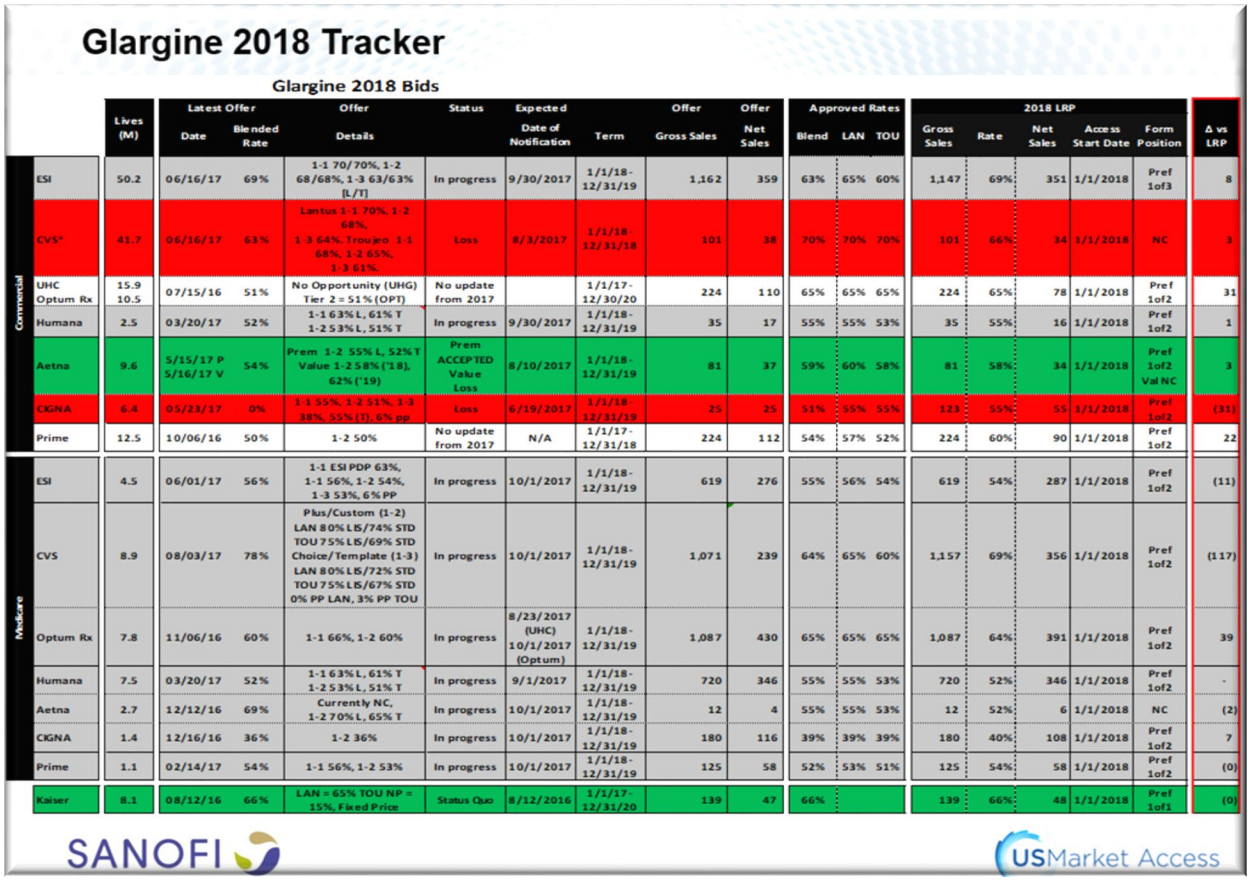
Rebate contracts confirm that Sanofi increased its offer up to almost 55%[367] off its WAC of $248.51 for Lantus vials and $372.76 for Lantus pens.[368]

i. Rebates Vary Widely by Payer

Rebates also vary greatly across payers. For example, payers with more bargaining power (i.e., more members) enjoy higher rebates than payers with less bargaining power (i.e., fewer members). Although the investigation did not seek out agreements between PBMs and health insurers, manufacturer rebate agreements do support the assertion that smaller health insurers do not always enjoy the same level of rebate offers as their larger peers. For example, in 2014, Novo Nordisk offered WellPoint, the largest for-profit managed health care company with over 40 million members, a larger rebate (40.625%) for Novolin vials for preferred formulary placement as 1 of 2 manufacturers on their client's commercial formulary compared to North Carolina State Employees (27.625%).[369] Similarly, Eli Lilly proposed a widely divergent rebate bid within a

[363] SANOFI_SFC_00012279.
[364] SANOFI_SFC_00012279, at SANOFI_SFC_00012280.
[365] SANOFI_SFC_00012279, at SANOFI_SFC_00012281.
[366] SANOFI_SFC_00012279, at SANOFI_SFC_00012280.
[367] Cigna-SFC-00009781, at Cigna-SFC-00009786.
[368] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019) (attachment 1(a) and (b)).
[369] Cigna-SFC-00009550, at Cigna-SFC-00009552.

few months of each other for Humulin and Humalog to a commercial health plan in Puerto Rico called SIS (25%),[370] Cigna (45%-55% depending on formulary placement),[371] a PBM called Abarca Health (up to 54%),[372] and Optum's Part D business (68%).[373] A Sanofi presentation for its long-acting insulin products further underscores how rebates can vary not only between companies, but between books of business within those companies, with larger accounts tending to receive larger rebate offers:[374]



Glargine 2018 Tracker

Glargine 2018 Bids

		Lives (M)	Latest Offer Date	Latest Offer Blended Rate	Offer Details	Status	Expected Date of Notification	Term	Offer Gross Sales	Offer Net Sales	Approved Rates Blend	Approved Rates LAN	Approved Rates TOU	2018 LRP Gross Sales	2018 LRP Rate	2018 LRP Net Sales	2018 LRP Access Start Date	2018 LRP Form Position	Δ vs LRP
Commercial	ESI	50.2	06/16/17	69%	1-1 70/70%, 1-2 68/68%, 1-3 63/63% [L/T]	In progress	9/30/2017	1/1/18-12/31/19	1,162	359	63%	65%	60%	1,147	69%	351	1/1/2018	Pref 1of3	8
	CVS*	41.7	06/16/17	63%	Lantus 1-1 70%, 1-2 68%, 1-3 64%. Toujeo 1-1 68%, 1-2 65%, 1-3 61%.	Loss	8/3/2017	1/1/18-12/31/18	101	38	70%	70%	70%	101	66%	34	1/1/2018	NC	3
	UHC Optum Rx	15.9 10.5	07/15/16	51%	No Opportunity (UHG) Tier 2 = 51% (OPT)	No update from 2017		1/1/17-12/30/20	224	110	65%	65%	65%	224	65%	78	1/1/2018	Pref 1of2	31
	Humana	2.5	03/20/17	52%	1-1 63% L, 61% T 1-2 53% L, 51% T	In progress	9/30/2017	1/1/18-12/31/19	35	17	55%	55%	53%	35	55%	16	1/1/2018	Pref 1of2	1
	Aetna	9.6	5/15/17 P 5/16/17 V	54%	Prem 1-2 55% L, 52% T Value 1-2 58% ('18), 62% ('19)	Prem ACCEPTED Value Loss	8/10/2017	1/1/18-12/31/19	81	37	59%	60%	58%	81	58%	34	1/1/2018	Pref 1of2 Val NC	3
	CIGNA	6.4	05/23/17	0%	1-1 55%, 1-2 51%, 1-3 38%, 55% (T), 6% pp	Loss	6/19/2017	1/1/18-12/31/19	25	25	51%	55%	55%	123	55%	55	1/1/2018	Pref 1of2	(31)
	Prime	12.5	10/06/16	50%	1-2 50%	No update from 2017	N/A	1/1/17-12/31/18	224	112	54%	57%	52%	224	60%	90	1/1/2018	Pref 1of2	22
Medicare	ESI	4.5	06/01/17	56%	1-1 ESI PDP 63%, 1-1 56%, 1-2 54%, 1-3 53%, 6% PP	In progress	10/1/2017	1/1/18-12/31/19	619	276	55%	56%	54%	619	54%	287	1/1/2018	Pref 1of2	(11)
	CVS	8.9	08/03/17	78%	Plus/Custom (1-2) LAN 80% LIS/74% STD TOU 75% LIS/69% STD Choice/Template (1-3) LAN 80% LIS/72% STD TOU 75% LIS/67% STD 0% PP LAN, 3% PP TOU	In progress	10/1/2017	1/1/18-12/31/19	1,071	239	64%	65%	60%	1,157	69%	356	1/1/2018	Pref 1of2	(117)
	Optum Rx	7.8	11/06/16	60%	1-1 66%, 1-2 60%	In progress	8/23/2017 (UHC) 10/1/2017 (Optum)	1/1/18-12/31/19	1,087	430	65%	65%	65%	1,087	64%	391	1/1/2018	Pref 1of2	39
	Humana	7.5	03/20/17	52%	1-1 63% L, 61% T 1-2 53% L, 51% T	In progress	9/1/2017	1/1/18-12/31/19	720	346	55%	55%	53%	720	52%	346	1/1/2018	Pref 1of2	-
	Aetna	2.7	12/12/16	69%	Currently NC, 1-2 70% L, 65% T	In progress	10/1/2017	1/1/18-12/31/19	12	4	55%	55%	53%	12	52%	6	1/1/2018	NC	(2)
	CIGNA	1.4	12/16/16	36%	1-2 36%	In progress	10/1/2017	1/1/18-12/31/19	180	116	39%	39%	39%	180	40%	108	1/1/2018	Pref 1of2	7
	Prime	1.1	02/14/17	54%	1-1 56%, 1-2 53%	In progress	10/1/2017	1/1/18-12/31/19	125	58	52%	53%	51%	125	54%	58	1/1/2018	Pref 1of2	(0)
	Kaiser	8.1	08/12/16	66%	LAN = 65% TOU NP = 15%, Fixed Price	Status Quo	8/12/2016	1/1/17-12/31/20	139	47	66%			139	66%	48	1/1/2018	Pref 1of1	(0)

SANOFI

USMarket Access

b. PBM Contracting Practices May Contribute to High Rebates and High List Prices in the Insulin Therapeutic Class

In response to the Committee's April 2nd letter, CVS Caremark, Express Scripts, and OptumRx stated that they work to obtain the lowest net cost (the drug price realized by plan sponsors after receiving rebates, discounts, and other fees from manufacturers) by soliciting

[370] LLY-SFCOM-UR-00003596, at LLY-SFCOM-UR-00003597.
[371] LLY-SFCOM-UR-00003325, at LLY-SFCOM-UR-00003326.
[372] LLY-SFCOM-UR-00003532. *See Smarter PBM Platform Selected by PerformRx*, PR Newswire (Oct. 22, 2018), https://www.prnewswire.com/news-releases/abarcas-smarter-pbm-platform-selected-by-performrx-300734745.html. (Abarca is a PBM with a significant customer base in Puerto Rico. It serves more than 2.5 million lives, but is relatively small when compared to CVS Caremark, Express Scripts, and OptumRx.)
[373] LLY-SFCOM-UR-00003449.
[374] SANOFI_SFC_00010668.

manufacturers to submit competing rebate offers.[375] While net cost is an important data point to consider, it does not address WAC, which can affect the price patients pay at the counter. Information collected for this investigation suggests that certain contracting and business practices may create incentives for PBMs to favor drugs with high rebates and, in turn, discourage manufacturers from competing to lower WAC prices.

i. Use of Exclusion Lists

Prior to 2012, most health insurers offered patients open formularies, giving them the ability to access "non-formulary" drugs with higher copays.[376] This changed in 2012 when CVS Caremark began excluding drugs from its formulary and expanded the practice in the following years.[377] Other PBMs and insurers would follow suit,[378] although internal documents show that health plan clients expressed concern about patients being able to access insulin and other prescription medications.[379] Today, the practice is widely used by PBMs, as demonstrated by the roughly 400 medications Express Scripts excludes from its 2021 formularies—an almost eight-fold increase since 2014.[380]

An internal Sanofi memo detailed the company's view on how the ACA changed market dynamics between manufacturers and health plans. The memo also laid out some of the ACA provisions that provided the government additional regulatory power over the private health care market that likely resulted in increased costs to health plans and more restrictive formularies. Portions of the memo and Sanofi's view on how the ACA altered the market dynamics between pharmaceutical companies and payers are listed verbatim below:

- ***Guaranteed Issue/Elimination of Pre-Existing Condition Denials****. Beginning in 2014, health plans are no longer allowed to deny enrollment or policy enrollment based [on] their costly pre-existing conditions. This increases health plans' costs.*

- ***Elimination of lifetime and annual covered benefit spending.*** *Before the health care law, many health plans set an annual or lifetime limit – a dollar limit on their yearly spending for each enrollee's covered benefits. Enrollee's [sic] would need*

[375] Letter from Enu Mainigi, Counsel, Williams & Connolly, on Behalf of CVS Health Corp., to Senator Grassley and Senator Wyden (Apr. 26, 2019); Letter from Kristin Julason Damato, Vice President Government Affairs, Cigna Corporation, to Senator Grassley and Senator Wyden (Dec. 7, 2020); ORX_Sen_Fin_00001935.
[376] SANOFI_SFC_00009132. *See also* Joshua Cohen et al., *Rising Drug Costs Drives the Growth of Pharmacy Benefit Managers Exclusion Lists: Are Exclusion Decisions Value-Based?*, HEALTH SERV. RES. (Aug. 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6056588/.
[377] SANOFI_SFC_00009132, at SANOFI_SFC_00009134.
[378] SANOFI_SFC_00009132, at SANOFI_SFC_00009134.
[379] A series of internal memos outlined health plans' concerns about Express Scripts' decision to begin excluding drugs from their national formulary. Some clients threatened to terminate their relationship with the PBM. Cigna-SFC-00015251. Another client's insurance board ruled it could not "adopt this strategy … due to their union contract obligations and their diabetes education funded by Novolog." Cigna-SFC-00015246. Other clients raised concerns related to disruption to their beneficiaries, such as "increased costs due to additional office visits and additional member hassle." Cigna-SFC-00015242. And, "major member disruption." Cigna-SFC-00015244. *See* Cigna-SFC-00015236-60.
[380] In 2014, Express Scripts excluded approximately 57 drugs from its formulary. In 2021, that figure jumped to over 400. *See 2021 National Perferred Formulary Exclusion Lists*, EXPRESS SCRIPTS (2021), https://www.express-scripts.com/art/open_enrollment/DrugListExclusionsAndAlternatives.pdf.

to pay for the medical expenses beyond those limits. ACA no longer allows plans to do this. This increases health plan's [sic] costs.

- ***Medical loss ratio.*** *Health plans must meet certain thresholds when it comes to revenue and expenses. The intent of the MLR is to eliminate excess profits and encourage administrative efficiencies. Plans must demonstrate that at least 80% of their revenues (85% in the large group market) must be accounted for with enrollee medical expenses. If they do not, consumers must receive rebate checks to bring the accounting into line with the threshold. The US government has publicized that in 2012, consumers received $500 million in MLR rebate checks and avoided $3.4 billion in upfront premium increases that would have occurred had this and other polices not been in place. This is money that has been taken out of the health care plan sector.*

- ***Government premium rate reviews.*** *Health plans must submit to the government justification for any premium rate increases of 10% or greater. The US government has publicized that in 2012, consumers saved $1.2 billion as a result of this policy. This is money that has been taken out of the health plan sector.*

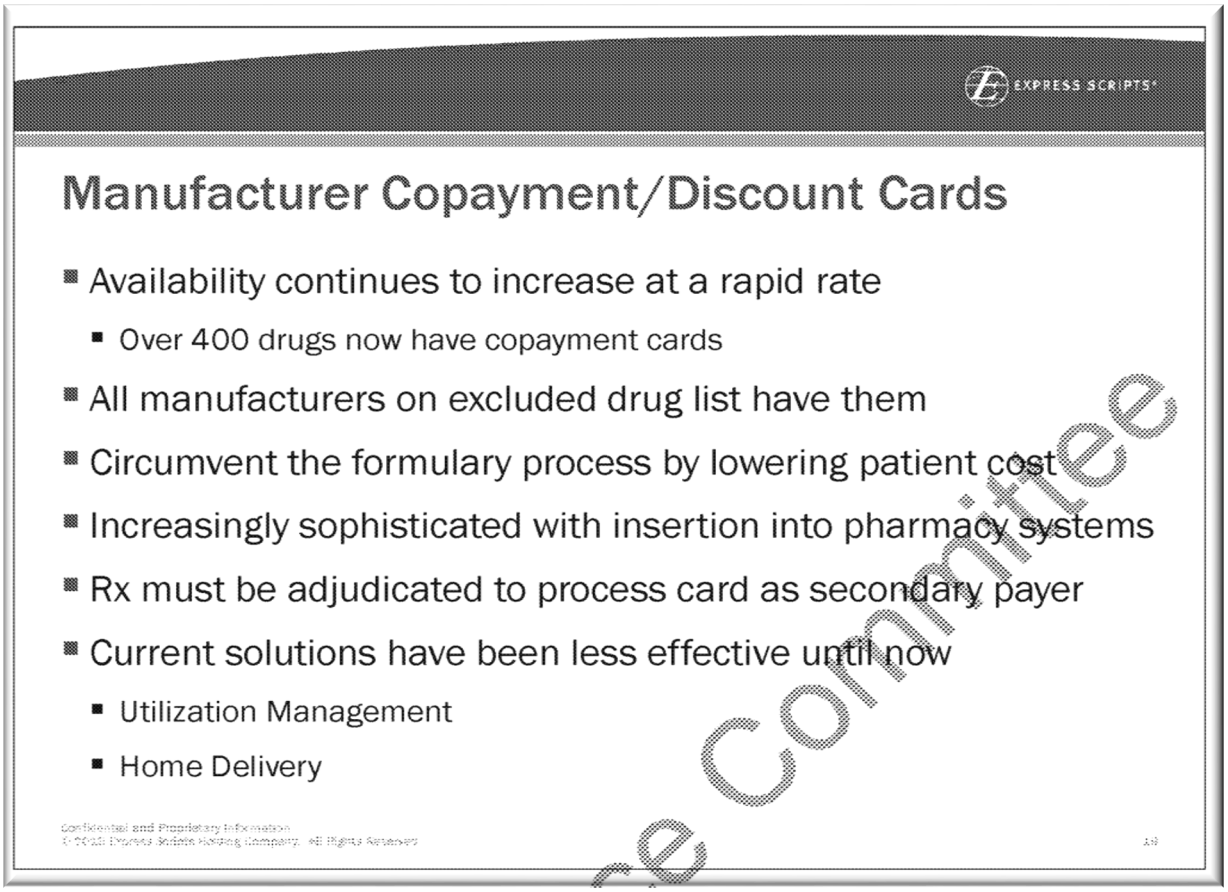
- ***Fees to support the exchanges****. In order to manage some of the risk of high cost enrollee's [sic] in the exchanges, health fees have been imposed on plans outside of the exchanges. Additionally, for health plans that participate in the exchanges, fees are imposed for participation. This increases plan's [sic] costs. The 10 essential health benefits. The ACA requires plans to cover 10 essential health benefits: 1) ambulatory patient services; 2) emergency services; 3) hospitalization; 4) maternity and newborn care; 5) mental health and substance use disorder services, including behavioral health treatment; 6) prescription drugs; 7) rehabilitative services and devices; 8) laboratory services; 9) preventive and wellness services and chronic disease management; and 10) pediatric services, including oral and vision care. For those plans that did not offer such robust benefits previously, their costs increased with ACA . . .*

- ***Uncertainty on enrollment and patient mix.*** *Exchange plans are expected to cover the medical expenses of a currently uninsured population. No historical data exists as to whether or not the consumer penalties associated with not buying insurance (the individual mandate) is significant enough to encourage enrollment of healthy individuals. In the event health plans end up covering only the sick, and those expenses exceed the revenue generated from premiums, plans will incur losses. While there are risk protections in place to help compensate for some of these risks and losses, much uncertainly [sic] still exists.*

- ***[Formulary coverage policy.]*** *Finally, the ACA set a precedent with is formulary coverage policy. While this policy does not place pressure on plan's [sic] margins, it does provide an excuse for health plans to assert more exclusivity on drug formularies. ACA regulation allows plans to cover one drug per USP category. (Medicare requires at least two drugs per category). Plans may choose to exploit*

this precedent setting government policy as they operate in the non-exchange market in order to leverage more rebates and reduce costs.[381]

Increased use of manufacturer co-payment and discount cards also made it difficult to control drug spending. An internal Express Scripts presentation underscores the PBM industry's view that co-pay coupons circumvent the formulary process by lowering patient costs and incentivizing patients to use drugs with higher list prices.[382] An excerpt concerning manufacturer copay coupons taken from an Express Scripts internal memo is shown below.[383]



When a drug is excluded from a formulary it means that it will not be covered by the insurer unless an exception is granted for the patient.[384] In the insulin therapeutic class, PBMs consider certain insulins interchangeable, meaning that their P&T committees have determined the competing brands are similar in their safety, efficacy, and kinetics.[385] The P&T's determination allows PBMs to solicit competing bids from manufacturers in an effort to obtain

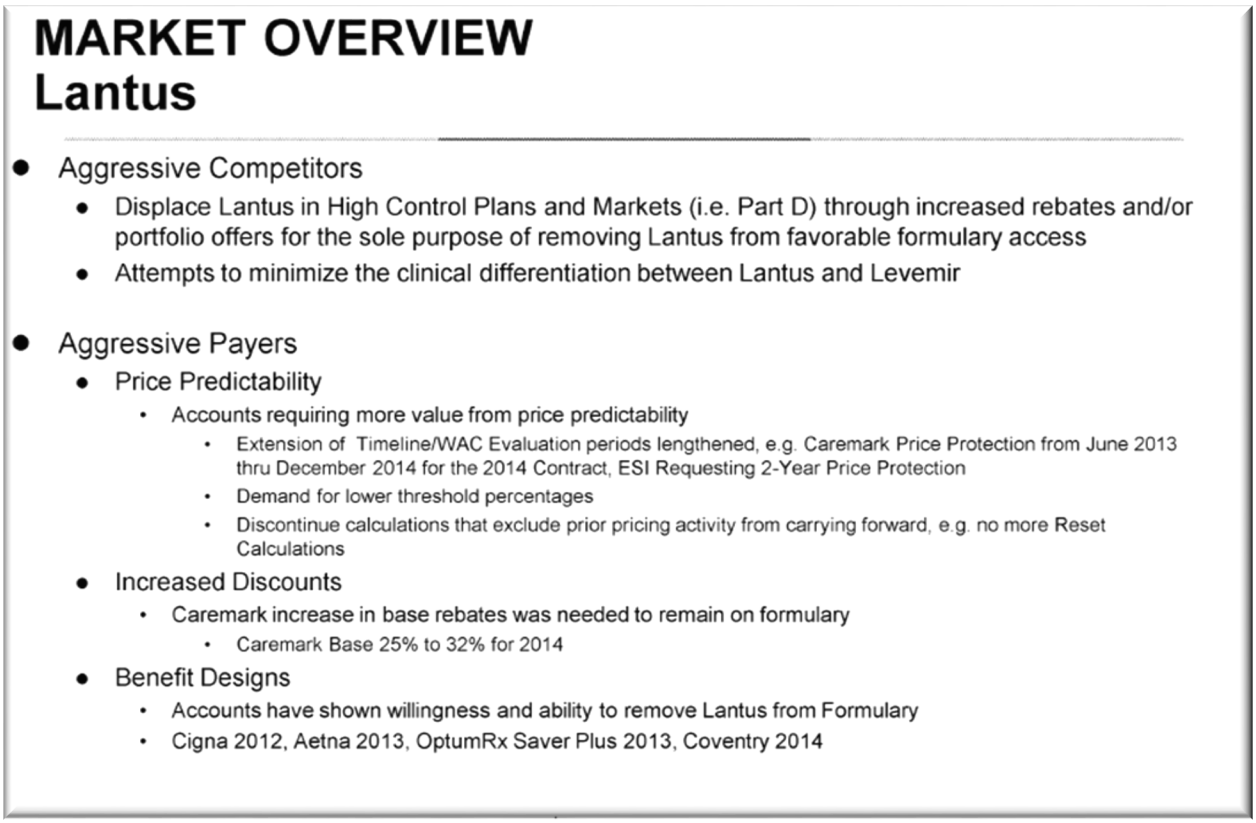
[381] SANOFI_SFC_00009132, at SANOFI_SFC_00009132-33.
[382] Cigna-SFC-00018522, at Cigna-SFC-00018540-41.
[383] Cigna-SFC-00018522, at Cigna-SFC-00018540.
[384] Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Apr. 16, 2019).
[385] *Id. See also* ORX_Sen_Fin_0004777 (OptumRx's P&T had designated Basaglar, Lantus, Levemir, and Toujeo as part of an "essential class"); ORX_Sen_Fin_0005377, at ORX_Sen_Fin_0005383 (Drugs designated as an "essential class" are similar in their safety and efficacy when used to treat the same or similar medical condition).

the lowest net cost for their clients. While formulary exclusions are intended help control drug costs, they can affect a patient's ability to access medication, and revenue generated by drug manufacturers from their products.[386] For the patient, if a drug is excluded, they can be forced to either switch to another product, which could affect adherence and health outcomes, or pay significantly more to stay on their preferred medication. For manufacturers, the investigation found that the mere threat of exclusion typically forces them to offer substantially greater discounts to maintain formulary position, reducing net price. When exclusions are actually imposed, manufacturers often face a significant loss of market share, leading to lower revenue. On the other hand, being the exclusive therapy on a formulary can be advantageous for a brand's market share and revenue, which incentivizes companies to offer large discounts to maintain such status.[387] The use of exclusions has led to a market dynamic in which manufacturers offer ever-higher rebates to avoid exclusion, which appears to have contributed to higher list prices.

The investigation found several instances where manufacturers increased their rebate bids following the threat of formulary exclusion.

Prior to 2013, Sanofi offered an average rebate of 5% on Lantus.[388] However, in 2013, Sanofi began to increase its rebate and discount offerings to health plans for two reasons. First, Sanofi increased its rebate and discount offerings to respond to Novo Nordisk's aggressive rebate strategy.[389] Beginning in 2013, competitors sought to "[d]isplace Lantus in High Control Plans and Markets (i.e., Part D) through increased rebates" for the purposes of capturing market share.[390] Secondly, Sanofi increased its rebate and discount offerings because payers began to demand increased discounts from drug manufacturers to remain on their formulary.[391] A Sanofi memo, shown below, further explains this dynamic:[392]

[386] Letter from Raphael Prober, Counsel, Akin Gump, on Behalf of Novo Nordisk, to Senator Grassley and Senator Wyden (June 28, 2019).
[387] *See* LLY-SFCOM-UR-00003699. This June 2015 email exchange amongst Eli Lilly employees shows how manufacturers seek to maintain exclusive status for their drugs and will offer increased rebates to maintain preferred status.
[388] SANOFI_SFC_00008916-17.
[389] SANOFI_SFC_00014532, at SANOFI_SFC_00014533.
[390] SANOFI_SFC_00009211, at SANOFI_SFC_0009217.
[391] SANOFI_SFC_00009211, at SANOFI_SFC_0009217.
[392] SANOFI_SFC_00009211, at SANOFI_SFC_0009217.



While PBMs may have initially utilized formulary exclusions in the insulin therapeutic class as a way to drive cost down for their clients, internal correspondence and memoranda suggest that increased use of formulary exclusions have had unintended consequences: WAC prices have continued to increase, leading to higher prices for some at the pharmacy counter.

For example, in 2013, Express Scripts threatened to move patients to other diabetes drugs in order to "break even on [the] rebate line" unless Sanofi increased its Medicare Part D rebate offer for Lantus in 2014.[393] As a result, Sanofi considered increasing its rebate offer from 7.45% to 15% in order to prevent formulary exclusion.[394] Sanofi also faced similar pressure to increase rebates for Express Scripts' commercial contracts. Internal memoranda collected from Sanofi suggest that "Sanofi was notified by [Express Scripts] that Lantus was positioned to be removed from the formulary effective 2013 . . . [as a result] rebates were re-negotiated."[395] An excerpt from this memo, discussing the threat to Lantus, is shown below.[396]

[393] SANOFI_SFC_00009282, at SANOFI_SFC_00009287-88.
[394] SANOFI_SFC_00009282, at SANOFI_SFC_00009287.
[395] SANOFI_SFC_00008920, at SANOFI_SFC_00008923.
[396] SANOFI_SFC_00008920, at SANOFI_SFC_00008923.

Lantus Contracting History with ESI

Account Management and Contracting have worked closely together to maintain a 5% rebate for Commercial contracts through 2012. Sanofi was notified by ESI that Lantus was positioned to be removed from formulary effective 2013. Rebates were re-negotiated resulting in a 6% Lantus Vial & 9% Lantus SoloStar rebate (no price protection).

Lantus Overall Threat

The Commercial business is at additional threat due to competitive rebate pressures and changing formulary design as well as Lantus pricing actions.

- ESI has shared that Novo has been extremely aggressive the last few months and this has triggered the need to revise our offer.
    - For 2014 ESI made Humalog exclusive in the RAI category, moving Novolog to Not Covered and made Byetta & Bydureon the only options in the GLP1 category, moving Victoza to Not Covered.
- Comments during discussion with ESI confirmed that modeling has occurred and that the current contracted offer will result in a Not Covered position for 2015. This is based on competitive offers by Novo and client plans requesting exclusive offers for comparison.
- They have shared that the basal category is under consideration for exclusion list status for 2015. This interest in an exclusive offer is consistent with recent actions they have taken to reduce the number of branded options available to patients.
- Lantus price increases over the past two years have positioned Sanofi as a cost driver that has triggered significant attention from ESI.

Express Scripts is an important account to retain for Sanofi's diabetes drugs because of the large volume of its customer base. According to internal memoranda, in 2014, Express Scripts and its affiliated businesses managed the prescription drug claims of over 4.6 million people, representing 15% of the total business in the Medicare Part D channel.[397] Rebate agreements confirm Sanofi renegotiated rebates and entered into an agreement to provide up to 10.625% for Lantus, effective January 1, 2014.[398] Rebates were renegotiated again that same year, and Sanofi increased its rebate offer up to 14.625%, effective October 1, 2014.[399]

Around this same time, payers eventually learned that Sanofi had offered competitive rebates to Express Scripts which caused them to question their rebate status with Lantus.[400] As a result, payers began to demand higher rebates and threatened to exclude Lantus from their formulary to achieve this result. For example, in 2014, UnitedHealthcare (UHC) threatened to remove Lantus from its commercial formulary because of Lantus's price increases.[401] Sanofi offered an enhanced rebate for FY2015 in the 15% range, but UHC rejected Sanofi's offer and removed Lantus from its commercial formulary.[402] Sanofi responded with a last minute bid of 45% rebate for Tier 2 which UHC countered with 45% for Tier 3.[403] According to Sanofi, UHC's counteroffer was "ultimately accepted over access concerns to future products and the need to secure access to patient lives."[404] Rebate agreements confirm Sanofi renegotiated rebates

[397] SANOFI_SFC_00009282, at SANOFI_SFC_00009283.
[398] Cigna-SFC-00010029, at Cigna-SFC-00010040.
[399] Cigna-SFC-00010043, at Cigna-SFC-00010044.
[400] For example, in 2014, internal memoranda suggest that Sanofi was "at risk with [Prime Therapeutics] due to public comments around increases in Lantus rebates impacting the U.S. market for diabetes." According to Sanofi, at the time, "Prime is questioning their current rebate status with Lantus . . . [and] are requesting/requiring an increase in 2015." SANOFI_SFC_00014267.
[401] SANOFI_SFC_00008934.
[402] SANOFI_SFC_00008934.
[403] SANOFI_SFC_00008934.
[404] SANOFI_SFC_00008934. Emphasis included in the original.

and entered into an agreement to provide up to 45% for Lantus, effective December 15, 2015.[405] An excerpt of this email exchange is shown below.[406]

From: Ingram, Garrett PH/US
Sent: Tuesday, August 19, 2014 4:12 PM
To: Guenter, Peter PH/FR; Purcell, Andrew PH/US; Bartner, Natalie PH/US; Whitaker, Anne PH/US; Kaseta, Michael PH/US
Cc: Du, Wei Wei PH/FR; Bray, Scott PH/US; Borneman, James PH/US; Loreaux, Sandy PH/US; McClellan, Mike PH/US
Subject: RE: Lantus Weekly Report - Week Ending August 1, 2014

Andrew, Peter & all,

Per Andrew's response the contract is performing to the expectations/forecasts we set when we signed the deal. We will continue to monitor and focus on accelerating pull through. Below is our initial assessment. Additionally, attached are the whitepapers & financials for the OptumRx Commercial & Part D deals. Due to the sequence of events we have completed a post action review that we will be sharing with you in September. Our response to customer feedback resulted in incremental impact. Look forward to reviewing learnings with you. Please let me know if you have any questions or feedback. Best,

Garrett

UHC Commercial and Part D Response

Overview: Driven by increasing costs in the basal category, including sanofi price increases on Lantus, UHC approached sanofi with a request for incremental commercial rebate targets. Following a series of sanofi offers in the 15% range, UHC removed Lantus from commercial formulary. Sanofi responded with a last minute bid of 45% for Tier 2 which was rejected by UHC who counteroffered with a 45% rebate for Tier 3 + 7% cumulative PP. Although this offer was deemed to be negative financially vs. a no-contract scenario, the offer was ultimately accepted over access concerns to future products and the need to secure access to patient lives.

In Part D, UHC similarly moved to remove Lantus from formulary in 2015, particularly unhappy about the December 2013 pricing action and suggesting that agreed terms of 35% +7% PP were insufficient. Final terms of 55% + 6% PP were agreed to which also included access to the Saver Plus formulary, a segment of lives of which Lantus had previously been excluded. Lantus Vial added - 7/1/14 and SoloSTAR -10/1/14.

Similarly, in 2016, Express Scripts threatened to remove Lantus and Toujeo from its Medicare Part D formulary and requested that Sanofi submit its "best and final offer" or else face formulary exclusion.[407] According to internal memoranda, during negotiations, Express Scripts told Sanofi that it was justified in removing Lantus and Toujeo from its Medicare Part D formulary because it had allowed "quite a few years of price increases" and that Novo Nordisk's rebate offer was more competitive.[408] In response to Express Scripts' threat, Sanofi discussed revising its rebate offer up to 40% with 4% price protection for Lantus and Toujeo.[409]

[405] ORX_Sen_Fin_0009099, at ORX_Sen_Fin_0009126.
[406] SANOFI_SFC_00008934.
[407] SANOFI_SFC_00012556, at SANOFI_SFC_00012558.
[408] SANOFI_SFC_00012556, at SANOFI_SFC_00012558.
[409] SANOFI_SFC_00012556.

Although contracts with PBMs included larger and larger rebates, manufacturers still expected to remain profitable—up to a point. For example, on July 28, 2017, one Sanofi official wrote to colleagues after considering their offer to CVS Caremark for placement on the Part D formulary: "After inclusion of additional fees, we are still profitable up to an 89% rebate."[410] The official included an analysis that assumed "CVS would need to shift 68.9% of [its] glargine volume to Novo to break even (at an assumed 81% rebate offer)."[411] In its analysis, Sanofi compared various negotiation scenarios including a "no contract" scenario, which it determined would be more profitable to the company even with the resulting reduction in sales volume and revenue.[412] It appears that one of the deciding factors was optics, as one colleague put bluntly: "How would it look to be removed from the largest Medicare plan?"[413]

As PBMs expanded the practice of using exclusions to extract greater rebates, Sanofi's counterstrategy was to bundle unrelated products that had been excluded—Lantus and an epinephrine injection called Auvi-Q—to win formulary inclusion for both. (Bundling is a practice where manufacturers offer rebates and discounts for multiple products, but only if certain conditions are met.) Both drugs had been excluded from various accounts, such as some of Aetna's Part D plans, resulting in rapid erosion of market share:[414]

Background:

- As of 3Q14, Aetna has approximately 2.3 Million Medicare Part D lives (~6% of MMA channel) in the U.S.
- Aetna acquired Coventry in May 2013 and enhanced Medicare footprint by adding > 1.0 Million Part D members with largest enrollment in Texas, Michigan, California and Pennsylvania.
- Lantus is in a Not Covered position for 60% of the business and Non-Preferred for 40% of the business.
- Lantus Family market share share fell from 66.3% (1/13) to 47.3% (1/14) and is currently 33.7% (9/14). Lantus was moved to Not Covered on Aetna's MMA formulary on 1/1/13.
- Auvi-Q is in a Not Covered position for 100% of the business and market share is 0.6% (9/14).

Sanofi faced significant financial pressure across all accounts, and sought to include bundling agreements in several of its contracts. While negotiating contracts for the 2015/2016 plan year, Express Scripts advised Sanofi that they needed to be far more aggressive with rebate offers to gain access to the PBM's commercial book of business than in past years.[415] Internally, Sanofi officials warned in a memo that "Novo, specifically Levemir, has changed the game with regard to rebates," and that Sanofi would "need to rebate aggressively."[416] The memo noted that Lantus and Auvi-Q were initially bundled together—an offer that had since been withdrawn from consideration.[417] A separate presentation describes "[c]ontracts that increase Lantus rebates if Auvi-Q is added to [the] formulary thus creating a bundled arrangement," and notes that the company had even considered a "triple product bundle" with Toujeo, despite concerns about the

[410] SANOFI_SFC_00010874.
[411] *Id. See also* SANOFI_SFC_00010880, at SANOFI_SFC_00010884.
[412] SANOFI_SFC_00010874, at SANOFI_SFC_00010877-79; SANOFI_SFC_00010880, at SANOFI_SFC_00010883.
[413] SANOFI_SFC_00010874.
[414] SANOFI_SFC_00013990.
[415] SANOFI_SFC_00014648.
[416] SANOFI_SFC_00014648.
[417] SANOFI_SFC_00014648, at SANOFI_SFC_00014653.

arrangements triggering Medicaid best price.[418] It's important to note that this counterstrategy was not limited to Sanofi. Another internal memo shows that Sanofi's competitors were using the same strategy: "Lantus is losing accounts and share within the institutional channel because of aggressive discounting and bundled contract offerings from Novo Nordisk and Lilly."[419]

Sanofi was not the only company that sought to use bundling to its advantage. For example, Novo Nordisk secured contract terms from CVS's Part D business in 2013 that tied its "exclusive" rebates for insulin to formulary access for a Type 2 diabetes drug called Victoza. The exclusive rebates of 57.5% for Novolin, Novolog, and Novolog Mix 70/30 were more than three times higher than the 18% rebate for plans that included two insulin products on their formulary.[420] In order to qualify for the exclusive rebate, the plans would also need to list Victoza, a GLP-1 agonist,[421] on their formulary, exclude all competing insulin products, and ensure "existing patients using a [c]ompeting [p]roduct may not be grandfathered."[422] CVS also appears to have been prohibited from rebidding for products within the therapeutic class for placement on the national formulary until January 1, 2015, absent safety issues with one of the drugs.[423]

Following years of rebate and list price increases, manufacturers faced increased pressure from patients, payers, and the Federal government to decrease insulin's WAC price.[424] However, internal memoranda and correspondence collected for this investigation suggest that the downstream impact of lowering the WAC prices presented hurdles for pharmaceutical companies. A June 23, 2018 email memorializes a portion of a conversation Eli Lilly's President of the Diabetes Unit, Enrique Conterno, had with the CEO of OptumRx who allegedly "re-stated that [OptumRx] would be fully supportive of Lilly pursuing a lower list price option", but indicated that OptumRx would encounter challenges, namely, "the difficulty of persuading many of their customers to update contracts without offering a lower net cost to them."[425] In response, one executive noted, "we wouldn't be able to lower our list price without impacting our net price," and counseled waiting until early 2020 to reduce prices.[426] Two weeks prior to this email, Eli Lilly executives raised the possibility that PBMs would object to a list price reset because it would result in (1) a reduction in administrative fees for PBMs, (2) a reduction in rebates, which would impact PBMs' ability to satisfy rebate guarantees with some clients, and (3) impair their clients' ability to lower premiums for patients, thereby impacting their market competitiveness.[427] An excerpt of this email is shown below.[428]

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[418] SANOFI_SFC_00013800, at SANOFI_SFC_00013801.
[419] SANOFI_SFC_00009001, at SANOFI_SFC_00009002.
[420] NNI-FINANCE-000039, at NNI-FINANCE-000051.
[421] *GLP-1 agonists: Diabetes drugs and weight loss*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/type-2-diabetes/expert-answers/byetta/faq-20057955 (last viewed Jan 1, 2020).
[422] NNI-FINANCE-000039, at NNI-FINANCE-000052.
[423] NNI-FINANCE-000039, at NNI-FINANCE-000052.
[424] *See* LLY-SFCOM-UR-00005526.
[425] LLY-SFCOM-UR-00006684.
[426] LLY-SFCOM-UR-00006684.
[427] LLY-SFCOM-UR-00006563.
[428] LLY-SFCOM-UR-00006563.

Message

From: Terrence M Lyons [redacted]
Sent: 6/14/2018 2:56:33 PM
To: Enrique A Conterno [redacted]
CC: Frank D Cunningham [redacted] Michael B Mason [redacted]; Joshua L Smiley [redacted]
Subject: Reply: Tomorrow

Enrique:

I anticipate that the PBMs may raise the following objections and/or considerations in connection with a contemplated list price reset:

(1) Reduction in the absolute amount of Admin Fees earned upon insulin claims/utilization (since this is expressed as a percentage) while still performing comparable/identical services governed by the Admin Fee;
(2) Reduction in absolute rebate amounts pressuring the PBMs ability to satisfy contractually obligated rebate guarantees with some clients (employers and insurance plans) in the near/intermediate term;
(3) Inability to modify/resubmit premiums and associated formularies for Part D plans for the 2018 (and perhaps 2019) plan year(s), or risk that such adjustments may impair market competitiveness (i.e rebate levels on lower gross price levels translating to higher plan premiums).

TML

Terrence M. Lyons
Vice President Finance | CFO Lilly Diabetes
[redacted]

The internal memoranda and correspondence collected for this investigation show that exclusion lists have contributed to higher rebates in the insulin therapeutic class. Manufacturers increase rebates to respond to formulary exclusion threats, and to preserve revenue and market share through patient access. It also appears that increases in rebates are associated with increased list prices. This supports the notion that PBM demands for rebates contribute to rising insulin prices.

ii. Administrative Fees

Eli Lilly's reluctance to lower the list price of drugs—due partly to its effect on PBM revenue from administrative fees—illustrates a dynamic that the HHS OIG has identified as an area of concern for potential violations of the Anti-Kickback Statute.[429] According to rebate agreements collected for this investigation, PBMs earn administrative fees for each unit of a manufacturer's drug.[430] These fees, which are negotiated between the manufacturer and PBM in

[429] *See* DEP'T HEALTH AND HUMAN SERVS., OFF. OF INSPEC. GEN., FRAUD AND ABUSE; REMOVAL OF SAFE HARBOR PROTECTION FOR REBATES INVOLVING PRESCRIPTION PHARMACEUTICALS AND CREATION OF NEW SAFE HARBOR FOR PROTECTION FOR CERTAIN POINT-OF-SALE REDUCTIONS IN PRICE ON PRESCRIPTION PHARMACEUTICALS AND CERTAIN PHARMACY BENEFIT MANGER SERVICE FEES (Feb. 6, 2019), https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals. According to the HHS OIG, if administrative fees are tied to the list price of a prescription pharmaceutical product, based on sales volume, or far exceed fair market value of the services performed, these fees could function as a kickback. *Id.* HHS OIG proposed creating a new safe harbor that would provide a pathway, specific to PBMs, to protect remuneration in the form of flat service fees. *Id.*
[430] *See* ORX_Sen_Fin_0009384, at ORX_Sen_Fin_0009389. It's important to note that administrative fees only meant to be applied to drugs utilized by commercial and Medicare Part D plans. These are not charged on products utilized by Medicaid or the Children's Health Insurance Program (CHIP). *Id.*

rebate contracts, are meant to cover services such as reporting and monitoring health insurers' compliance with the rebate eligibility requirements, examples of which are detailed in a rebate contract between CVS Caremark and Novo Nordisk:[431]

> (h) Administrative Services. In consideration of the Administrative Fees, PBM will: (i) negotiate and contract with Part D Plan Sponsors for participation in the Rebates provided under this Agreement; (ii) notify Part D Plan Sponsors of the applicable requirements for receiving Rebates on Products in accordance with PBM's standard business practices; (iii) monitor Part D Plan Sponsor compliance with the Rebate eligibility requirements; (iv) calculate the amounts of Rebates applicable to Products for each Part D Plan Sponsor and invoice Manufacturer for such Rebates; (v) prepare detailed reports on Product utilization and Rebate calculations as described herein; (vi) allocate and distribute Rebates to Part D Plan Sponsors under the terms of PBM's agreements with Part D Plan Sponsors and provide supporting reports to the Part D Plan Sponsors; (vii) utilize internal control measures to protect against payment of unearned Rebates; and (viii) provide such other services related to the administration of the Rebate program as agreed upon by the parties from time to time. Administrative Fees are separate and apart from the Rebates paid to Part D Plans.

Administrative fees paid by drug manufacturers are calculated as a percentage off WAC.[432] Some Part D contracts even require manufacturers to pay administrative fees during the coverage gap phase (the phase that occurs between the initial coverage limit and the catastrophic coverage phase) of Medicare Part D.[433]

Although Part D plans are required to report rebates to CMS, they are not required to report administrative fees collected and retained by PBMs "if the fees are for bona fide services and are at fair market value."[434] This basic lack of transparency in the Medicare program has been an area of concern to HHS OIG, as has the competing interests that PBMs and manufacturers find themselves in due to the administrative fees being based on the WAC price. According to HHS OIG:

> When PBMs contract to administer the pharmacy benefit for health plans, the PBMs are the health plans' agents. However, the contracting health plans may not always know the services their PBMs are providing to pharmaceutical manufacturers. Manufacturers often pay PBMs fees for certain services (e.g., utilization management, medical education, medication monitoring, data management, etc.), and these fees may be calculated as a percentage of the list price of a particular drug product. If service fees paid by manufacturers are tied to the list price of the prescription pharmaceutical product, based on sales volume, or far exceed the fair market value of the services performed, these fees could function as a disguised kickback.[435]

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[431] CVSCM_SFC_0005005, at CVSCM_SFC_0005009.
[432] CVSCM_SFC_0005005, at CVSCM_SFC_0005018. *See also* ORX_Sen_Fin_0009384, at ORX_Sen_Fin_0009389.
[433] *See* CVSCM_SFC_0005005, at CVSCM_SFC_0005010.
[434] DEP'T HEALTH AND HUMAN SERVS., OFF. OF INSPEC. GEN., CONCERNS WITH REBATES IN THE MEDICARE PART D PROGRAM, at 4 fn. 16 (Mar. 11, 2011), https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf.
[435] *See* DEP'T HEALTH AND HUMAN SERVS., OFF. OF INSPEC. GEN., FRAUD AND ABUSE; REMOVAL OF SAFE HARBOR PROTECTION FOR REBATES INVOLVING PRESCRIPTION PHARMACEUTICALS AND CREATION OF NEW SAFE HARBOR FOR PROTECTION FOR CERTAIN POINT-OF-SALE REDUCTIONS IN PRICE ON PRESCRIPTION PHARMACEUTICALS AND

The amount of administrative fees paid industry-wide is not known because they are contained in the confidential rebate contracts with manufacturers and are not disclosed by the PBMs. However, a recent study by the *Pew Charitable Trusts* estimated that, between 2012 and 2016, the amount of administrative and other fees nearly tripled, reaching more than $16 billion.[436] While such totals are far from inconsequential, they appear to make up a relatively small amount of the $370 billion spent on retail prescription drugs in the United States,[437] and make up a relatively small share of the cost of individual pharmaceutical products.[438]

Administrative fees vary by contract, but generally fall between 3% and 5% in the insulin therapeutic class. For example, in 2019, OptumRx's administrative fee for Lantus represented 4.75% of WAC.[439] However, documents collected during the investigation show that PBMs have been collecting substantially greater revenue from administrative fees as WAC prices increase and the fees grow:[440]

Rationale for Recommendation:

- The recommendation is in response to the customer's request to increase Admin Fees from 3.00% to 4.75%.
- Factors leading to the reassessment and increase include:
  - Alignment with market competitive rates
    - Prime Therapeutics → 3%, Caremark →4% ESI →4.875% *note that ESI rate increased in 2016 by .5points*
  - Request of manufacturers to provide increased transparency to client-level compliance with rebate eligibility from prior levels
  - Increased number of manufacturer requested audits
  - Increased complexity of manufacturer required conditions for rebate eligibility
- The incremental 1.75% is <u>not</u> negotiable. If we do not agree to the 1.75% it will be captured from product(s) base rebate.

While the Committee's investigation did not request documents related to the agreement between PBMs and health insurers, Express Scripts provided a *pro forma* contract between the State of Tennessee and Cigna Corporation which suggests PBMs also charge health insurers non-rebate, administrative fees for providing pharmacy benefit management service—essentially profiting from all sides of the transaction.[441] This contract provides that Express Scripts earns administrative fees and, depending on the agreement, clinical fees[442] from the State of

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CERTAIN PHARMACY BENEFIT MANGER SERVICE FEES (Feb. 6, 2019), https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals.

[436] *The Prescription Drug Landscape Explored*, Pew Charitable Trust, at 35 (Mar. 2019), https://www.pewtrusts.org/-/media/assets/2019/03/the_prescription_drug_landscape-explored.pdf.

[437] *National Health Expenditures 2018 Highlights*, CTRS. FOR MEDICARE AND MEDICAID SERV. (2018), https://www.cms.gov/files/document/highlights.pdf

[438] *See Prescription Economics in the U.S. Drug Channel System*, DRUG CHANNEL INSTITUTE (Aug. 2017), http://www.drugchannelsinstitute.com/files/Drug_Channel_Economics-Pembroke-August2017.pdf.

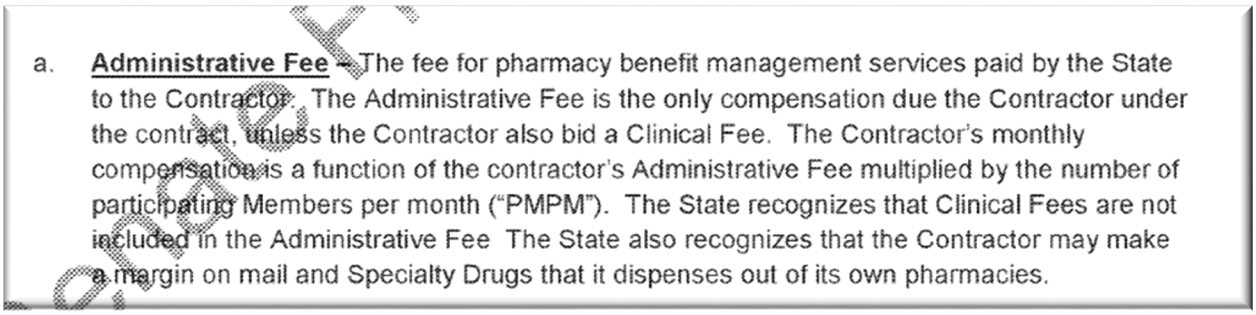
[439] ORX_Sen_Fin_0009384, at ORX_Sen_Fin_0009389.

[440] *See* SANOFI_SFC_00012321.

[441] Cigna-SFC-00017902, at Cigna-SFC-00017903.

[442] Clinical fees are defined as the amount paid to the PBM for their management of clinical programs such as safety and monitoring review, prior authorization, and step therapy edits and prior authorization and appeals. Cigna-SFC-00017902, at Cigna-SFC-00017904.

Tennessee, calculated as an agreed upon percentage multiplied by the number of participating members per month.[443] An excerpt from Express Scripts' pro forma contract is shown below.[444]



a. **Administrative Fee** – The fee for pharmacy benefit management services paid by the State to the Contractor. The Administrative Fee is the only compensation due the Contractor under the contract, unless the Contractor also bid a Clinical Fee. The Contractor's monthly compensation is a function of the contractor's Administrative Fee multiplied by the number of participating Members per month ("PMPM"). The State recognizes that Clinical Fees are not included in the Administrative Fee The State also recognizes that the Contractor may make a margin on mail and Specialty Drugs that it dispenses out of its own pharmacies.

The use of administrative fees between plans and PBMs is further supported by correspondence between Express Scripts and the Securities and Exchange Commission in 2017. The company explained that administrative fees and the percentage of rebates delivered to the plan are both negotiating levers PBMs use with their plan clients:

> The pricing for our PBM offering depends upon the benefit design selected by each individual client. The overall pricing in our client contracts depends on several components, including ingredient costs, administrative fees and rebates. We customize the economics of each client contract based on the client's assessment of how it can cost effectively deliver the pharmacy benefit package that provides appropriate care and value to its members. For example, one client may prefer to keep a greater percentage of rebates and compensate us for our services through greater administrative fees, while another client may prefer to keep a smaller percentage of rebates in exchange for reduced administrative fees. Furthermore, client pricing varies based on the mix of prescriptions dispensed — specifically the type of drug and the distribution method by which the drug is dispensed.[445]

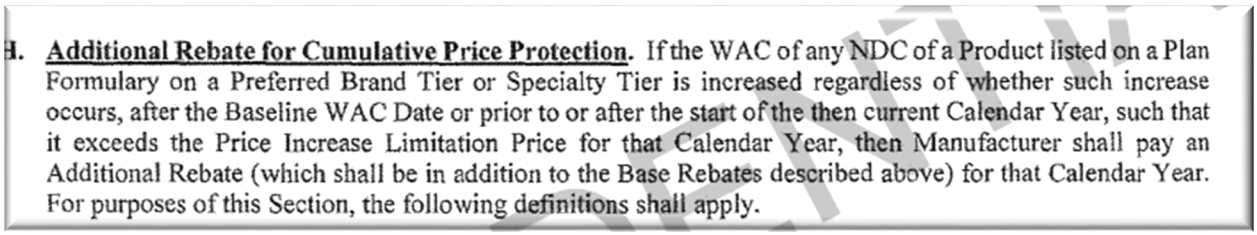
Finally, it is noteworthy that industry observers have suggested that the recent partnership between Express Scripts and Prime Therapeutics may serve as a vehicle to avoid increasing legislative and regulatory scrutiny related to administrative fees by channeling such fees through a Swiss-based group purchasing organization (GPO), Ascent Health.[446] While there are several regulatory and legislative efforts underway to prohibit manufacturers from paying administrative fees to PBMs, there is no such effort to change the GPO safe harbor rules.[447] New arrangements used by PBMs to collect fees should be an area of continued investigative interest for Congress.

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[443] Cigna-SFC-00017902, at Cigna-SFC-00017903.
[444] Cigna-SFC-00017902, at Cigna-SFC-00017903.
[445] *Express Scripts Response to Staff of the U.S. Securities Exchange Committee*, SEC (June 26, 2017), https://www.sec.gov/Archives/edgar/data/0001532063/000119312517213574/filename1.htm
[446] *See* Adam, Fein, *Express Scripts + Prime Therapeutics: Our Takeaways From This Market Changing Deal*, DRUG CHANNELS (Jan. 7, 2020), https://www.drugchannels.net/2020/01/express-scripts-prime-therapeutics-our.html.
[447] *Id.* It's important to note that GPOs are also compensated via manufacturer-paid administrative fees. *Id.*

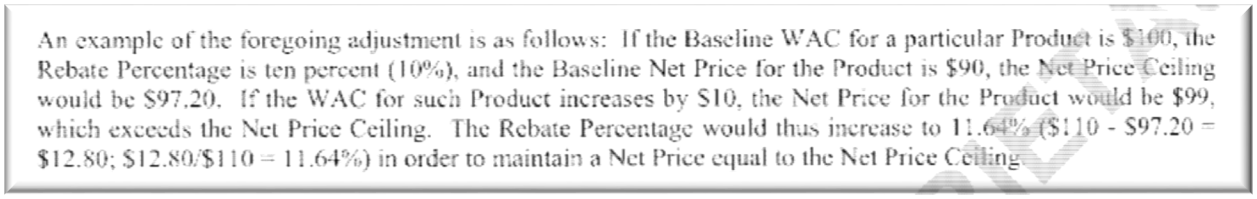
iii. Price Protection Clauses

In addition to rebates and administrative fees, PBMs also negotiate a price protection provision in their contract such that when a drug company increases the list price of its drug beyond a certain agreed upon percentage, the plan receives an additional rebate.[448] The caps in price protection terms vary widely. For example, one contract amendment between OptumRx and Sanofi had "price protection factors" that allowed the manufacturer to implement annual price increases from as little as 0% to as much as 12% depending on the therapy.[449]An example of a price protection clause in a rebate agreement between CVS Caremark and Sanofi is shown below:[450]



H. **Additional Rebate for Cumulative Price Protection.** If the WAC of any NDC of a Product listed on a Plan Formulary on a Preferred Brand Tier or Specialty Tier is increased regardless of whether such increase occurs, after the Baseline WAC Date or prior to or after the start of the then current Calendar Year, such that it exceeds the Price Increase Limitation Price for that Calendar Year, then Manufacturer shall pay an Additional Rebate (which shall be in addition to the Base Rebates described above) for that Calendar Year. For purposes of this Section, the following definitions shall apply.

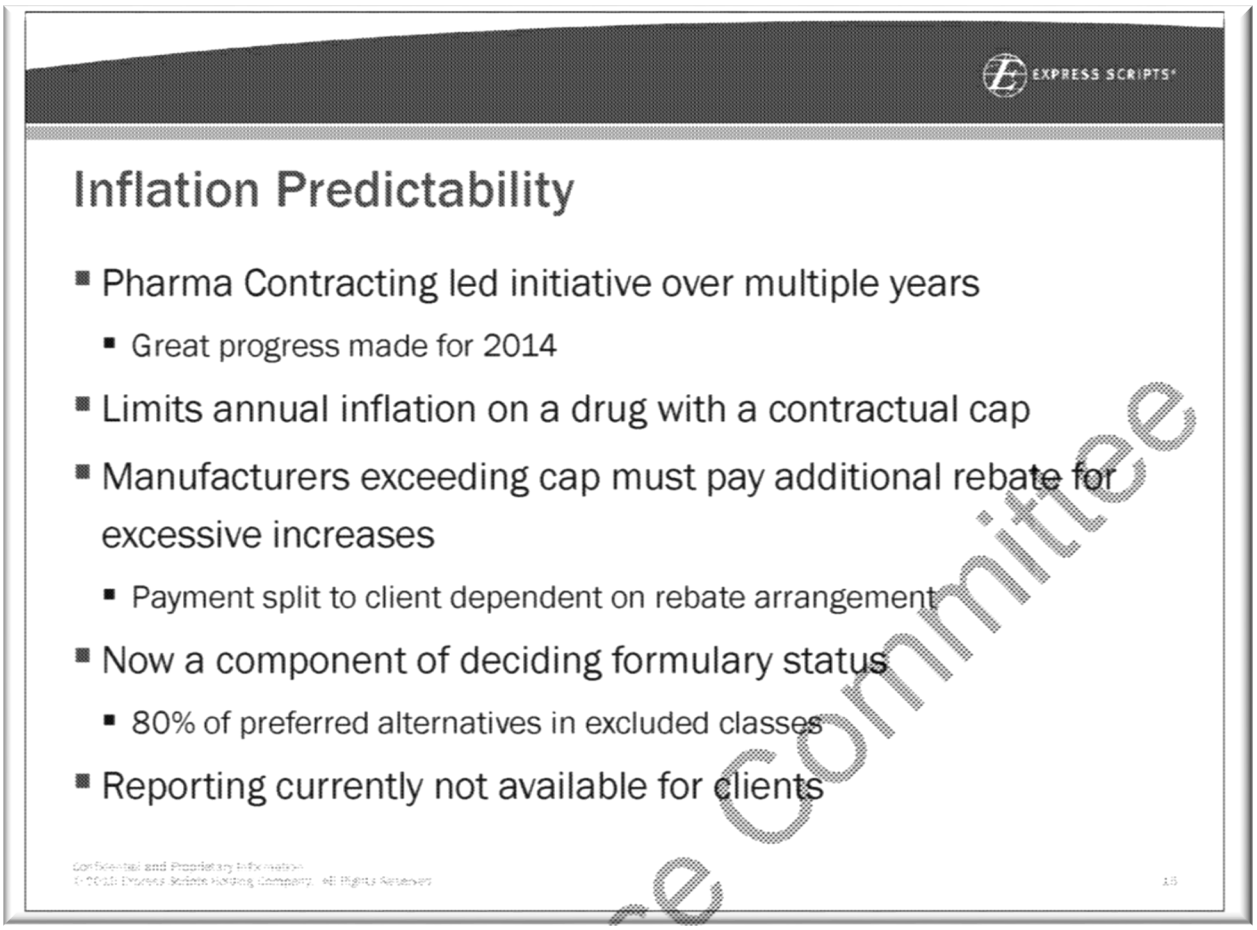
Another CVS contract with Novo Nordisk shows how price protection clauses can also be tied to a drug's net price (i.e. a manufacturer's revenue after rebates and discounts), as it was with Levemir, Novolog, and Novolog Mix 70/30:[451]



An example of the foregoing adjustment is as follows: If the Baseline WAC for a particular Product is $100, the Rebate Percentage is ten percent (10%), and the Baseline Net Price for the Product is $90, the Net Price Ceiling would be $97.20. If the WAC for such Product increases by $10, the Net Price for the Product would be $99, which exceeds the Net Price Ceiling. The Rebate Percentage would thus increase to 11.64% ($110 - $97.20 = $12.80; $12.80/$110 = 11.64%) in order to maintain a Net Price equal to the Net Price Ceiling.

Such payments are intended to limit annual inflation of a drug's price, and require manufacturers that exceed the cap to pay an additional rebate. An internal presentation from Express Scripts suggests that a portion of these payments may be retained by the PBM.[452] Shown below.[453]

[448] *See* CVSCM_SFC_0004331, at CVSCM_SFC_0004356.
[449] ORX_Sen_Fin_0009384. Please note that the Committee has redacted non-insulin therapies from this document.
[450] CVSCM_SFC_0004331, at CVSCM_SFC_0004356.
[451] NNI-FINANCE-000039, at NNI-FINANCE-000052-53
[452] Cigna-SFC-00018522, at Cigna-SFC-00018536.
[453] Cigna-SFC-00018522, at Cigna-SFC-00018536.



Although price protection clauses are intended to deter manufacturers from increasing prices too quickly, the investigation identified examples of manufacturers who found ways around them. For example, Novo Nordisk avoided price protection payments and rebate payments by timing drug price increases to occur just before or just after price protection penalties would have been triggered. In so doing, the company dodged millions of dollars in penalties for exceeding the contractual ceiling prices.

For example, in October 2014, company employees requested approval to increase the price of NovoLog and Novolin, noting that the "price increase is timed for mid-quarter to minimize price protection impact," and estimated that the moves would result in a $6 million upside for the brands that year.[454] A later email showed a similar strategy, as Novo Nordisk avoided $25 million in rebates and price protection penalties for Levemir by simply following Sanofi's price increase. Sanofi had taken a price increase of 11.9% on Lantus vials and pens the night before,[455] and Novo Nordisk employees saw an opportunity to avoid price protection by quickly following suit:

> Please note that many of our contracts look at the WAC price on the 45th day of the quarter (and monthly paid contracts at the 15th day), so … we will determine if it

[454] NNI-FINANCE-001715.
[455] NNI-FINANCE-001719-20.

makes better financial sense (due to rebate payments and price protection) to align the increase to the same date as NovoLog® (11/18).[456]

Following the analysis, the employee recommended that the company wait in order to capture a multi-million-dollar financial benefit:[457]

> After analyzing the additional cost of rebates and price protection, based on specific contracting terms, it was determined that it makes better financial sense **(~+$10M benefit)** to wait until after the 45th day of the quarter (11/18 is the first feasible date for the increase) vs increasing price today (effective 11/8). **Therefore, we are asking for your approval to follow their 11.9%** on November 18th** (first feasible increase date post the 15th). Approving this request will have a **benefit to 2014 of ~$25M.**

Novo Nordisk capitalized on this opportunity, making it an integral part of their pricing strategy. The company even built these avoided rebates and penalties into their revenue forecasts. In an email from May 2015, the Pricing Committee was asked to approve a planned price increase to specifically avoid price protection clauses for NovoLog and NovoLin:[458]

> We have secured Brand alignment on the timing and magnitude of the proposed increases. Please note that the price increase is timed for just after mid-quarter to minimize rebate and price protection impact. *(Many contracts base the rebate calculation on the WAC in effect at the 45th day of the quarter so taking on May 19 minimizes rebate impact in 2Q).*

Novo Nordisk repeatedly targeted CVS Caremark's Part D contract provisions to avoid paying price protection penalties. By increasing drug prices days before the price protection clauses took effect, Novo Nordisk avoided paying CVS Caremark millions of dollars in payments. In May 2014, the Pricing Committee was asked to approve the prices of NovoLog by the 27th of the month or "sooner to minimize the impact of price protection."[459] By increasing the list price by this date, Novo Nordisk estimated it would avoid paying roughly $12 million in price protection rebates.[460] Indeed, the contract between the two companies shows that the "Baseline Net Price," which the price protection caps are based on, is defined as the "Net Price in effect as of June 1st of the prior Contract Year and Baseline WAC means WAC in effect as of June 1st of the prior Contract Year."[461] This contract further defines the price protection provisions:

> The Net Price for each Product's Formulary Status shall be reviewed monthly by comparing the Net Price of the applicable calendar month to the Baseline Net Price. If the Product's Net Price has been increased by more than eight percent (8.00%) over Baseline Net Price ("Net Price Ceiling"), the Rebate percentage(s) for such product will be increased for such calendar month such that the Net Price will equal the Net Price Ceiling. The increased Rebate percentage(s) shall remain in effect during the remainder of the current Contract Year and shall return to their original percentage at the beginning of the next Contract Year.[462]

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[456] NNI-FINANCE-001719-18
[457] NNI-FINANCE-001719.
[458] NNI-FINANCE-001766.
[459] NNI-FINANCE-001709.
[460] NNI-FINANCE-001709.
[461] NNI-FINANCE-000082.
[462] NNI-FINANCE-000082, at NNI-FINANCE-000086.

The Pricing Committee approved the request and increased NovoLog and Novolin on May 28, 2014, three days before the 2015 CVS Caremark Part D pricing protection went into effect.[463] Two days later, Novo Nordisk took another price increase aimed at CVS Caremark Part D's 2015 price protection loophole, this time with its basal insulin, Levemir. Contract Operations Vice President Farruq Jafery informed the Pricing Committee that Sanofi had increased the price of Lantus—16.1% for the vial and 9.9% for the pen[464]—and that Novo Nordisk should follow their actions. He recommended Novo Nordisk follow Sanofi's lead and swiftly institute an identical pricing change (as discussed in further detail above) to avoid $13 million in incremental price protection rebates.[465]

However, by the time the 2016 contract bid cycle started in August 2015, CVS Caremark had caught on to Novo Nordisk's strategy and began to push back against Novo Nordisk's practices related to price protection:[466]

Background on CVS:

We know CVS has stated their disappointment with our price increase strategy (ie: taking just after the 45th day) and how it essentially results in a lower price protection, admin fee and rebate payment for that quarter/time after our increase. I don't think there's any disputing how we operationalize our price and that we do it this way to create the most value to NNI, but it has been costing CVS a good amount of money.

When CVS was here last week they reiterated their concern and Farruq/Brenda have committed to working on solution (WAC as of dispensed date), to be operationalized in 2016 with a resolution from a financial perspective to be effective 1/1/16 (ie: if implemented in 7/1/16 they will receive adjustment for the 1st half of 2016). CVS is requesting this to go back to 7/1/15.

To appease CVS, Novo Nordisk considered delaying a price increase on Levemir, but as the increase "capitalize[d] on all contracts" the company questioned the financial implications of such a move:

> We're scheduled to take a Levemir price increase next week (8/18) and Karen is about to finalize the formal email to [the] PC. The 18th is the first day after the 45th day we could operationalize the increase. We're doing it to capitalize on all contracts (rebate and PP payments). Specifically with CVS Maria is estimating that it will result in about $3.8M favorably to NNI (on the flipside cost CVS $3.8M then if they had WAC as of dispensed). Our price increase on **Levemir roughly garners us $2.5M per week and it costs CVS about $634k, so financially it makes sense to take the increase by about $2M per week. Question: Is there any appetite to delay the increase by a week or two so it's not apparent to CVS or are we okay recommending to PC as planned?**[467]

Despite their concerns with CVS, Novo Nordisk would approve the increase just after the 45th day of the quarter, even as the pricing committee agreed that CVS would "be upset regardless."[468] However, Novo Nordisk was not the only insulin manufacturer that repeatedly

[463] NNI-FINANCE-001965.
[464] NNI-FINANCE-001711, at NNI-FINANCE-001712.
[465] NNI-FINANCE-001711, at NNI-FINANCE-001712.
[466] NNI-FINANCE-001792, at NNI-FINANCE-001793.
[467] NNI-FINANCE-001792, at NNI-FINANCE-001793-94. Emphasis added.
[468] NNI-FINANCE-001792.

sought to avoid price protections. Eli Lilly internal communications also cited the elimination of price protection penalties as a reason for price increase timing.[469] These examples suggest that payers and PBMs accept list price increases as long as the increases do not affect their ability to collect higher rebates and discounts from manufacturers. However, this approach can lead to higher prices for the Federal government and individual consumer.

V. Conclusion

Diabetes is one of the most pervasive and deadly diseases in the United States. Millions of Americans live with this disease, and millions more are expected to be diagnosed this year alone. This disease also disproportionately impacts minority communities, rural communities, and those who are 65 and older. As insulin's list price has grown over time, so too have costs to consumers and the Federal government. As a result of these price increases, some diabetic patients have reportedly resorted to rationing their insulin medication, putting their lives at risk. Rising drug costs have also further strained the U.S. health care system.

The Committee conducted this investigation to better understand how the list price of insulin, a drug that's been available to patients for almost a century, has doubled (and, in some cases tripled) over the past decade. In pursuit of the facts, the Committee requested and reviewed over 100,000 pages of internal documents, memoranda, and rebate agreements produced by the three largest insulin manufacturers (Sanofi, Novo Nordisk, and Eli Lilly) and the three largest PBMs (CVS Caremark, Express Scripts, and OptumRx) in the United States. While the Committee feels that it received sufficient information to support the findings in this report, it notes that Novo Nordisk, CVS Caremark, Express Scripts, and OptumRx failed to fully respond to the Committee's document requests.

The investigation underscores how the opaque business practices of pharmaceutical manufacturers and PBMs have huge implications for patients, payers, and the Federal government, with respect to insulin and therapies for other diseases.

Insulin manufacturers compete fiercely, using rebates as bargaining chips to receive preferred formulary placement for their products and to block competition. The companies undertake these bidding wars to maximize revenue and capture—or maintain—market share. Furthermore, in some cases the investigation found that while insulin manufacturers closely monitor their competitors' pricing actions when determining their own list prices over time, there were multiple instances of companies increasing prices in lockstep with competitors. In part, insulin manufacturers make those decisions due to countervailing pressures in their relationships with PBMs. Higher list price increases the dollar value of rebates, discounts, and other fees that a manufacturer can offer to a PBM and health plans, which are based on a percentage of the list price. Internal documents showed that insulin manufacturers were sensitive not only to their own bottom lines, but the bottom line of PBMs and of health plans that set formularies, without which a manufacturer's product would likely lose significant market share.

PBMs appeared to be complicit in this behavior. There appeared to be little, if any, attempt by PBMs to discourage manufacturers from increasing the list price of their products. Instead, the Committee found that PBMs used their size and aggressive negotiating tactics, such as the threat of excluding drugs from formularies, to extract more generous rebates, discounts,

[469] LLY-SFCOM-UR-00003202, at LLY-SFCOM-UR-00003204-05.

and fees from insulin manufacturers. To be clear, PBMs have an incentive for manufacturers to keep list prices high, since the rebates, discounts, and fees PBMs negotiate are based on a percentage of a drug's list price—and PBMs retain at least a portion of what they negotiate. In fact, the investigation found instances in which insulin manufacturers were dissuaded from setting lower list prices for their products, which would have likely lowered out-of-pocket costs for patients, due to concerns that PBMs and health plans would react negatively.

Lastly, it is clear that the average net prices for insulin—that is, the revenue manufacturers receive after paying rebates—have declined in recent years due to the growth of rebate sizes. However, manufacturers are still retaining higher average net prices, and thus, generating more revenue per unit of insulin, than they were during the first decade of the 21st century. Large rebates have shrunk the percentage of gross revenue that manufacturers retain, but the exponential growth of WAC prices over the last 20 years has benefited insulin manufacturers by slowing margin declines, and PBMs by increasing revenue derived from rebates and fees.

In recent years, Senator Grassley and Senator Wyden have worked together to bring unparalleled transparency to pharmaceutical pricing and marketing. While this investigation was focused on insulin, it brings Congress and the public one step closer to better understanding the complex market dynamics of the U.S. drug pricing system. Undoubtedly, there is more work to be done. The Committee will continue to shed light on pharmaceutical pricing practices that cause financial harm and worse health outcomes for the American people.

Appendix

1. Documents Produced by Eli Lilly
2. Documents Produced by Sanofi
3. Documents Produced by Novo Nordisk
4. Documents Produced by CVS Health Corp. (CVS Caremark)
5. Documents Produced by OptumRx
6. Documents Produced by Cigna Corporation (Express Scripts)

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
NORTHEASTERN DISVISION

HAMBLEN COUNTY, TENNESSEE,

Plaintiff,

v.

ELI LILLY AND COMPANY; NOVO NORDISK INC.; SANOFI-AVENTIS U.S. LLC; CVS HEALTH CORPORATION; CVS PHARMACY, INC.; CAREMARKPCS HEALTH, LLC; CAREMARK, LLC; CAREMARK RX, LLC; EVERNORTH HEALTH, INC. (F/K/A EXPRESS SCRIPTS HOLDING COMPANY); EXPRESS SCRIPTS, INC.; EXPRESS SCRIPTS ADMINISTRATORS, LLC; MEDCO HEALTH SOLUTIONS, INC.; ESI MAIL PHARMACY SERVICES, INC.; EXPRESS SCRIPTS PHARMACY, INC.; UNITEDHEALTH GROUP, INC.; OPTUM, INC.; OPTUMRX INC.; OPTUMRX HOLDINGS I LLC; OPTUMINSIGHT, INC.,

Defendants.

Civil Action No. _____

COMPLAINT

JURY TRIAL DEMANDED

Complaint and Demand for Jury Trial

TABLE OF CONTENTS

INTRODUCTION 1

PARTIES 10

A. Plaintiff 10

B. Manufacturer Defendants 11

C. PBM Defendants 15

JURISDICTION AND VENUE 38

ADDITIONAL FACTUAL ALLEGATIONS 39

A. Diabetes and Insulin Therapy 39

- The Diabetes Epidemic 39
- Insulin: A Century-Old Drug 40
- The Current Insulin Landscape 42
- Insulin Adjuncts: Type 2 Medications 42

B. The Dramatic Rise in the Price of Diabetes Medications in the U.S. 45

- The Defendant-Manufacturers Have Increased Prices in Lockstep 48

C. Pharmaceutical Payment and Supply Chain 52

D. The PBMs' Role in the Pharmaceutical Payment Chain 53

- The Rise of the PBMs in the Pharmaceutical Supply Chain 55
- The Insular Nature of the Pharmaceutical Industry 57

E. The Insulin Pricing Scheme 61

F. Defendants Play Down the Insulin Pricing Scheme and Its Harms 65

G. Defendant Profit from the Insulin Pricing Scheme 72

- The PBMs Pocket a Substantial Share of Manufacturer Payments 73
- The Insulin Pricing Scheme Allows the PBMs to Profit Off Pharmacies 80

- The Insulin Pricing Scheme Increases PBM Mail-Order Profits 84

H. Plaintiff Purchases the At-Issue Drugs Directly from Defendants 85

I. Defendants Deceived Plaintiff 87

J. The Insulin Pricing Scheme Has Damaged Plaintiff 100

K. Defendants' Recent Efforts in Response to Rising Insulin Prices 102

CLAIMS FOR RELIEF 105

FIRST CLAIM FOR RELIEF (Violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962(c)) (against Defendants Eli Lilly, Novo Nordisk, Sanofi, CVS Caremark, and Express Scripts) 105

A. Defendants Are Culpable "Persons" Under RICO. 105

B. The Manufacturer-PBM RICO Enterprises 106

C. The Enterprises Misrepresent and Fail to Disclose Material Facts in Furtherance of the Insulin Pricing Scheme. 110

D. Defendants' Use of the U.S. Mails and Interstate Wire Facilities 112

E. Conduct of the Manufacturer-PBM Enterprises' Affairs 114

F. Defendants' Pattern of Racketeering Activity 115

G. The RICO Defendants' Motive 117

H. The Manufacturer-PBM Enterprises' Insulin Pricing Scheme Injured Plaintiff.....117

SECOND CLAIM FOR RELIEF (Violations of RICO, 18 U.S.C. § 1962(d) By Conspiring to Violate 18 U.S.C. § 1962(c))(against all Defendants).....119

THIRD CLAIM FOR RELIEF (Unlawful Restraint of Trade, Tenn. Code Ann. §§ 47-25-101, *et seq*) (against all Defendants) 121

FOURTH CLAIM FOR RELIEF (Violation of Tennessee Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101, *et seq*) (against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark) 122

FIFTH CLAIM FOR RELIEF (Breach of Contract) (against Defendants Express Scripts, and CVS Caremark) 125

.
SIXTH CLAIM FOR RELIEF (Unjust Enrichment) (against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark) 126

MOTION FOR INJUNCTION 128

PRAYER FOR RELIEF 128

JURY DEMAND 130

Plaintiff, Hamblen County, Tennessee ("Plaintiff," the "County" or "Hamblen County"), by and through undersigned counsel, brings this lawsuit against the above-named Defendants and alleges as follows:

INTRODUCTION

1. The cost of diabetes medications has risen more than tenfold over the past 20 years. Over the same period of time, the average cost of consumer goods and services has risen just 1.75-fold. The skyrocketing prices of diabetes medications are not tethered the rising cost of goods, production costs, investment in research and development, or competitive market forces. Instead, Defendants engineered these price increases via an opaque, conspiratorial kickback scheme (referred to herein as the "Insulin Pricing Scheme"), which has exponentially increased their profits at the expense of payors like Plaintiff and its plan members. The Insulin Pricing Scheme is a multibillion-dollar industry.

2. Diabetes is widespread. The total estimated cost of diabetes in the U.S. in 2017, according to the American Diabetes Association, was $327 billion. One in four healthcare dollars is spent caring for people with diabetes.

3. As of 2020, more than 13% of adults in Tennessee have been diagnosed with diabetes.[1] An additional 9.9% of the Tennessee adult population are prediabetic, with blood glucose levels higher than normal but not yet high enough to be diagnosed as diabetic.[2] In Hamblen, approximately 11.4%, of adult residents are living with diabetes.[3] In Tennessee alone,

[1] Tennessee Diabetes Action Legislative Report, Feb. 2021, https://www.capitol.tn.gov/Archives/senate/112GA/committees/health-welfare/2021/Diabetes%20Legislative%20Report_FinalDraft.%2001-29-2021%208%2045%20pm.pdf.

[2] *Id.*

[3] United States Diabetes Surveillance System, https://gis.cdc.gov/grasp/diabetes/diabetesatlas-analysis.html# (last visited January 26, 2024).

diabetes costs an estimated $5.2 billion per year in direct medical costs attributed to diabetes.[4] An additional $2.1 billion is spent on indirect costs from attributed to diabetes.[5]

4. Diabetics in Tennessee generally rely on daily insulin treatments, oral medications, or a combination of both to treat and control diabetes. Defendants Eli Lilly, Novo Nordisk, and Sanofi (collectively, the "Manufacturer Defendants" or the "Manufacturers") manufacture the vast majority of insulins and other diabetic medications available in the United States. In 2020, as in the years preceding, the Manufacturer Defendants controlled 92% by volume, and 96% by revenue, of the global market for diabetes drugs.

5. Defendants CVS Caremark, Express Scripts, and OptumRx (collectively, the "PBM Defendants" or the "PBMs") are pharmacy benefit managers that work with the Manufacturer Defendants to dictate the availability and price of the at-issue drugs for most of the U.S. market.[6] The PBM Defendants are, at once, (1) the three largest pharmacy benefit managers in the United States (controlling more than 80% of the PBM market); (2) the largest pharmacies in the United States (comprising three of the top five dispensing pharmacies in the U.S.); and (3) housed within the same corporate families as three of the largest insurance companies in the United States—Aetna (CVS Health), Cigna (Express Scripts), and UnitedHealthcare (OptumRx).

6. These corporate conglomerate Defendants sit at 4th (CVS Health), 5th (UnitedHealth Group), and 12th (Cigna) on the Fortune 500 list as of year-end 2022.

[4] Tennessee Diabetes Profile, https://www.cdc.gov/diabetes/programs/stateandlocal/state-diabetes-profiles/tennessee.html (last visited January 26, 2024).

[5] *Id.*

[6] In the context of this Complaint, the "at-issue drugs" or "at-issue medications" are: Apidra, Basaglar, Humalog, Humulin N, Humulin R, Humulin R 500, Humulin 70/30, Lantus, Levemir, Novolin N, Novolin R, Novolin 70/30, Novolog, Ozempic, Soliqua, Toujeo, Tresiba, Trulicity, and Victoza.

Figure 1: Manufacturers, PBMs & PBM-Affiliated Insurers

Manufacturers	PBMs	PBM-Affiliated Insurer
Eli Lilly		
Novo Nordisk		
Sanofi		
	CVS	Aetna
	Express Scripts	Cigna
	Optum	UnitedHealthcare

7. For transactions in which the PBM Defendants control the insurer, the PBM, and the pharmacy (e.g., Aetna–Caremark–CVS Pharmacy), these middlemen capture as much as half of the money spent on each insulin prescription (up from 25% in 2014), even though they contribute nothing to the development, manufacture, innovation, or production of the drugs.

8. As part of this work, the PBM Defendants establish national formulary offerings (i.e., approved drug lists), which, among other things, set the baseline for which diabetes medications are covered and which are not covered by nearly every payor in the United States, including in Tennessee and, more specifically, Hamblen County.

9. The Manufacturers and PBMs understand that the PBMs' national formularies drive drug utilization. The more accessible a drug is on the PBMs' national formularies, the more that drug will be purchased throughout the United States. Conversely, exclusion of a drug from one or more of the PBMs' formularies can render the drug virtually inaccessible for millions of covered persons.

10. Given the PBMs' market power and the crucial role their standard formularies play in the pharmaceutical pricing chain, both Defendant groups understand that the PBM Defendants wield enormous control over drug prices and purchasing behavior.

11. The unfair and deceptive conspiracy at the root of this complaint—the Insulin Pricing Scheme—was borne from this mutual understanding.

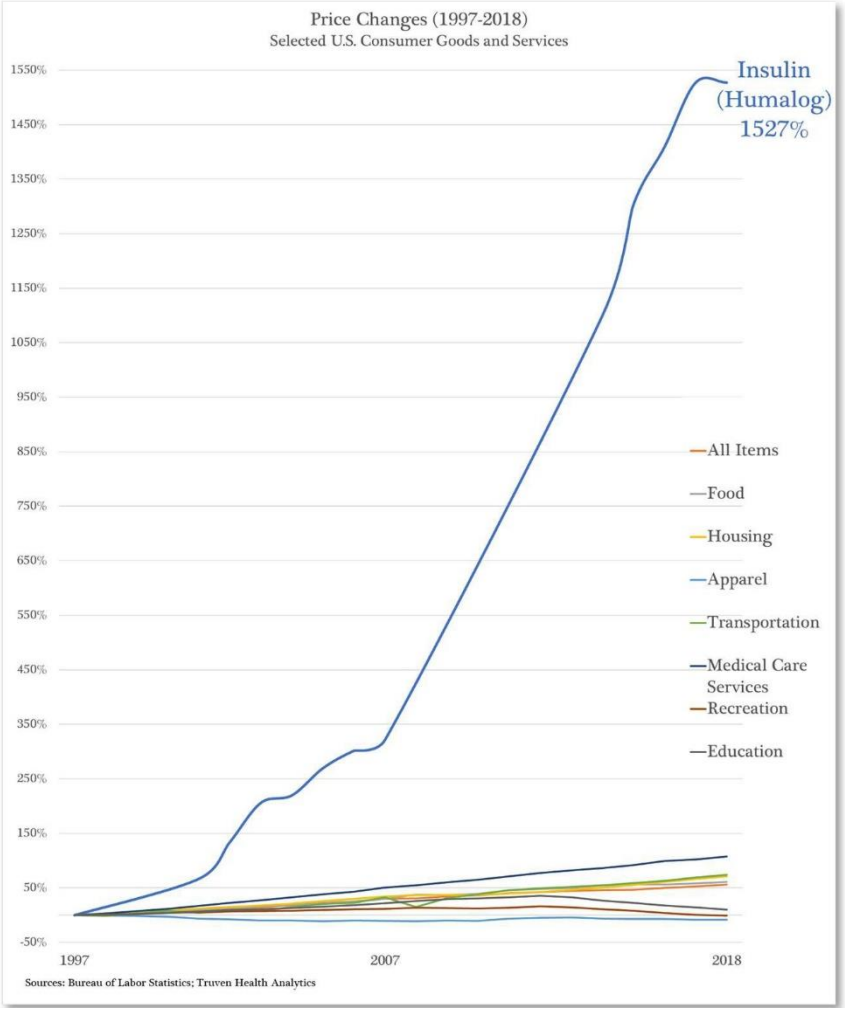
12. The Manufacturers set the initial list (wholesale) price for their respective insulin medications. Over the last 20 years, list prices have sharply increased in lockstep, even though the cost to produce these drugs decreased during that period.

13. Insulins, which today cost Manufacturers as little as $2 to produce, and which were originally priced at $20 the 1990s, now range in price from $300 to $700.

14. The Manufacturer Defendants have in tandem increased the prices of their insulins up to 1,000%, taking the same increase down to the decimal point within a few days of one another and, according to a U.S. Senate Finance Committee investigation, "sometimes mirroring" one another in "days or even hours."[7] Figure 2 shows the rate at which Defendant Eli Lilly raised the list price of its analog insulin, Humalog, compared to the rate of inflation for other consumer goods and services during the period from 1997- 2018.

[7] Charles E. Grassley & Ron Wyden, *Staff Report on Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug, Sen. Fin. Comm.*, at 6, 54, 55 (Jan. 2021), https://www.finance.senate.gov/imo/media/doc/GrassleyWyden%20Insulin%20Report%20 FINAL%201). Pdf (hereinafter "Grassley & Wyden" or "January 2021 Senate Insulin Report").

Figure 2: Price Increase of Insulin vs. Selected Consumer Goods, 1997-2018



15. Today's exorbitant prices do not accord with insulin's origins. The discoverers sold the original patent for $1 to ensure that the medication would remain affordable. But today, insulin is the poster child for skyrocketing pharmaceutical prices.

16. Nothing about these medications has changed over the past 100 years; today's $350 insulin is the same product Defendants once sold for $20.

How the Insulin Pricing Scheme Works

17. In the simplest terms, there are three important participants in the insulin medication chain.

a. **Hamblen County.** During the relevant period, Plaintiff Hamblen County operated a health plan for its employees and their dependents. The plan includes pharmacy benefits, meaning Plaintiff purchased the at-issue drugs for its beneficiaries. Operators of self-funded plans, like Plaintiff, may be referred to as payors or plan sponsors (or PBM "clients").

b. **PBMs.** Payors routinely engage pharmacy benefit managers to manage their prescription benefits, which includes negotiating prices with drug manufacturers and (ostensibly) helping payors manage drug spending. Each pharmacy benefit manager maintains a formulary—a list of covered medications. A pharmacy benefit manager's power to include or exclude a drug from its formulary theoretically should incentivize manufacturers to lower their list price. Pharmacy benefit managers also contract with pharmacies to reimburse them for medications purchased by the plan's beneficiaries. Pharmacy benefit managers are compensated by retaining a portion of what should—again in theory—be shared savings on the cost of medications.

c. **Manufacturers.** Manufacturers produce the at-issue insulin medications.[8] Each sets a list price for each of its products. The terms "list price" often is used interchangeably with the Wholesale Acquisition Cost (WAC) (defined by federal law as the undiscounted list price for a drug or biological to wholesalers or direct purchasers). The manufacturers self-report

[8] There are three types of insulin medications. First are *biologics*, which are manufactured insulins derived from living organisms. Second are *biosimilars*, which are "highly similar" copies of biologics. They are similar in concept to "generic" drugs; but in seeking approval they use biologics (rather than drugs) as comparators. Third, the confusingly-named *authorized generics* are not true generics—they are an approved brand-name drug marketed without the brand name on the label. FDA approved the original insulins as drug products rather than biologics, so although there was a regulatory pathway to introduce biosimilars generally (copies of biologics), companies could not introduce insulin biosimilars because their comparators were "drugs" rather than "biologics." In 2020, FDA moved insulin to the biologic regulatory pathway, thus opening the door to approval of biosimilars through an abbreviated approval process.

list prices to publishing compendiums such as First DataBank, Medi-Span, or Redbook, who then publish those prices.[9]

18. Given the PBMs' purchasing power and their control over formularies that govern the availability of drugs, their involvement should theoretically drive down list prices. Instead, to gain access to the PBMs' formularies, the Manufacturers artificially inflate their list prices and then pay a significant, but undisclosed, portion of the inflated price back to the PBMs (the "Manufacturer Payments").[10] The Manufacturer Payments bear a variety of dubious labels—rebates, discounts, credits, inflation/price protection fees, administrative fees, etc. By whatever name, the inflated list prices and resulting Manufacturer Payments are a quid pro quo for inclusion and favorable placement on the PBMs' formularies.[11]

19. Contracts between PBM Defendants and payors like Plaintiff tie the definition of "rebates" to patient drug utilization. But the contracts between PBMs and Manufacturers define "rebates" and other Manufacturer Payments differently—e.g., calling rebates for formulary placement "administrative fees." Defendants thus profit from the "rebates" and other Manufacturer Payments, and the payments are beyond a payor's contractual audit right to verify the accuracy of "rebate" payments they receive.

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[9] The related term Average Wholesale Price (AWP) is the published price for a drug sold by wholesalers to retailers.

[10] In this Complaint, "Manufacturer Payments" is defined as all payments or financial benefits of any kind conferred by the Manufacturer Defendants to PBM Defendants (or a subsidiary, affiliated entity, or group purchasing organization or rebate aggregator acting on a PBM's behalf), either directly via contract or indirectly via Manufacturer-controlled intermediaries. Manufacturer Payments includes rebates, administrative fees, inflation fees, pharmacy supplemental discounts, volume discounts, price or margin guarantees, and any other form of consideration exchanged.

[11] Favorable or preferred placement may, for example, involve placing a branded product in a lower cost-sharing tier or relaxing utilization controls (such as prior authorization requirements or quantity limits). Favorable placement of a relatively more expensive drug encourages use of that drug and leads to higher out-of-pocket costs for payors and copayors.

20. The PBMs' staggering revenues vastly exceed the fair market value of the services they provide and, specifically, the amount of Manufacturer Payments the PBMs receive in connection with the at-issue drugs vastly exceeds the fair market value of the services they provide with respect to those drugs.

21. The Manufacturers' list prices are not the result of free-market competition for payors' business. The Manufacturers' list prices are so untethered from the net prices that the Manufacturers ultimately realize that the Manufacturers know the list price constitutes a false price. It does not reflect the Manufacturers' actual costs to produce the at-issue drugs or the fair market value of the drugs.[12]

22. The PBMs grant formulary status based upon the highest inflated price—a price that the PBMs know is false—and based upon which diabetes medications will generate the largest profits for themselves.

23. The Insulin Pricing Scheme creates a "best of both worlds" scenario for Defendants. The Manufacturer Defendants buy formulary access and increase their revenues while the PBM Defendants receive significant secret Manufacturer Payments.

24. The PBM Defendants profit off the Insulin Pricing Scheme in numerous ways, including by: (1) retaining a significant, but undisclosed, share of the Manufacturer Payments, either directly or through rebate aggregators, (2) using the price produced by the Insulin Pricing Scheme to generate unwarranted profits from pharmacies, and (3) relying on those same artificial

[12] "Net price" refers to the price the manufacturer ultimately realizes, i.e., the list price less rebates, discounts, etc. (net sales divided by volume). At times, Defendants' representatives use "net price" to refer to the amount payors or plan members pay for medications. In this Complaint, "net price" refers to the former—the amount that the Defendant Manufacturers realize for the at-issue drugs, which is roughly the List Price less Manufacturer Payments.

list prices to drive up the PBMs' margins and pharmacy related fees, including those relating to their mail-order pharmacies.

25. As detailed below, although the PBM Defendants represent both publicly and directly to their client payors that they use their market power to drive down prices for diabetes medications, these representations are false and deceptive. Instead, the PBMs intentionally incentivize the Manufacturers to inflate list prices, and the PBMs' "negotiations" intentionally drive up the price of the at-issue drugs and are directly responsible for the skyrocketing price of diabetes medications, which confers unearned benefits upon the PBMs and Manufacturers alike.

26. Because the purchase price of every at-issue diabetes medication flows from the false list price generated by Defendants' unfair and deceptive scheme, every payor in the United States that purchases these life-sustaining drugs, including Plaintiff, has been directly harmed by the Insulin Pricing Scheme.

27. Even if temporary reductions in Plaintiff's costs for the at-issue drugs occurred from time to time, those costs remained higher than the prices that would have resulted from a transparent exchange in an open and competitive market.

28. As a payor for and purchaser of the at-issue drugs, and, as a direct result of the Insulin Pricing Scheme, Hamblen County has spent exorbitant amounts of capital on the at-issue diabetes medications.

29. A substantial portion of this exorbitant amount is attributable to Defendants' artificially inflated prices that did not arise from transparent or competitive market forces; rather, these inflated costs can be attributed to undisclosed dealings between the Manufacturer Defendants and the PBM Defendants as further described herein.

30. This action alleges that Defendants violated the Racketeer Influenced and Corrupt Organizations Act, Tennessee Consumer Protection Act, and Tennessee common law by engaging in the Insulin Pricing Scheme. The Insulin Pricing Scheme directly and foreseeably caused and continues to cause harm to Plaintiff.

31. This action seeks injunctive relief, restitution, disgorgement, actual damages, treble damages, punitive damages, and attorneys' fees and costs to address and abate the harm caused by the Insulin Pricing Scheme.

32. The relevant period for damages alleged in this Complaint is from 2003 through the present.

PARTIES

A. Plaintiff

33. Plaintiff Hamblen County is a body corporate and politic under the laws of the State of Tennessee.

34. Plaintiff, as a government entity, provides vital services to its population of over 64,000 residents including public safety, emergency management, and health services.

35. Any increase in spending has a detrimental effect on Plaintiff's overall budget and, in turn, negatively impacts its ability to provide necessary services to the community.

36. The Insulin Pricing Scheme has had such an effect.

37. Additionally, as a government employer, Plaintiff provides health benefits to its employees, retirees, and their dependents ("Beneficiaries"). These benefits include paying for Beneficiaries' pharmaceutical drugs, including the at-issue diabetes medications. Plaintiff also purchases the at-issue diabetes medications for use in county-run facilities.

38. Plaintiff maintains a self-insured health plan for its Beneficiaries.

39. Exclusive of the costs associated with providing diabetes medications at county-run facilities, such as correctional facilities, Plaintiff spends thousands of dollars per year on the costs of providing diabetes medications for its health-plan members. Accordingly, during the relevant period, and to the detriment of its Beneficiaries and taxpayers, Plaintiff has paid millions of dollars more for insulin than it otherwise would have paid absent Defendants' conduct.

40. Plaintiff seeks to recover for the losses it has suffered due to Defendants' illegal Insulin Pricing Scheme.

B. Manufacturer Defendants

41. **Defendant Eli Lilly and Company ("Eli Lilly")** is an Indiana corporation with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

42. Eli Lilly is registered to do business in the State of Tennessee. Eli Lilly may be served through its registered agent: National Registered Agents, Inc., 300 Montvue Road, Knoxville, Tennessee 37919-5546.

43. In Tennessee and nationally, Eli Lilly manufactures, promotes, and distributes several at-issue diabetes medications: Humulin N, Humulin R, Humalog, Trulicity, and Basaglar.

44. Eli Lilly's global revenues in 2019 were $4.13 billion from Trulicity, $2.82 billion from Humalog, $1.29 billion from Humulin and $1.11 billion from Basaglar.

45. Eli Lilly's global revenues in 2018 were $3.2 billion from Trulicity, $2.99 billion from Humalog, $1.33 billion from Humulin and $801 million from Basaglar.

46. Eli Lilly transacts business in Tennessee and in Hamblen County, targeting these markets for its products, including the at-issue diabetes medications.

47. Eli Lilly employs sales representatives throughout Tennessee to promote and sell Humulin N, Humulin R, Humalog, Trulicity, and Basaglar.

48. Eli Lilly also directs advertising and informational materials to Tennessee and Hamblen County physicians and potential users of Eli Lilly's products.

49. At all times relevant hereto, in furtherance of the Insulin Pricing Scheme, Eli Lilly published its prices for the at-issue diabetes medications throughout Tennessee with the express knowledge that payment and reimbursement by Plaintiff would be based on those false list prices.

50. During the relevant time period, Plaintiff purchased Eli Lilly's at-issue drugs at a price based on false list prices generated by the Insulin Pricing Scheme through its employee health plans and for use in county-run facilities.

51. All of the Eli Lilly diabetes medications related to the at-issue transactions were paid for and/or reimbursed in Tennessee based on the specific false and inflated prices Eli Lilly caused to be published in Tennessee in furtherance of the Insulin Pricing Scheme.

52. **Defendant Sanofi-Aventis U.S. LLC ("Sanofi")** is a Delaware limited liability company with its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

53. Sanofi may be served through its registered agent: Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808.

54. Sanofi manufactures, promotes, and distributes pharmaceutical drug both in Tennessee and nationally, including several at-issue diabetes medications: Lantus, Toujeo, Soliqua, and Apidra.

55. Sanofi's global revenues in 2019 were $3.50 billion from Lantus and $1.03 billion from Toujeo, $400 million from Apidra and $144 million from Soliqua.

56. Sanofi's global revenues in 2018 were $3.9 billion from Lantus, $923 million from Toujeo, $389 million from Apidra and $86 million from Soliqua.

57. Sanofi does business in Tennessee and in Hamblen County, targeting these markets for its products, including the at-issue diabetes medications.

58. Sanofi employs sales representatives throughout Tennessee and in this District to promote and sell Lantus, Toujeo, Soliqua, and Apidra.

59. Sanofi also directs advertising and informational materials to Tennessee physicians and potential users of Sanofi's products for the specific purpose of selling the at-issue drugs in Tennessee and Hamblen County and profiting from the Insulin Pricing Scheme.

60. At all times relevant hereto, in furtherance of the Insulin Pricing Scheme, Sanofi published its prices of its at-issue diabetes medications throughout Tennessee for the purpose of payment and reimbursement by payors, including Plaintiff.

61. During the relevant time period, Plaintiff Hamblen County purchased Sanofi's at-issue drugs at prices based on false list prices generated by the Insulin Pricing Scheme through its employee health plans and for use in county-run facilities.

62. All of the Sanofi diabetes medications related to the at-issue transactions were paid for and/or reimbursed in Tennessee and Hamblen County based on the specific false and inflated prices Sanofi caused to be published in Tennessee in furtherance of the Insulin Pricing Scheme.

63. **Defendant Novo Nordisk Inc. ("Novo Nordisk")** is a Delaware corporation with its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

64. Novo Nordisk is registered to do business in the State of Tennessee. Novo Nordisk may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

65. Novo Nordisk manufactures, promotes, and distributes pharmaceutical drugs both in Tennessee and nationally, including at-issue diabetic medications: Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic.

66. Nordisk's global revenues in 2019 were $2.89 billion from Novolog, $973 million from Levemir, $968 million from Tresiba, $2.29 billion from Victoza and $1.17 billion from Ozempic.[13]

67. Novo Nordisk's global revenues in 2018 were $4.19 billion from Novolog, $1.66 billion from Levemir, $1.19 billion from Tresiba, $3.61 billion from Victoza and $185 million from Ozempic.

68. Novo Nordisk transacts business in Tennessee and in Hamblen County, targeting these markets for its products, including the at-issue diabetes medications.

69. Novo Nordisk employs sales representatives throughout Tennessee and Hamblen County to promote and sell Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic.

70. Novo Nordisk also directs advertising and informational materials to Tennessee and Hamblen County physicians and potential users of Novo Nordisk's products.

71. At all times relevant hereto, in furtherance of the Insulin Pricing Scheme, Novo Nordisk published its prices of its at-issue diabetes medications throughout Tennessee for the purpose of payment and reimbursement by Plaintiff.

72. During the relevant time period, Plaintiff purchased Novo Nordisk's at-issue diabetes medications at prices based on false list prices generated by the Insulin Pricing Scheme through its employee health plans and for use in county-run facilities.

[13] Novo Nordisk, Annual Report (Form 20-F) (Dec. 31, 2019).

73. All Novo Nordisk diabetes medications related to the at-issue transactions were paid for and/or reimbursed in Tennessee based on the specific false and inflated prices Novo Nordisk caused to be published in Tennessee in furtherance of the Insulin Pricing Scheme.

74. Collectively, Defendants Eli Lilly, Novo Nordisk, and Sanofi are referred to as the "Manufacturer Defendants" or the "Manufacturers."

C. PBM Defendants

75. **Defendant CVS Health Corporation ("CVS Health")** is a Delaware corporation with its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895. CVS Health transacts business and has locations throughout the United States and Tennessee.

76. CVS Health may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

77. CVS Health—through its executives and employees, including its CEO, Chief Medical Officer, Executive Vice Presidents, Senior Executives in Trade Finance, Senior Vice Presidents, and Chief Communication Officers—is directly involved in creating and implementing the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs involved in the Insulin Pricing Scheme.

78. CVS Health's conduct had a direct effect in Tennessee and damaged Plaintiff Hamblen County as a payor and purchaser.

79. On a regular basis, CVS Health executives and employees communicate with and direct its subsidiaries related to the at-issue PBM services and formulary activities.

80. In each annual report for at least the last decade, CVS Health (or its predecessor) has repeatedly and explicitly stated that CVS Health:

- designs pharmacy benefit plans that minimize the costs to the client while prioritizing the welfare and safety of the clients' members;

- negotiates with pharmaceutical companies to obtain discounted acquisition costs for many of the products on CVS Health's drug lists, and these negotiated discounts enable CVS Health to offer reduced costs to clients; and

- utilizes an independent panel of doctors, pharmacists, and other medical experts, referred to as its Pharmacy and Therapeutics Committee, to select drugs that meet the highest standards of safety and efficacy for inclusion on its drug lists.

81. CVS Health publicly represents that it constructs programs that lower the cost of the at-issue diabetes medications. For example, in 2016, CVS Health announced a new program to "reduce overall spending in diabetes" that is available in all states, including Tennessee, stating:

> *CVS Health* introduced a new program available to help the company's pharmacy benefit management (PBM) clients to improve the health outcomes of their members, *lower pharmacy costs [for diabetes medications]* through aggressive trend management and decrease medical costs . . . [and that] participating clients could save between $3000 to $5000 per year for each member who successfully improves control of their diabetes" (emphasis supplied).[14]

82. In 2017, CVS Health stated that "*CVS Health* pharmacy benefit management (PBM) strategies reduced trend for commercial clients to 1.9 percent per member per year the lowest in five years. Despite manufacturer price increases of near 10 percent, *CVS Health* kept drug price growth at a minimal 0.2 percent."

83. In November 2018, CVS Health acquired Aetna for $69 billion and became the first combination of a major health insurer, PBM, and mail-order and retail pharmacy chain. As a result, CVS Health controls the health plan/insurer, the PBM, and the pharmacies utilized by approximately 40 million Aetna members in the United States, including in Tennessee. CVS Health controls the entire drug pricing chain for these 40 million Americans.

[14] CVS HEALTH, *CVS Health Introduces New "Transform Diabetes Care" Program to Improve Health Outcomes and Lower Overall Health Care Costs* (Dec. 13, 2016), https://cvshealth.com/newsroom/press-releases/cvs-health-introduces-newtransform-diabetes-care-program-improve-health.

84. CVS Health is the immediate or indirect parent of many pharmacy subsidiaries that own and operate hundreds of pharmacies throughout Tennessee that dispensed and received payment for the at-issue diabetes medications throughout the relevant time period.

85. **Defendant CVS Pharmacy, Inc. ("CVS Pharmacy")** is a Rhode Island corporation whose principal place of business is at the same location as CVS Health. CVS Pharmacy is a wholly owned subsidiary of CVS Health.

86. CVS Pharmacy is the immediate or indirect parent of many pharmacy subsidiaries that own and operate hundreds of pharmacies throughout Tennessee and is directly involved in these pharmacies dispensing and payment policies related to the at issue diabetes medications.

87. CVS Pharmacy is also the immediate and direct parent of Defendant Caremark Rx, LLC.

88. CVS Pharmacy is registered to do business in Tennessee and has been since at least 1997.

89. CVS Pharmacy is registered to do business in the State of Tennessee. CVS Pharmacy may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

90. During the relevant time period, CVS Pharmacy provided retail pharmacy services in Tennessee that gave rise to the Insulin Pricing Scheme, which damaged Plaintiff.

91. **Defendant Caremark Rx, LLC** is a Delaware limited liability company and an immediate or indirect parent of many subsidiaries, including pharmacy benefit management and mail-order subsidiaries that engaged in the activities in Tennessee that gave rise to this Complaint.

92. Caremark Rx, LLC is a wholly owned subsidiary of Defendant CVS Pharmacy and its principal place of business is at the same location as CVS Pharmacy and CVS Health.

93. Caremark Rx, LLC is registered to do business in Tennessee and has been since at least 2007. Caremark Rx, LLC may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

94. During the relevant time period, Caremark Rx, LLC provided PBM and mail order pharmacy services in Tennessee that gave rise to the Insulin Pricing Scheme and damaged payors in Tennessee, including Plaintiff.

95. Defendant Caremark, LLC is a California limited liability company whose principal place of business is at the same location as CVS Health. Caremark, LLC is a wholly owned subsidiary of Caremark Rx, LLC.

96. Caremark, LLC is registered to do business in Tennessee and has been since at least 2007. Caremark, LLC may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

97. During the relevant time period, Caremark, LLC provided PBM and mail order pharmacy services in Tennessee and Hamblen County that gave rise to the Insulin Pricing Scheme, which damaged Plaintiff.

98. **Defendant CaremarkPCS Health, LLC** is a Delaware limited liability company whose principal place of business is at the same location as CVS Health. CVS Health is the direct or indirect parent company of CaremarkPCS Health LLC.

99. CaremarkPCS Health, LLC, doing business as CVS Caremark, provides pharmacy benefit management services.

100. CaremarkPCS Health, LLC is registered to do business in Tennessee and has been since at least 2009. CaremarkPCS Health, LLC may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

101. During the relevant time period, CaremarkPCS Health, LLC provided PBM services in the State of Tennessee, which gave rise to the Insulin Pricing Scheme and damaged Plaintiff Hamblen.

102. Defendants CaremarkPCS Health, LLC and Caremark, LLC are agents and/or alter egos of Caremark Rx, LLC, CVS Pharmacy, and CVS Health.

103. As a result of numerous interlocking directorships and shared executives, Caremark Rx, LLC, CVS Pharmacy, and CVS Health are directly involved in the conduct of and control CaremarkPCS Health, LLC and Caremark, LLC's operations, management, and business decisions related to the at-issue formulary construction; Manufacturer Payments; and mail-order and retail pharmacy services—to the ultimate detriment of Plaintiff. For example:

a. During the relevant time period, these parent and subsidiaries have had common officers and directors, including:

- Thomas S. Moffatt, Vice President and Secretary of Caremark Rx, LLC, CaremarkPCS Health LLC, and Caremark, LLC, is also a Vice President, Assistant Secretary, and Senior Legal Counsel at CVS Health and the Vice President, Secretary and Senior Legal Counsel of CVS Pharmacy;

- Melanie K. Luker, Assistant Secretary of Caremark Rx, LLC, CaremarkPCS Health, LLC, and Caremark, LLC, is also a Manager of Corporate Services at CVS Health;

- Carol A. Denale, Senior Vice President and Treasurer of Caremark Rx, LLC, is also Senior Vice President, Treasurer and Chief Risk Officer at CVS Health Corporation;

- John M. Conroy has been Vice President of Finance at CVS Health since 2011, and was also President and Treasurer of Caremark, LLC and CaremarkPCS Health LLC in 2019; and

- Sheelagh Beaulieu has been the Senior Director of Income Tax at CVS Health while also acting as the Assistant Treasurer at CaremarkPCS Health LLC and Caremark LLC.

b. CVS Health owns all the stock of CVS Pharmacy, which, in turn, owns all the stock of Caremark Rx, LLC, which, in turn, owns all the stock of Caremark LLC. CVS Health also directly or indirectly owns all the stock of CaremarkPCS Health LLC.

c. CVS Health, as a corporate family, does not operate as separate entities. The public filings, documents, and statements of CVS Health present its subsidiaries, including CVS Pharmacy, CaremarkPCS Health, LLC, Caremark, LLC and Caremark Rx, LLC as divisions or departments of one unified "diversified health services company" that "works together across our disciplines" to "create unmatched human connections to transform the health care experience." The day-to-day operations of this corporate family reflect these public statements. These entities are a single business enterprise and should be treated as such as to all legal obligations discussed in this Complaint.[15]

d. All executives of CaremarkPCS Health, LLC, Caremark, LLC, Caremark Rx, LLC, and CVS Pharmacy ultimately report to the executives at CVS Health, including the President and CEO of CVS Health.

e. As stated above, CVS Health's CEO, Chief Medical Officer, Executive Vice Presidents, Senior Executives in Trade Finance, Senior Vice Presidents, and Chief Communication Officers are directly involved in the policies and business decisions of CaremarkPCS Health, LLC and Caremark, LLC that gave rise to Plaintiff Hamblen County's claims in this Complaint.

[15] CVS Caremark/CVS Health, Annual Report (Form 10-K) (Dec. 31, 2009-2019); CVS Health, *Our Purpose*, https://cvshealth.com/about-cvs-health/our-purpose (last visited Sept. 9, 2022); CVS Health, *Quality of Care*, https://cvshealth.com/health-withheart/improving-health-care/quality-of-care (last visited Sept. 9, 2022).

104. Collectively, Defendants CVS Health, CVS Pharmacy, Caremark Rx, LLC, Caremark, LLC and CaremarkPCS Health, LLC, including all predecessor and successor entities, are referred to as "CVS Caremark."

105. CVS Caremark is named as a Defendant in its capacities as a PBM and pharmacy.

106. In its capacity as a PBM, CVS Caremark coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the price of the at-issue diabetes medications, as well as for the placement of these Manufacturers' diabetes medications on CVS Caremark's formularies.

107. CVS Caremark has the largest PBM market share based on total prescription claims managed, representing approximately 40% of the national market. CVS Caremark's pharmacy services segment generated $141.5 billion in total revenues last year.

108. At all times relevant hereto, CVS Caremark offered pharmacy benefit services nationwide and to Tennessee payors, and derived substantial revenue therefrom, and, in doing so, made the at-issue misrepresentations (discussed below) and utilized the false prices generated by the Insulin Pricing Scheme to unlawfully profit off of payors like Plaintiff.

109. At all times relevant hereto, CVS Caremark offered pharmacy benefit management services nationwide and maintained standard formularies that are used nationwide, including in Tennessee. During the relevant time period, those formularies included diabetes medications, including all of those at issue in this Complaint.

110. CVS Caremark purchases drugs directly from manufacturers and through drug wholesalers for dispensing through its mail-order pharmacy.

111. During the relevant time period, CVS Caremark provided PBM services to Plaintiff and, in doing so, CVS Caremark set the price that Plaintiff paid for the at-issue drugs based on the

false list prices generated by the Insulin Pricing Scheme. Plaintiff paid CVS Caremark for the at-issue drugs.

112. In its capacity as a retail pharmacy, CVS Caremark further and knowingly profited from the false list prices produced by the Insulin Pricing Scheme by pocketing the spread between acquisition cost for the drugs at issue (an amount well below the list price generated by the Insulin Pricing Scheme), and the amounts it received from payors (which amounts were based on the false list prices and, in many cases, were set by CVS Caremark in its capacity as a PBM).

113. During the relevant time period, CVS Caremark provided mail-order and retail pharmacy services to Plaintiff and, in doing so, Plaintiff paid CVS Caremark for the at-issue drugs at prices based on the false list prices generated by the Insulin Pricing Scheme.

114. At all times relevant hereto, CVS Caremark dispensed the at-issue medications nationwide and directly to Plaintiff through its mail-order and retail pharmacies and derived substantial revenue from these activities in Tennessee.

115. At all times relevant hereto, CVS Caremark had express agreements with Defendants Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid by the Manufacturer Defendants to CVS Caremark, as well as agreements related to the Manufacturers' at-issue drugs sold through CVS Caremark's mail-order pharmacies.

116. **Defendant Evernorth Health, Inc. ("Evernorth")**, formerly known as Express Scripts Holding Company, is a Delaware corporation with its principal place of business at 1 Express Way, St. Louis, Missouri 63121.[16]

[16] Until 2021, Evernorth Health, Inc. conducted business under the name Express Scripts Holding Company. For the purposes of this Complaint "Evernorth" refers to Evernorth Health, Inc and Express Scripts Holding Company.

117. Evernorth may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

118. Evernorth, through its executives and employees, including its CEO and Vice Presidents, is directly involved in shaping the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs, related to the Insulin Pricing Scheme.

119. Evernorth's conduct had a direct effect in Tennessee and with respect to Plaintiff Hamblen County.

120. On a regular basis, Evernorth executives and employees communicate with and direct Evernorth's subsidiaries related to the at-issue PBM services and formulary activities.

121. Evernorth is the immediate or indirect parent of pharmacy and PBM subsidiaries that operate throughout Tennessee, which engaged in the activities that gave rise to this Complaint.

122. In December 2018, Evernorth merged with Cigna in a $67 billion deal to consolidate their businesses as a major health insurer, PBM, and mail-order pharmacy. As a result, the Evernorth corporate family controls the health plan/insurer, the PBM, and the mail-order pharmacies utilized by approximately 15 million Cigna members in the United States, including in Tennessee. Evernorth controls the entire drug pricing chain for these 15 million Americans.

123. In each annual report for at least the last decade, Evernorth has repeatedly and explicitly:

- Acknowledged that it is directly involved in the company's PBM services, stating "[Evernorth is] the largest stand-alone PBM company in the United States."

- Stated that Evernorth: "provid[es] products and solutions that focus on improving patient outcomes and assist in controlling costs; evaluat[es] drugs for efficacy, value and price to assist clients in selecting a cost-effective formulary; [and] offer[s] cost-effective home delivery pharmacy and specialty services that result in cost savings for plan sponsors and better care for members."

124. **Defendant Express Scripts, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. Express Scripts, Inc.'s principal place of business is the same location as Evernorth.

125. Express Scripts, Inc. is registered to do business in Tennessee and has been since at least 2017. Express Scripts, Inc. may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 39719-5546.

126. Express Scripts, Inc. is the immediate or indirect parent of pharmacy and PBM subsidiaries that operate throughout Tennessee that engaged in the conduct that gave rise to this Complaint.

127. During the relevant time period, Express Scripts Inc. was directly involved in the PBM and mail-order pharmacy services that gave rise to the Insulin Pricing Scheme and damaged Plaintiff.

128. Indeed, Express Scripts, Inc. provided pharmacy benefit services to Plaintiff, based on Plaintiff's reliance upon Express Scripts, Inc.'s response to Plaintiff's Request for Proposals.

129. **Defendant Express Scripts Administrators, LLC**, doing business as Express Scripts and formerly known as Medco Health, LLC, is a Delaware limited liability company and is a wholly owned subsidiary of Evernorth. Express Scripts Administrators, LLC's principal place of business is at the same location as Evernorth.

130. Express Scripts Administrators, LLC is registered to do business in Tennessee and may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

131. During the relevant time period, Express Scripts Administrators, LLC provided the PBM services in Tennessee discussed in this Complaint that gave rise to the Insulin Pricing Scheme that damaged Plaintiff.

132. **Defendant Medco Health Solutions, Inc. ("Medco")** is a Delaware Corporation with its principal place of business located at 100 Parsons Pond Road, Franklin Lakes, New Jersey.

133. Medco is registered to do business in Tennessee and may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

134. In 2012, Express Scripts acquired Medco for $29 billion.

135. Prior to the merger, Express Scripts and Medco were two of the largest PBMs in the United States and in Tennessee.

136. Prior to the merger, Medco provided the at-issue PBM and mail-order services, which gave rise to the Insulin Pricing Scheme and damaged Plaintiff, within Tennessee.

137. Following the merger, all of Medco's PBM and mail-order pharmacy functions were combined into Express Scripts. The combined company (Medco and Express Scripts) continued under the name Express Scripts with all of Medco's payor customers becoming Express Scripts' customers. The combined company covered over 155 million lives at the time of the merger.

138. At the time of the merger, on December 6, 2011, in his testimony before the Senate Judiciary Committee, David B. Snow, the then-CEO of Medco, publicly represented that "the merger of Medco and Express Scripts will result in immediate savings to our clients and, ultimately, to consumers. This is because our combined entity will achieve even greater [Manufacturer Payments] from drug manufacturers and other suppliers."

139. The then-CEO of Express Scripts, George Paz, during a Congressional subcommittee hearing in September 2011, echoed these sentiments: "A combined Express Scripts and Medco will be well-positioned to protect American families from the rising cost of prescription medicines."

140. **Defendant ESI Mail Pharmacy Service, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. ESI Mail Pharmacy Service, Inc.'s principal place of business is the same location as Evernorth.

141. ESI Mail Pharmacy Service, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

142. During the relevant time period, ESI Mail Pharmacy Services provided the mail-order pharmacy services in Tennessee discussed in this Complaint, which gave rise to the Insulin Pricing Scheme and damaged Plaintiff.

143. **Defendant Express Scripts Pharmacy, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. Express Scripts Pharmacy, Inc.'s principal place of business is at the same location as Evernorth.

144. Express Scripts Pharmacy, Inc. is registered to do business in Tennessee and has been since 2021. Express Scripts Pharmacy, Inc. may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

145. During the relevant time period, Express Scripts Pharmacy, Inc. provided the mail-order pharmacy services in Tennessee discussed in this Complaint, which gave rise to the Insulin Pricing Scheme and damaged Plaintiff.

146. As a result of numerous interlocking directorships and shared executives, Evernorth and Express Scripts, Inc. control Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., and Express Scripts Pharmacy, Inc's operations, management, and business decisions related to the at-issue formulary construction, negotiations, and mail-order pharmacy services to the ultimate detriment of Plaintiff. For example:

a. During the relevant time period, these parent and subsidiaries have had common officers and directors:

- Officers and/or directors shared between Express Scripts, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; David Queller, President; Jill Stadelman, Managing Counsel; and Scott Lambert, Treasury Manager Director;
- Executives shared between Express Scripts Administrators, LLC and Evernorth include Bradley Phillips, Chief Financial Officer; and Priscilla Duncan, Associate Senior Counsel;
- Officers and/or directors shared between ESI Mail Pharmacy Service, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; Priscilla Duncan, Associate Senior Counsel; and Joanne Hart, Treasury Director; and
- Officers and/or directors shared between Express Scripts Pharmacy, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; Jill Stadelman, Managing Counsel; Scott Lambert, Treasury Manager Director; and Joanne Hart, Treasury Director.

b. Evernorth directly or indirectly owns all the stock of Express Scripts Administrators, LLC, Medco Health Solutions, Inc., ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc. and Express Scripts, Inc.

c. The Evernorth corporate family does not operate as separate entities. The public filings, documents, and statements of Evernorth present its subsidiaries, including Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc. and Express Scripts, Inc., as divisions or departments of a single company that "unites businesses that have as many as 30+ years of experience . . . to

take health services further with integrated data and analytics that help us deliver better care to more people." The day-to-day operations of this corporate family reflect these public statements. All of these entities comprise a single business enterprise and should be treated as such as to all legal obligations detailed in this Complaint. All of the executives of Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc., and Express Scripts, Inc. ultimately report to the executives, including the CEO, of Evernorth.

d. As stated above, Evernorth's CEO and other executives and officers are directly involved in the policies and business decisions of Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., Express Scripts Pharmacy, Inc., and Express Scripts, Inc. that gave rise to Plaintiff's claims in this Complaint.

147. Collectively, Defendants Evernorth Health, Inc., Express Scripts, Inc., Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., and Express Scripts Pharmacy, Inc., including all predecessor and successor entities, are referred to as "Express Scripts."

148. Express Scripts is named as a Defendant in its capacities as a PBM and mail order pharmacy.

149. In its capacity as a PBM, Express Scripts coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the price of the at-issue diabetes medications, as well as for the placement of these Manufacturers' diabetes medications on Express Script's formularies.

150. Prior to merging with Cigna in 2019, Express Scripts was the largest independent PBM in the United States. During the relevant period of this Complaint, Express Scripts controlled

30% of the PBM market in the United States. Express Scripts has only grown larger since the Cigna merger.

151. In 2017, annual revenue for Express Scripts was over $100 billion.

152. As of December 31, 2018, more than 68,000 retail pharmacies, representing over 98% of all retail pharmacies in the nation, participated in one or more of Express Scripts' networks.

153. Express Scripts transacts business throughout the United States and Tennessee.

154. At all times relevant hereto, Express Scripts derived substantial revenue providing pharmacy benefits in Tennessee.

155. At all times relevant hereto, and contrary to their express representations, Express Scripts knowingly insisted that its payor clients use the false list prices produced by the Insulin Pricing Scheme as the basis for reimbursement of the at-issue drugs.

156. At all times relevant hereto, Express Scripts concealed its critical role in the generation of those false list prices.

157. At all times relevant hereto, Express Scripts maintained standard formularies that are used nationwide, including in Tennessee. During the relevant time period, those formularies included drugs produced by the Manufacturer Defendants, including the at-issue diabetes medications.

158. During the relevant time period, Express Scripts provided PBM services to Plaintiff and, in doing so, Express Scripts set the price that Plaintiff paid for the at-issue drugs, at prices based on the false list prices generated by the Insulin Pricing Scheme, and Plaintiff paid Express Scripts for the at-issue drugs.

159. In its capacity as a mail-order pharmacy, Express Scripts received payments from Tennessee payors for, and set the out-of-pocket price paid for, the at-issue drugs based on the falsely inflated prices generated by the Insulin Pricing Scheme and, as a result, damaged Plaintiff.

160. At all times relevant hereto, Express Scripts offered pharmacy benefit management services nationwide and maintained standard formularies that are used nationwide, including in Tennessee. During the relevant time period, those formularies included diabetes medications, including all of those at issue in this Complaint.

161. Express Scripts purchases drugs directly from manufacturers for dispensing through its mail-order pharmacy.

162. At all times relevant hereto, Express Scripts dispensed the at-issue medications nationwide and directly to Plaintiff through its mail-order pharmacies and derived substantial revenue from these activities in Tennessee.

163. During the relevant time period, in addition to its critical role in the Insulin Pricing Scheme, which detrimentally affected all payors and purchasers of the at-issue drugs, Express Scripts also provided PBM services directly to Plaintiff Hamblen County.

164. During the years when some of the largest at-issue price increases occurred, Express Scripts worked directly with OptumRx to negotiate Manufacturer Payments on behalf of OptumRx and its clients in exchange for preferred formulary placement.

165. For example, in a February 2014 email released by the U.S. Senate in conjunction with its January 2021 report titled "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug" ("January 2021 Senate Insulin Report"), Eli Lilly describes a "Russian nested

doll situation" in which Express Scripts was negotiating rebates on behalf of OptumRx related to the at-issue drugs for Cigna (who later would become part of Express Scripts).[17]

166. At all times relevant hereto, Express Scripts had express agreements with Defendants Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid by the Manufacturer Defendants to Express Scripts, as well as agreements related to the Manufacturers' at-issue drugs sold through Express Scripts' mail-order pharmacies.

167. **Defendant UnitedHealth Group, Inc**. is a corporation organized under the laws of Delaware with its principal place of business at 9900 Bren Road East, Minnetonka, Minnesota, 55343.

168. UnitedHealth Group, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

169. UnitedHealth Group, Inc. is a diversified managed healthcare company. In 2015, UnitedHealth Group reported revenue in excess of $257 billion, and the company is currently ranked sixth on the Fortune 500 list. UnitedHealth Group, Inc. offers a spectrum of products and services including health insurance plans through its wholly owned subsidiaries and prescription drugs through its PBM, OptumRx.

170. Over one-third of the overall revenues of UnitedHealth Group come from OptumRx.

[17] CHARLES E. GRASSLEY & RON WYDEN, STAFF REPORT ON INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG, S. FIN. COMM., https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf; Letter from Joseph B. Kelley, Eli Lilly Vice President, Global Gov. Affairs, to Charles E. Grassley & Ron Wyden, S. Fin. Comm. (Mar. 8, 2019), https://www.finance.senate.gov/imo/media/doc/Eli%20Lilly_Redacted%20v1.pdf

171. UnitedHealth Group, through its executives and employees, is directly involved in the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs and related to the Insulin Pricing Scheme. For example, UnitedHealth Group executives structure, analyze, and direct the company's overarching policies, including with respect to PBM and mail-order services, as a means of maximizing profitability across the corporate family.

172. UnitedHealth Group's Sustainability Report states that "OptumRx works directly with pharmaceutical manufacturers to secure discounts that lower the overall cost of medications and create tailored formularies – or drug lists – to ensure people get the right medications. [*UnitedHealth Group*] then negotiate[s] with pharmacies to lower costs at the point of sale . . . [*UnitedHealth Group*] also operate[s] [mail-order pharmacies] . . .. [*UnitedHealth Group*] work[s] directly with drug wholesalers and distributors to ensure consistency of the brand and generic drug supply, and a reliance on that drug supply."

173. In addition to being a PBM and a mail-order pharmacy, UnitedHealth Group owns and controls a major health insurance company, UnitedHealthcare. As a result, UnitedHealth Group controls the health plan/insurer, the PBM, and the mail-order pharmacies utilized by approximately 26 million UnitedHealthcare members in the United States, including those in Tennessee. UnitedHealth Group controls the entire drug pricing chain for these 26 million Americans.

174. UnitedHealth Group's conduct had a direct effect in Tennessee and damaged Plaintiff.

175. UnitedHealth Group states in its Annual Reports that UnitedHealth Group "utilizes Optum's capabilities to help coordinate patient care, improve affordability of medical care, analyze

cost trends, manage pharmacy benefits, work with care providers more effectively and create a simpler consumer experience."

176. **Defendant Optum, Inc.** is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. Optum, Inc. is a health services company managing subsidiaries that administer pharmacy benefits, including Defendant OptumRx, Inc.

177. Optum, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

178. Optum, Inc. is directly involved, through its executives and employees, in the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs and related to the Insulin Pricing Scheme, which had a direct effect in Tennessee and damaged Plaintiff.

179. For example, according to Optum Inc.'s press releases, Optum, Inc. is "UnitedHealth Group's information and technology-enabled health services business platform serving the broad healthcare marketplace, including care providers, plan sponsors, payors, life sciences companies and consumers."[18] In this role Optum, Inc. is directly responsible for the "business units – OptumInsight, OptumHealth and OptumRx"[19] and the CEOs of all these companies report directly to Optum, Inc. regarding their policies, including those that inform the at-issue formulary construction and mail order activities.

180. Defendant OptumRx, Inc. is a California corporation with its principal place of business at 2300 Main Street, Irvine, California, 92614.

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[18] UNITEDHEALTH GROUP, https://www.unitedhealthgroup.com/ (last visited on Sept. 9, 2022); *UnitedHealth Group Announces "Optum" Master Brand for Its Health Services Businesses*, FIERCE HEALTHCARE (Apr. 11, 2011, 9:21 AM), https://www.fiercehealthcare.com/healthcare/unitedhealth-group-announces-optummaster-brand-for-its-health-services-businesses.

[19] *Id.*; UNITEDHEALTH GROUP, *UnitedHealth Group Announces "Optum" Master Brand for Its Health Services Businesses* (Apr. 11, 2011), https://www.unitedhealthgroup.com/newsroom/2011/0411optum.html.

181. OptumRx, Inc. operates as a subsidiary of OptumRx Holdings I, LLC, which, in turn, operates as a subsidiary of Defendant Optum, Inc.

182. OptumRx, Inc. is registered to do business in Tennessee and has been since at least 2008. OptumRx, Inc. may be served through its registered agent: 300 Montvue Road, Knoxville, Tennessee 37919-5546.

183. During the relevant time period, OptumRx, Inc. provided the PBM and mail order pharmacy services in Tennessee that gave rise to the Insulin Pricing Scheme, which damaged Plaintiff.

184. **Defendant OptumInsight, Inc**. is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota.

185. OptumInsight, Inc. is registered to do business in Tennessee and has been since at least 1997. OptumInsight, Inc. may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

186. OptumInsight, Inc. is an integral part of the Insulin Pricing Scheme and, during the relevant time period coordinated directly with the Manufacturer Defendants in furtherance of the conspiracy. OptumInsight analyzed data and other information from the Manufacturer Defendants to advise the other Defendants with regard to the profitability of the Insulin Pricing Scheme to the benefit of all Defendants.

187. As a result of numerous interlocking directorships and shared executives, UnitedHealth Group, OptumRx Holdings I, LLC, and Optum, Inc are directly involved in the conduct of and control OptumInsight and Optum Rx's operations, management, and business decisions related to the at-issue formulary construction, negotiations, and mail order pharmacy services to the ultimate detriment of Plaintiff. For example:

a. These parent and subsidiaries have common officers and directors, including:

- Sir Andrew Witty is president of UnitedHealth Group and CEO of Optum, Inc.;
- Dan Schumacher is president of Optum, Inc and is also named to the Office of the Chief Executive at UnitedHealth Group, Inc.;
- Terry Clark is a senior vice president and chief marketing officer at UnitedHealth Group and also oversees the branding, marketing and advertising for UnitedHealth Group and Optum, Inc.;
- Tom Roos serves as chief accounting officer for UnitedHealth Group and Optum, Inc.;
- Heather Lang is Deputy General Counsel, Subsidiary Governance at UnitedHealth Group, Inc. and also Assistant Secretary at OptumRx, Inc.;
- Peter Gill is Vice President at UnitedHealth Group, Inc. and also Treasurer at OptumRx, Inc.;
- John Santelli leads Optum Technology, the leading technology division of Optum, Inc serving the broad customer base of Optum and UnitedHealthcare and also serves as UnitedHealth Group's chief information officer; and
- Eric Murphy is the Chief Growth and Commercial Officer for Optum, Inc. and has also led OptumInsight, Inc.

b. UnitedHealth Group directly or indirectly owns all the stock of Optum, Inc., OptumRx, Inc., and OptumInsight, Inc.;

c. The UnitedHealth Group corporate family does not operate as separate entities. The public filings, documents, and statements of UnitedHealth Group present its subsidiaries, including Optum, Inc., OptumRx, Inc., and OptumInsight as divisions or departments of a single company that is "a diversified family of businesses" and that "leverages core competencies" to "help[] people live healthier lives and help[] make the health system work better for everyone." The day-to-day operations of this corporate family reflect these public statements. These entities are a single business

enterprise and should be treated as such as to all legal obligations detailed in this Complaint.[20]

d. All the executives of Optum, Inc., OptumRx, Inc., and OptumInsight ultimately report to the executives, including the CEO, of UnitedHealth Group.

e. As stated above, UnitedHealth Group's executives and officers are directly involved in the policies and business decisions of Optum, Inc., OptumRx, Inc., and OptumInsight that gave rise to Plaintiff's claims in this Complaint.

188. Collectively, Defendants UnitedHealth Group, Inc., OptumRx, Inc., OptumInsight, Inc. and Optum, Inc., including all predecessor and successor entities, are referred to as "OptumRx."

189. OptumRx is named as a Defendant in its capacities as a PBM and mail-order pharmacy.

190. OptumRx is a pharmacy benefit manager and, as such, coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the price of the at-issue diabetes medications, as well as for the placement of these Manufacturers' diabetes medications on OptumRx's drug formularies.

191. OptumRx provides pharmacy care services to more than 65 million people in the nation through a network of more than 67,000 retail pharmacies and multiple delivery facilities.[21]

192. In 2018, OptumRx managed more than $91 billion in pharmaceutical spending, representing 23% of the PBM market in the United States. OptumRx's 2018 revenue was $69 billion.

[20] UnitedHealth Group, Quarterly Report (Form 10-Q) (Mar. 31, 2017).
[21] UnitedHealth Group, Annual Report (Form 10-K) (Dec. 31, 2018).

193. In 2019, OptumRx managed more than $96 billion in pharmaceutical spending, with a revenue of $74 billion.[22]

194. At all times relevant hereto, OptumRx derived substantial revenue providing pharmacy benefits in Tennessee.

195. At all times relevant hereto, OptumRx offered pharmacy benefit management services nationwide and maintained standard formularies that are used nationwide, including in Tennessee. During the relevant time period, those formularies included diabetes medications, including all of those at issue in this Complaint.

196. At all times relevant hereto, and contrary to their express representations, OptumRx knowingly insisted that its payor clients use the false list prices produced by the Insulin Pricing Scheme as the basis for reimbursement of the at-issue drugs.

197. At all times relevant hereto, OptumRx concealed its critical role in the generation of those false list prices.

198. In its capacity as a mail-order pharmacy, OptumRx received payments from payors for, and set the out-of-pocket price paid for, the at-issue drugs based on the falsely inflated prices produced by the Insulin Pricing Scheme and, as a result, damaged Plaintiff.

199. At all times relevant hereto, OptumRx dispensed the at-issue medications nationwide and directly to Plaintiff and Plaintiff's Beneficiaries in Tennessee through its mail-order pharmacies and derived substantial revenue from these activities in Tennessee.

200. OptumRx purchases the Manufacturer Defendants' drugs, including the at issue diabetes medications, for dispensing through its mail-order pharmacies.

[22] UnitedHealth Group, Annual Report (Form 10-K) (Dec. 31, 2019).

201. At all times relevant hereto, OptumRx had express agreements with Defendants Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid by the Manufacturer Defendants to OptumRx, as well as agreements related to the Manufacturers' at-issue drugs sold through OptumRx's mail-order pharmacies.

202. Collectively, CVS Caremark, Optum Rx, and Express Scripts are referred to as the "PBM Defendants" or the "PBMs."

JURISDICTION AND VENUE

203. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1331 and pursuant to 18 U.S.C. § 1964(c) because this action alleges violations of the Racketeer influenced and Corrupt Organizations Act, 18 U.S.C. § 1962, which raises a federal question. This Court has supplemental jurisdiction over the state law claims in this action pursuant to 28 U.S.C. § 1367.

204. There is also federal subject matter jurisdiction over this action because complete diversity exists among the parties, 28 U.S.C. § 1332. The parties are citizens of different states, and the amount in controversy, exclusive of interests or costs, exceeds the sum or value of $75,000.

205. This Court also has personal jurisdiction over all Defendants under 18 U.S.C. § 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the Court in a single trial.

206. Venue is proper pursuant to 18 U.S.C. § 1965 because Defendants Sanofi, Novo Nordisk and Medco reside, are found, have an agent, or transact their affairs in this District, and the ends of justice require that any Defendant residing elsewhere be brought before this Court.

207. Venue is also proper in this District pursuant to 28 U.S.C. § 1391(b) and (c) because all Defendants transact business in, are found in, and/or have agents in this District, and because some of the actions giving rise to the Complaint took place within this District.

ADDITIONAL FACTUAL ALLEGATIONS

A. Diabetes and Insulin Therapy

The Diabetes Epidemic

208. Diabetes occurs when a person's blood glucose is too high. In people without diabetes, the pancreas secretes the hormone insulin, which controls the rate at which food is converted to blood glucose. When insulin is lacking or when cells stop responding to insulin, however, blood sugar stays in the bloodstream. Over time, this can cause serious health problems, including heart disease, blindness, and kidney disease.

209. There are two basic types of diabetes: Type 1 and Type 2. Roughly 90-95% of diabetics are Type 2, which develops when a person does not produce enough insulin or has become resistant to the insulin they produce. While Type 2 patients can initially be treated with tablets, in the long term most patients switch to insulin injections.

210. Diabetes has been on the rise for decades. In 1958, only 1.6 million Americans had diabetes. By the turn of the century, that number had grown to over ten million. Fourteen years later, the number had tripled. Today, more than 37 million Americans—approximately 11% of the country—live with the disease.

211. The prevalence of diabetes in Tennessee has increased as well. Over 760,000 Tennessee adults now live with diabetes and hundreds of thousands more have prediabetes.[23]

[23] https://www.cdc.gov/diabetes/programs/stateandlocal/state-diabetes-profiles/tennessee.html; Tennessee Diabetes Action Legislative Report, Feb. 2021, https://www.capitol.tn.gov/Archives/senate/112GA/committees/health-welfare/2021/Diabetes%20Legislative%20Report_FinalDraft.%2001-29-2021%208%2045%20pm.pdf.

Insulin: A Century-Old Drug

212. Despite its potentially deadly impact, diabetes is highly treatable. Patients able to follow a prescribed treatment plan consistently may avoid the health complications associated with the disease. Unlike many high-burden diseases, treatment for diabetes has been available for almost a century.

213. In 1922, Frederick Banting and Charles Best, while working at the University of Toronto, pioneered a technique for removing insulin from an animal pancreas that could then be used to treat diabetes. After discovery, Banting and Best obtained a patent and then sold it to the University of Toronto for $1 (equivalent of $14 today), explaining "[w]hen the details of the method of preparation are published anyone would be free to prepare the extract, but no one could secure a profitable monopoly."[24]

214. After purchasing the patent, the University of Toronto contracted with Defendants Eli Lilly and Novo Nordisk to scale their production. Under this arrangement, Eli Lilly and Novo Nordisk were allowed to apply for patents on variations to the manufacturing process.

215. Although early iterations of insulin were immediately perceived as lifesaving, there have been numerous incremental improvements since its discovery.

216. The earliest insulin was derived from animals and, until the 1980s, was the only diabetes treatment.

217. While effective, animal-derived insulin created the risk of allergic reaction. This risk was lessened in 1982 when synthetic insulin, known as human insulin, was developed by Defendant Eli Lilly. Eli Lilly marketed this insulin as Humulin. The development of human insulin

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[24] Jessica DiGiacinto & Valencia Higuera, *Everything You Need to Know About Insulin*, HEALTHLINE (Oct. 5, 2021), http://www.healthline.com/health/type-2-diabetes/insulin; M. BLISS, THE DISCOVERY OF INSULIN (2013).

benefited heavily from government and non-profit funding through the National Institute of Health and the American Cancer Society.

218. Over a decade later, Eli Lilly released the first analog insulin.

219. Analog insulin is laboratory-grown and genetically altered insulin. Analogs are slight variations on human insulin that make the injected treatment act more like the insulin naturally produced and regulated by the body.

220. Defendant Eli Lilly developed the first analog insulin, Humalog, in 1996.

221. Other rapid-acting analogs are Defendant Novo Nordisk's Novolog and Defendant Sanofi's Apidra, which have similar profiles. Diabetics use these rapid-acting insulins in combination with longer-acting insulins, such as Sanofi's Lantus and Novo Nordisk's Levemir.

222. The Manufacturer Defendants introduced these rapid-acting and long-acting analog insulins between 1996 and 2007.

223. In 2015, Sanofi introduced Toujeo, another long-acting insulin similar to Lantus; however, Toujeo is highly concentrated, making injection volume smaller than Lantus.

224. In 2016, Eli Lilly introduced Basaglar, which is a long-acting insulin biologically similar to Sanofi's Lantus.

225. Even though insulin was first extracted 100 years ago, and despite its profitability, only Defendants Eli Lilly, Novo Nordisk, and Sanofi manufacture insulin for the United States market. This did not occur by chance.

226. Many of the at-issue medications are now off-patent.

227. The Manufacturers maintain market domination through patent "evergreening." Drugs usually face generic competition when their 20-year patents expire. While original insulin formulas may technically be available for generic use, the Manufacturers "stack" patents around

the original formulas, making new competition more costly and risky. For example, Sanofi has filed more than 70 patents on Lantus—more than 95% were filed after the drug was approved by the FDA—potentially providing more than three additional decades of patent "protection" for the drug. The market therefore remains highly concentrated.

The Current Insulin Landscape

228. While insulin today is generally safer and more convenient to use than when originally developed in 1922, there remain questions about whether the overall efficacy of insulin has significantly improved over the last twenty years.

229. For example, while long-acting analogs may have certain advantages over human insulins, such as affording more flexibility around mealtime planning, it has yet to be shown that analogs lead to better long-term outcomes. Recent work suggests that older human insulins may work just as well for patients with Type 2 diabetes.

230. Moreover, all insulins at issue have either been available in the same form since the late 1990s/early 2000s or are biologically equivalent to insulins available then.

231. As Dr. Kasia Lipska, a Yale researcher, explained in the Journal of the American Medical Association:

> We're not even talking about rising prices for better products here. I want to make it clear that we're talking about rising prices for the same product . . . there's nothing that's changed about Humalog. It's the same insulin that's just gone up in price and now costs ten times more.[25]

232. Production costs have also decreased in recent years. A September 2018 study calculated that, based on production costs, a reasonable price for a year's supply of human insulin

[25] Natalie Shure, *The Insulin Racket*, American Prospect (June 24, 2019), https://prospect.org/health/insulin-racket/ (last visited Jan. 14, 2023).

is $48 to $71 per person and $78 to $133 for analog insulins. Another recent study found that the Manufacturers could profit at as little as $2 per vial.

233. United States diabetics spent an average of $5,705 each for insulin in 2016. According to a 2020 RAND report, the 2018 list price per vial across all forms of insulin was just $12 in Canada and less than $7 in Australia. In the U.S., it was $98.70.

234. While R&D costs often contribute significantly to a drug's price, the initial basic insulin research occurred 100 years ago and its costs have long-since been recouped. Other costs, such as developing the recombinant DNA-fermentation process and the creation of insulin analogs, were incurred decades ago.

Insulin Adjuncts: Type 2 Medications

235. The Manufacturer Defendants have released several non-insulin diabetes medications over the past decade. Novo Nordisk released Victoza in 2010, followed by Trulicity (Eli Lilly), Soliqua (Sanofi), and Ozempic (Novo Nordisk).[26] The following is a list of diabetes medications at issue in this lawsuit:

[26] Victoza, Trulicity, and Ozempic are glucagon-like peptide-1 receptor agonists ("GLP-1") and mimic the GLP-1 hormone produced in the body. Soliqua is a combination long-acting insulin and GLP-1 drug. Each of these drugs can be used in conjunction with insulins to control diabetes.

Table 1: Diabetes medications at issue in this case

Insulin Type	Action	Name	Company	FDA Approval	Current/Recent List Price
Human	*Rapid-Acting*	Humulin R	Eli Lilly	1982	$178 (vial)
		Humulin R 500	Eli Lilly	1982	$1784 (vial), $689 (pens)
		Novolin R	Novo Nordisk	1991	$165 (vial), $312 (pens)
	Intermediate	Humulin N	Eli Lilly	1982	$178 (vial), $566 (pens)
		Humulin 70/30	Eli Lilly	1989	$178 (vial), $566 (pens)
		Novolin N	Novo Nordisk	1991	$165 (vial), $312 (pens)
		Novolin 70/30	Novo Nordisk	1991	$165 (vial), $312 (pens)
Analog	*Rapid-Acting*	Humalog	Eli Lilly	1996	$342 (vial), $636 (pens)
		Novolog	Novo Nordisk	2000	$347 (vial), $671 (pens)
		Apidra	Sanofi	2004	$341 (vial), $658 (pens)
	Long-Acting	Lantus	Sanofi	2000	$340 (vial), $510 (pens)
		Levemir	Novo Nordisk	2005	$370 (vial), $555 (pens)
		Basaglar (Kwikpen)	Eli Lilly	2015	$392 (pens)
		Toujeo (Solostar)	Sanofi	2015	$466 (pens), $622 (max pens)
		Tresiba	Novo Nordisk	2015	$407 (vial) $610 (pens – 100u) $732 (pens – 200u)
Type 2 Medications		Trulicity	Eli Lilly	2014	$1013 (pens)
		Victoza	Novo Nordisk	2010	$813 (2 pens) $1220 (3 pens)
		Ozempic	Novo Nordisk	2017	$1022 (pens)
		Soliqua	Sanofi	2016	$928 (pens)

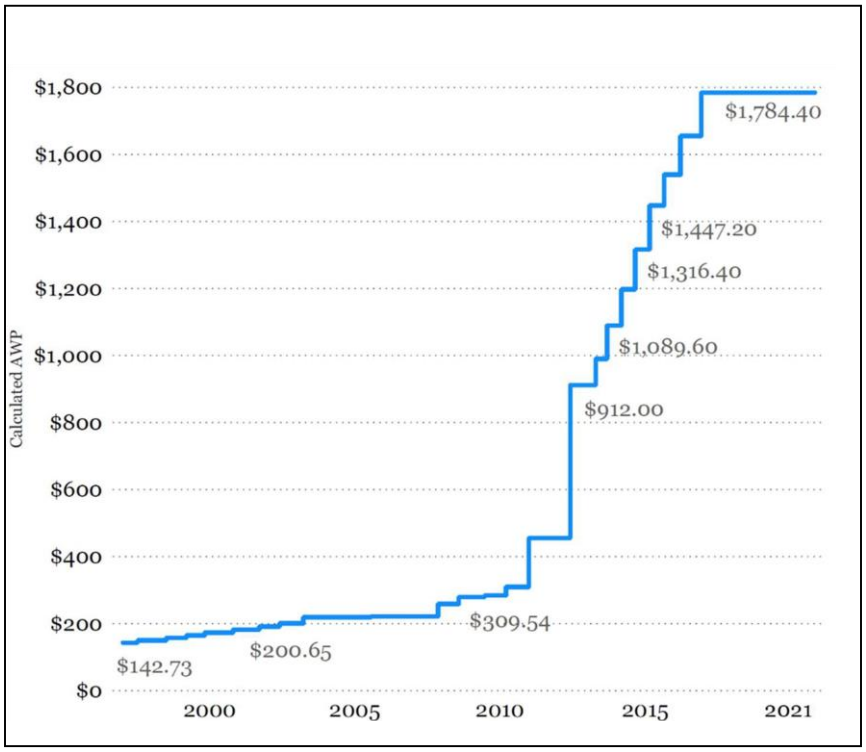
B. The Dramatic Rise in the Price of Diabetes Medications in the U.S.

236. Over the past 25 years, the list price of certain insulins has increased in some cases by more than 1000% (10x).

237. According to the U.S. Bureau of Labor Statistics, $165 worth of consumer goods and services in 1997 dollars would, in 2021, have cost $289 (1.75x).[27]

238. Since 1997, Eli Lilly has raised the list price of a vial of Humulin R (500U/mL) from $165 to $1784 in 2021 (10.8x).

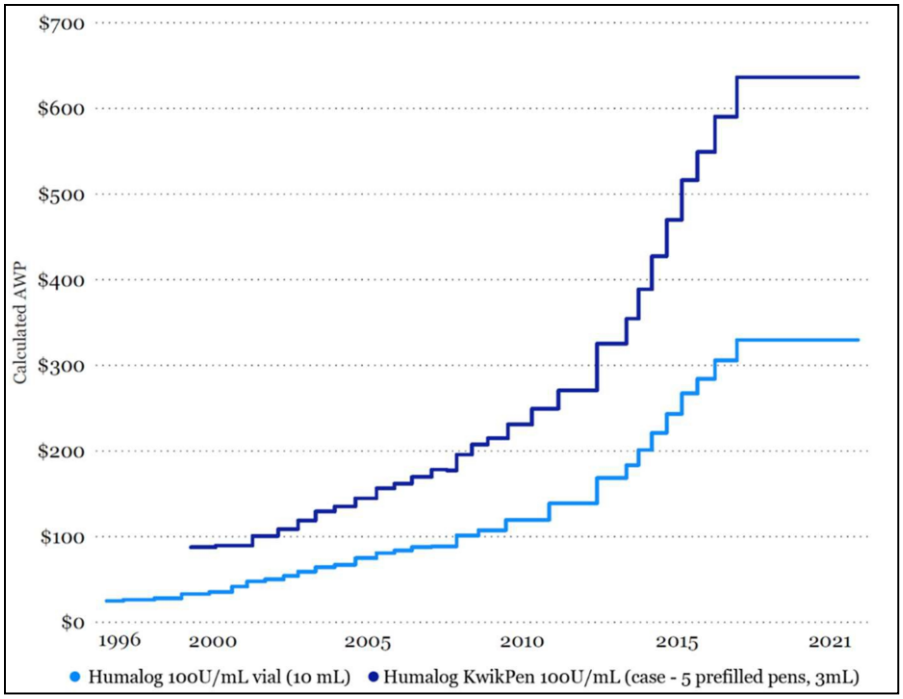
Figure 3: Rising list prices of Humulin R (500U/mL) from 1997-2021



239. Since 1996, Eli Lilly has raised the price for a package of Humalog pens from less than $100 to $663 (6.6x) and from less than $50 per vial to $342 (6.8x). (See Fig. 4.)

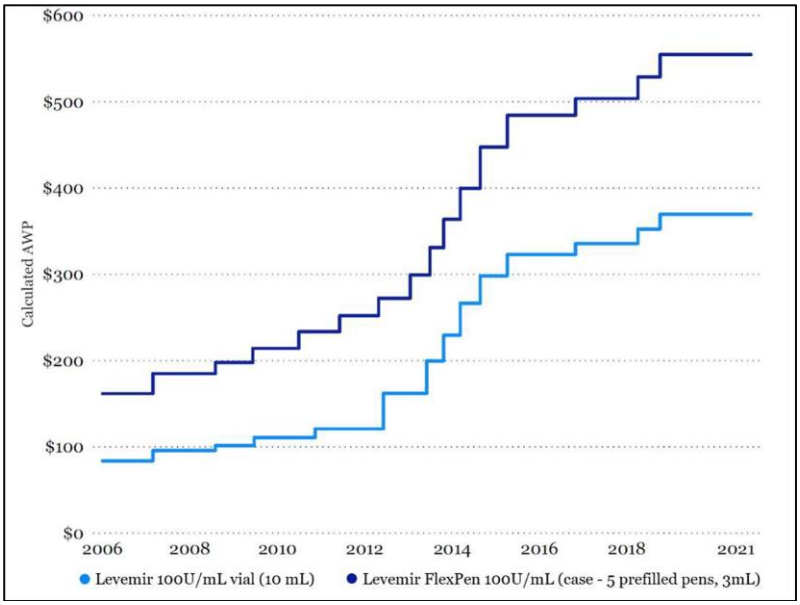
Figure 4: Rising list prices of Humalog vials and pens from 1996-2021

[27] https://www.bls.gov/data/inflation_calculator.htm (last visited Aug. 23, 2023). The Consumer Price Index (CPI) measures "the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services." (https://www.bls.gov/cpi/).



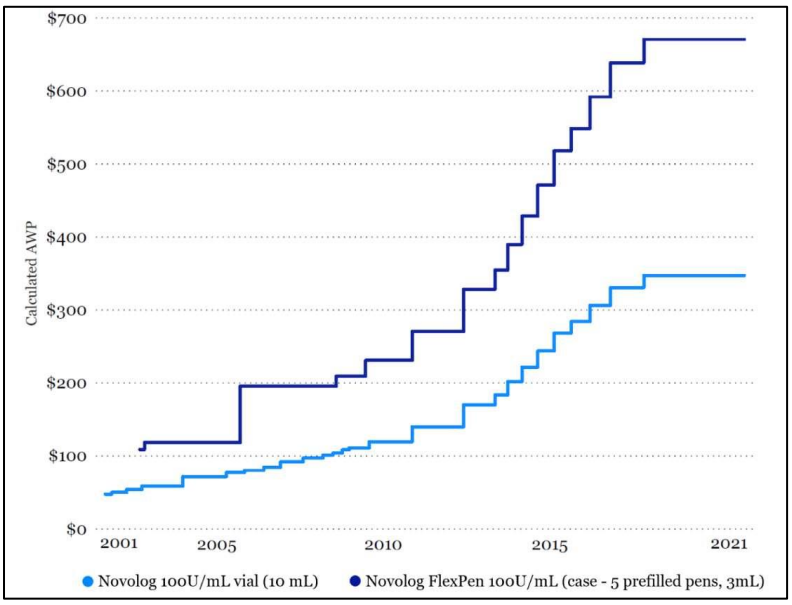
240. From 2006 to 2020, Novo Nordisk has raised Levemir's list price from $162 to $555 (3.4x) for pens and from under $100 to $370 per vial (3.7x).

Figure 5: Rising list prices of Levemir from 2006-2021



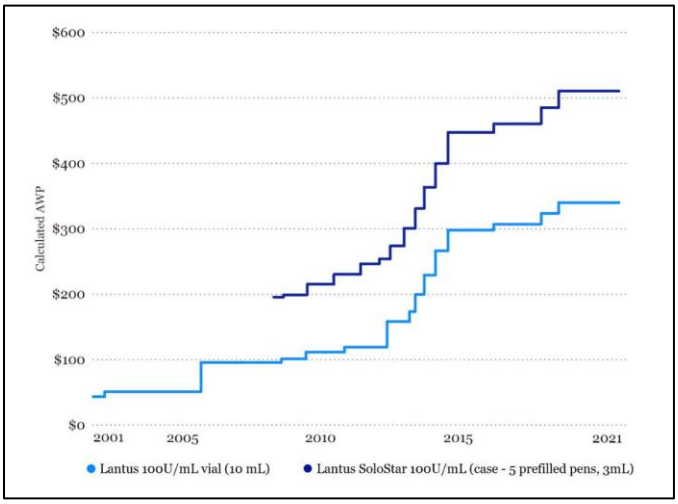
241. From 2002 to 2021, Novo Nordisk raised the list price of Novolog from $108 to $671 (6.2x) for a package of pens and from less than $50 to $347 (6.9x) for a vial.

Figure 6: Rising list prices of Novolog vials and pens from 2002-2021



242. Defendant Sanofi has kept pace. It manufactures a top-selling analog insulin—Lantus—which has been and remains a flagship brand for Sanofi. It has been widely prescribed nationally and within Tennessee, including to Plaintiff's Beneficiaries. Sanofi has raised the list prices for Lantus from less than $200 in 2006 to over $500 in 2020 (2.5x) for a package of pens and from less than $50 to $340 for a vial (6.8x). (See Fig. 7.)

Figure 7: Rising list prices of Lantus vials and pens from 2001-2021



243. The Manufacturer Defendants have similarly ballooned the prices for noninsulin diabetes medications.

244. Driven by these price hikes, payors' and diabetics' spending on these drugs has steadily increased with totals in the tens of billions of dollars. The Defendant-Manufacturers Have Increased Prices in Lockstep

245. The timing of the price increases reveals that the Manufacturer Defendants have not only dramatically increased prices for the at-issue diabetes treatments, but have done so in lockstep.

246. Between 2009 and 2015, for example, Sanofi and Novo Nordisk raised the list prices of their insulins in tandem 13 times, taking the same price increase down to the decimal point within a few days of each other (sometimes within a few hours).[28]

247. This conduct is known as "shadow pricing," which communicates between competitors their intention not to price compete against one another.

[28] Grassley & Wyden, *supra* note 2.

248. In 2016, Novo Nordisk and Sanofi's lockstep increases for the at-issue drugs represented the highest drug price increases in the pharmaceutical industry.

249. Eli Lilly and Novo Nordisk have engaged in the same lockstep behavior with respect to their rapid-acting analog insulins, Humalog and Novolog. Figure 8 demonstrates this collusive behavior with respect to Lantus and Levemir. Figure 9 demonstrates this behavior with respect to Novolog and Humalog.

Figure 8: Rising list prices of long-acting insulins

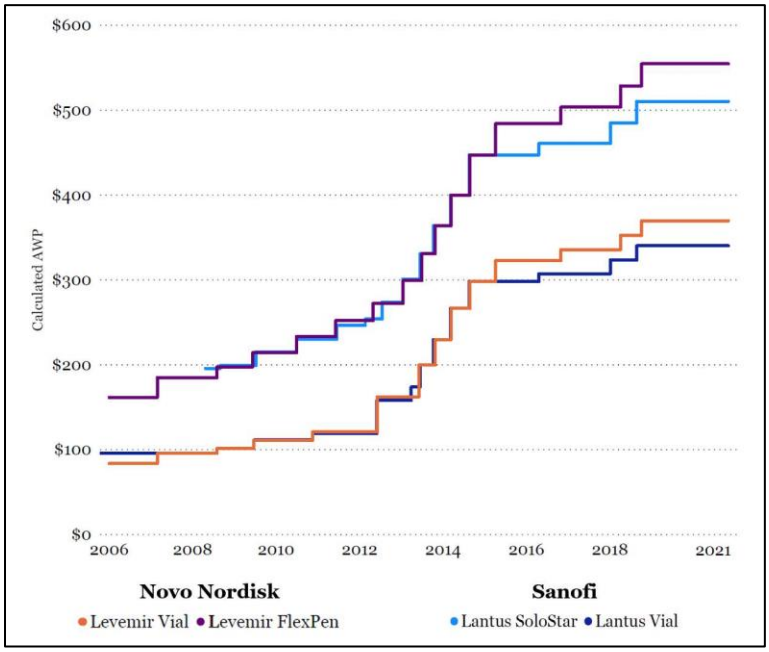
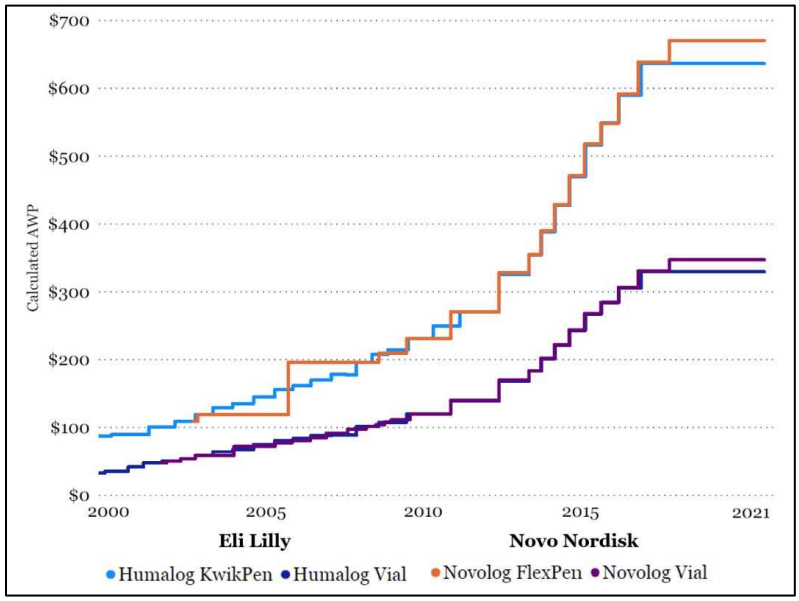
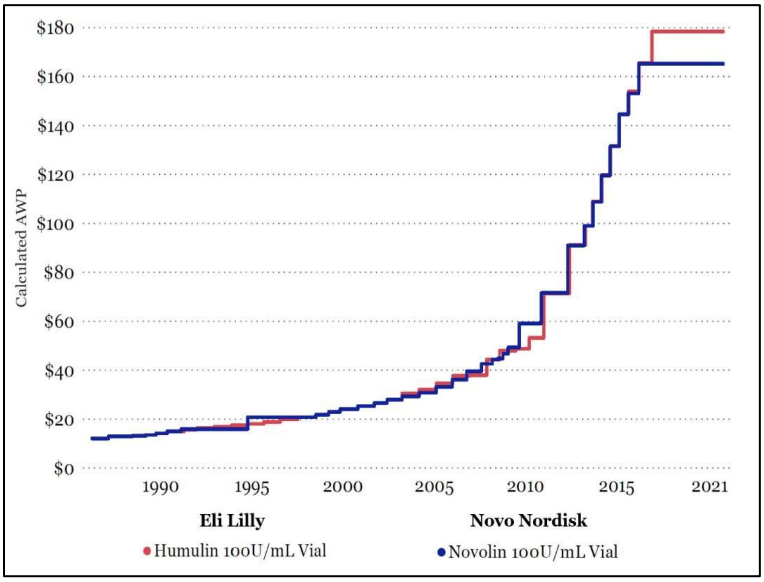


Figure 9: Rising list prices of rapid-acting insulins



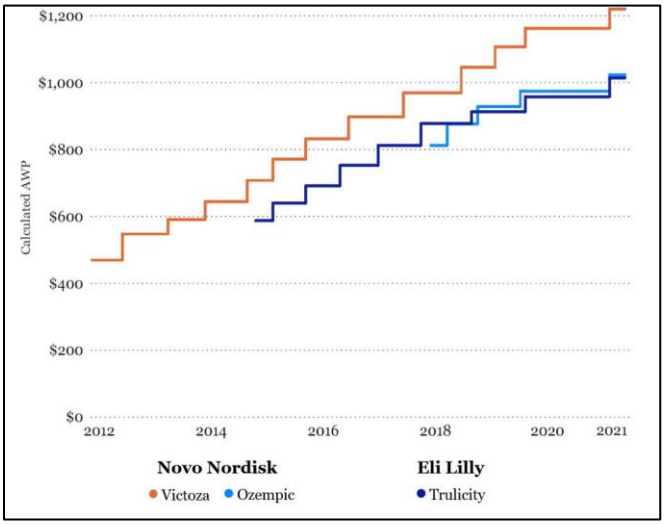
250. Figure 10 below demonstrates this behavior with respect to the human insulins—Eli Lilly's Humulin and Novo Nordisk's Novolin.

Figure 10: Rising list price increases for human insulins



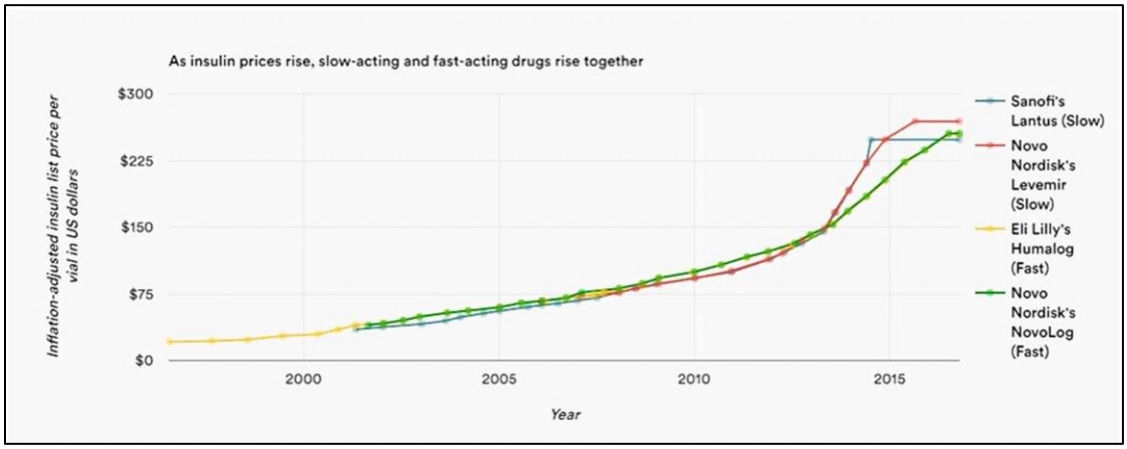
251. Figure 11 below demonstrates Novo Nordisk and Eli Lilly's lockstep price increases for their Type 2 drugs Trulicity, Victoza, and Ozempic.

Figure 11: Rising list prices of Type 2 drugs



252. Figure 12 below shows how, collectively, the Manufacturer Defendants have exponentially raised the prices of insulin products in near-perfect unison.

Figure 12: Lockstep insulin price increases



253. Because of the Manufacturer Defendants' collusive price increases, nearly a century after the discovery of insulin, diabetes medications have become unaffordable for many diabetics.

C. Pharmaceutical Payment and Supply Chain

254. The prescription drug industry is comprised of a deliberately opaque network of entities engaged in multiple distribution and payment structures. These entities include drug manufacturers, wholesalers, pharmacies, health plans/third-party payors, PBMs, and patients.

255. Given the complexities of the different parties involved in the pharmaceutical industry, there are many ways in which pharmaceutical drugs are distributed. Generally speaking, branded prescription drugs, such as the at-issue diabetes medications, are often distributed in one of three ways: (1) from manufacturer to wholesaler (distributor), wholesaler to pharmacy, and pharmacy to patient; (2) from manufacturer to mail-order pharmacy to patient; and (3) from manufacturer to mail-order pharmacy, mail-order pharmacy to self-insured payor, and then self-insured payor to patient.

256. The pharmaceutical industry, however, is unique in that the pricing chain is distinct from the distribution chain. The prices for the drugs distributed in the pharmaceutical chain are different for each participating entity, i.e., different actors pay different prices set by different entities for the same drugs. The unifying factor is that the price that each entity in the pharmaceutical chain pays for a drug is inexorably tied to the price set by the manufacturer. The pricing chain includes self-insured payors paying PBMs directly.

257. There is no transparency in this pricing system. Typically, only a brand drug's list price—also known as its Average Wholesale Price (AWP) or the mathematically related Wholesale Acquisition Cost (WAC)—is available.

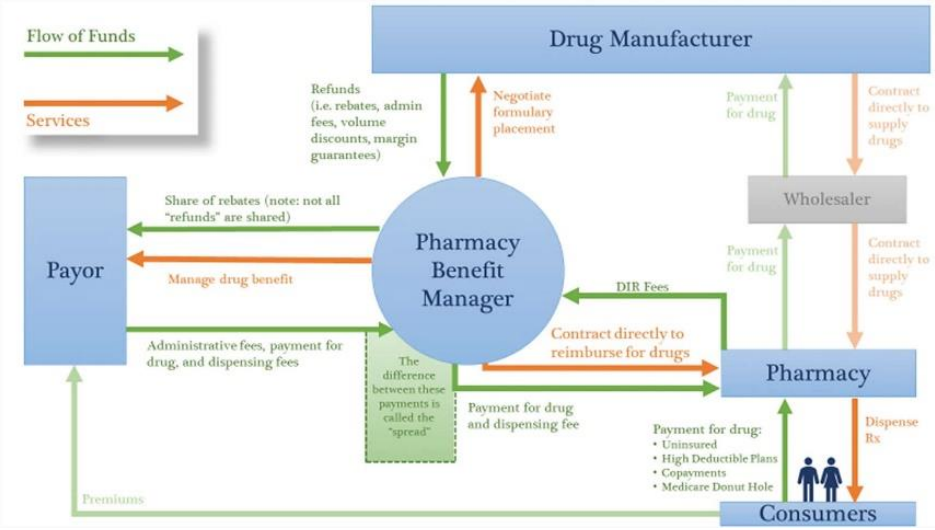
258. Drug manufacturers self-report AWP, or other prices upon which AWP is based, to publishing compendiums such as First DataBank, Redbook, and others who then publish those prices.

259. As a direct result of the PBMs' conduct, AWP persists as the most commonly and continuously used list price in reimbursement and payment calculations and negotiations for both payors and patients.

D. The PBMs' Role in the Pharmaceutical Payment Chain

260. The PBMs are at the center of this convoluted pharmaceutical payment chain, as illustrated in Figure 13 below.

Figure 13: Insulin distribution and payment chain



261. The PBM Defendants develop drug formularies, process claims, create a network of retail pharmacies, set the prices in coordination with the Manufacturers that the payor will pay for prescription drugs, and are paid by the payor to reimburse pharmacies for the drugs utilized by the payor's beneficiaries.

262. The PBMs also contract with a network of retail pharmacies. Pharmacies agree to dispense drugs to patients and pay fees back to the PBMs. The PBMs reimburse pharmacies for the drugs dispensed.

263. The PBM Defendants also own mail-order and specialty pharmacies, which purchase and take possession of prescription drugs, including those at-issue here, and directly supply those drugs to payors like Plaintiff Hamblen County, their Beneficiaries, and other patients, by mail.

264. Often, the PBM Defendants purchase drugs directly from the Manufacturers and distribute them directly to the patients. The prices that the PBM Defendants pay are significantly less than the purchase prices paid by payors.

265. Even where PBM Defendant mail-order pharmacies purchase drugs from wholesalers, their costs are set by direct contracts with the manufacturers.

266. In addition, and of particular significance here, the PBM Defendants contract with pharmaceutical manufacturers, including the Manufacturer Defendants. The PBMs extract from the Manufacturers rebates, fees, and other consideration that are paid back to the PBMs, including the Manufacturer Payments related to the at-issue drugs.

267. The Manufacturers also interact with the PBMs related to other services outside the scope of the Insulin Pricing Scheme, such as health and educational programs and patient and prescriber outreach with respect to drugs not at issue here.

268. These relationships allow PBMs to exert tremendous influence over what drugs are available throughout the United States, including in Hamblen County, on what terms, and at what prices.

269. Thus, PBMs are at the center of the flow of pharmaceutical money. Historically and today PBMs:

- negotiate the price that payors pay for prescription drugs (based on prices generated by the Insulin Pricing Scheme);

- separately negotiate a different (and often lower) price that pharmacies in their networks receive for the same drug;
- set the amount in fees that the pharmacy pays back to the PBM for each drug sold (based on prices generated by the Insulin Pricing Scheme);
- set the price paid for each drug sold through their mail-order pharmacies (based on prices generated by the Insulin Pricing Scheme); and
- negotiate the amount that the Manufacturers pay back to the PBM for each drug sold (based on prices generated by the Insulin Pricing Scheme).

270. Yet, for most of these transactions, only the PBMs are privy to the amount that any other entity in this supply chain is paying or receiving for the same drugs. The contracts between the PBMs and Manufacturers are undisclosed to Plaintiff. Payors, including Plaintiff, do not know and cannot learn the terms of those contracts.

271. This lack of transparency affords Defendants the opportunity to extract billions of dollars from this payment and supply chain without detection.

272. In every interaction that the PBMs have within the pharmaceutical pricing chain, they stand to profit from the prices generated by the Insulin Pricing Scheme.

The Rise of the PBMs in the Pharmaceutical Supply Chain

273. At first, in the 1960s, pharmacy benefit managers functioned largely as claims processors. Over time, however, they have taken on increasingly larger roles.

274. One of the roles the pharmacy benefit managers have taken on, as discussed above, was negotiating with drug manufacturers—ostensibly on behalf of payors. In so doing, the PBMs affirmatively represented that they were using their leverage to drive down drug prices.

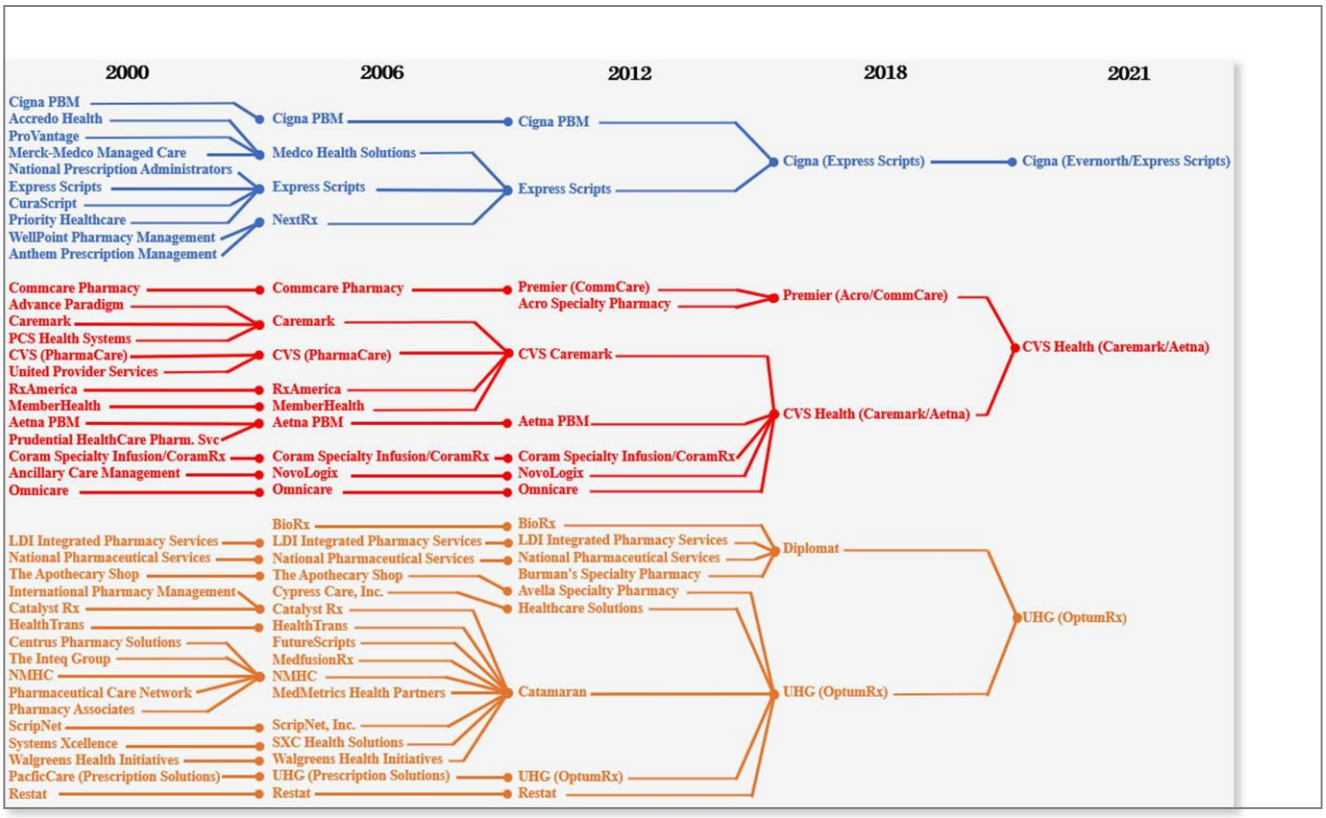
275. In the early 2000s, the PBMs started buying pharmacies, thus creating an additional incentive to collude with manufacturers to keep certain prices high.

276. These perverse incentives still exist today with respect to both retail and mail-order pharmacies housed within the PBMs' corporate families. Further recent consolidation in the industry has given the pharmacy benefit managers disproportionate market power.

277. Nearly forty pharmacy benefit manager entities have combined into what are now the three PBM Defendants. Moreover, each PBM Defendant now is owned by other significant players in the pharmaceutical chain, e.g., Express Scripts merged with Cigna; CVS bought Caremark, which now also owns Aetna; and UnitedHealth Group acquired OptumRx.

278. Figure 14 depicts this consolidation within the pharmacy benefit manager market.

Figure 14: PBM consolidation



279. After merging with or acquiring all of their competitors, and now backed by multibillion-dollar corporations, the PBM Defendants have taken over the market in the past

decade, controlling more than 80% of the market and managing pharmacy benefits for more than 270 million Americans.

280. Together, the PBM Defendants report more than $300 billion in annual revenue.

281. The PBMs use this market consolidation and the resulting purchasing power as leverage when negotiating with other entities in the pharmaceutical pricing chain.

The Insular Nature of the Pharmaceutical Industry

282. The insular nature of the pharmaceutical industry has provided Defendants with ample opportunity to contact and communicate with the other PBM and Manufacturer Defendants and to devise, coordinate, and carry out the Insulin Pricing Scheme.

283. The Manufacturer Defendants are all members of the industry-funded Pharmaceutical Research and Manufacturers of America ("PhRMA") and routinely communicate through PhRMA meetings and platforms in furtherance of the Insulin Pricing Scheme. According to PhRMA's 2019 IRS Form 990, it received $515,420,431 in "membership dues." All members are pharmaceutical companies.[29]

284. David Ricks (CEO of Eli Lilly), Paul Hudson (CEO of Sanofi), and Douglas Langa (President of Novo Nordisk and EVP of North American Operations), serve on the PhRMA board of directors and/or part of the PhRMA executive leadership team.

285. The PBM Defendants also routinely communicate through direct interaction with their competitors and the Manufacturers at trade associations and industry conferences.

[29] PhRMA 2019 Form 990, https://projects.propublica.org/nonprofits/organizations/530241211/202043189349300519/full; PhRMA, About PhRMA, https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/About-PhRMA2.pdf (last visited Aug.23,2023).

286. Each year during the relevant period, the main PBM trade association, the industry-funded Pharmaceutical Care Management Association ("PCMA"), held several yearly conferences, including its Annual Meeting and its Business Forum conferences.[30]

287. The PCMA is governed by PBM executives. The current (July 2023) board of the PCMA includes David Joyner (Executive Vice President and President of Pharmacy Services of PBM Defendant CVS Caremark); Adam Kautzner (President of PBM Defendant Express Scripts); and Heather Cianfrocco (CEO of PBM Defendant OptumRx).

288. In 2022, Former Express Scripts President Amy Bricker was the Chair of the PCMA board of directors and the only Express Scripts employee on the board. But when Ms. Bricker left Express Scripts in late 2022/early 2023, she was removed from the PCMA board. On February 3, 2023, PCMA issued a press release naming Mr. Kautzner to the board and appointing him Chairman of the Board of Directors. Mr. Kautzner was not on the board as of late 2022. Mr. Kauztner was added to the PCMA board and named Chair of the board to ensure that the PCMA board has directors from all three PBM Defendants and to facilitate the Insulin Pricing Scheme.

289. All PBM Defendants are members of the PCMA and, due to their leadership positions, have substantial control over that association.

290. Additionally, the Manufacturer Defendants are affiliate members of the PCMA.

291. Every year, high-level representatives and corporate officers from both the PBM and Manufacturer Defendants attend these conferences to meet in person and engage in discussions, including those in furtherance of the Insulin Pricing Scheme.

[30] The PCMA's industry funding in the form of "membership dues" is set out in its 2019 Form 990, https://projects.propublica.org/nonprofits/organizations/383676760/202042969349301134/full (last visited Aug, 23, 2023).

292. In fact, for at least the last eight years, all Manufacturer Defendants have been "Partners," "Platinum Sponsors," or "Presidential Sponsors" of these PBM conferences.

293. Notably, many of the forums at these conferences are specifically advertised as offering opportunities for private, non-public communications. For example, as Presidential Sponsors of these conferences, Manufacturer Defendants each hosted "private meeting rooms" that offer "excellent opportunities for . . . one-on-one interactions between PBM and pharma executives."[31]

294. Representatives from each Manufacturer Defendant have routinely met privately with representatives from each PBM Defendant during the Annual Meetings and Business Forum conferences that the PCMA holds (and the manufacturers sponsor) each year.

295. In addition, all PCMA members, affiliates and registered attendees of these conferences are invited to join PCMA-Connect, "invitation only LinkedIn group and online networking community."[32]

296. As PCMA members, the PBM and Manufacturer Defendants clearly utilized both PCMA-Connect, as well as the private meetings at the PCMA conferences, to exchange information and to reach agreements in furtherance of the Insulin Pricing Scheme.

297. Key at-issue lockstep price increases occurred shortly after the Defendants had convened at PCMA meetings. For example, on September 26 and 27, 2017, the PCMA held its annual meeting where each of the Manufacturer Defendants hosted private rooms and executives from each Defendant engaged in several meetings throughout the conference. Mere days after the

[31] PCMA, *The PCMA Annual Meeting 2021 Will Take Place at the Broadmoor in Colorado Springs, CO September 20 and 21*, https://www.pcmanet.org/pcmaevent/annual-meeting-2021/ (an event "tailored specifically for senior executives from PBMs and their affiliated business partners" with "private reception rooms" and "interactions between PBM members, drug manufacturers, and other industry partners") (last visited Aug 23, 2023).

[32] PCMA, *PCMA-Connect*, https://www.pcmanet.org/contact/pcma-connect/ (last visited Sept. 9, 2022).

conference, on October 1, 2017, Sanofi increased Lantus's list price by 3% and Toujeo's list by 5.4%. Novo Nordisk also recommended that their company make a 4% list price increase effective on January 1, 2018, to match the Sanofi increase.

298. Likewise, on May 30, 2014, Novo Nordisk raised the list price of Levemir a matter of hours after Sanofi made its list price increase on Lantus. These price hikes occurred just weeks after the 2014 PCMA spring conference in Washington, D.C., attended by representatives from all the PBM Defendants.

299. The PBMs control the PCMA and have exploited it to further their interests and to conceal the Insulin Pricing Scheme. The PCMA has brought numerous lawsuits and lobbying campaigns aimed at blocking drug-pricing transparency efforts, including recently suing the Department of Health and Human Services (HHS) to block the finalized HHS "rebate rule," which would eliminate anti-kickback safe harbors for Manufacturer Payments and instead offer them as direct-to-consumer discounts.

300. Notably, the PCMA's 2019 tax return reports more than a million dollars in revenue for "litigation support." Prior tax returns available at ProPublica reveal millions of dollars in revenue for "litigation support" (and tens of millions in revenue for "industry relations") year after year.[33]

301. Communications among the PBM Defendants are facilitated by the fluidity and frequency with which executives relocate from one PBM Defendant to another. For example:

- Mark Thierer worked as an executive at Caremark Rx (now CVS Caremark) prior to becoming the CEO of OptumRx in 2016 (he also served as Chairman of the Board for PCMA starting in 2012);

- Bill Wolfe was the President of the PBM Catalyst Rx (now OptumRx) prior to becoming the President of Aetna Rx in 2015 (he also served as a PCMA board member from 2015-2017 while with Aetna Rx);

[33] *See, e.g.*, PCMA 2019 Form 990, *supra* note 24, and prior years' returns on ProPublica.

- Derica Rice, former EVP for CVS Health and President of CVS Caremark, previously served as EVP and CFO for Eli Lilly;

- Duane Barnes was the Vice President of Medco (now Express Scripts) before becoming division President of Aetna Rx in 2006 (he also served as a PCMA board member);

- Everett Neville was the division President of Aetna Rx before becoming Senior Vice President of Express Scripts;

- Albert Thigpen was a Senior Vice President at CVS Caremark for 11 years before becoming a Senior Vice President at OptumRx in 2011;

- Harry Travis was the Chief Operating Officer at Medco (now Express Scripts) before becoming a Vice President at Aetna Rx in 2008; he served as SVP Member Services Operations for CVS Caremark from 2020-2022; and

- Bill Kiefer was a Vice President of Express Scripts for 14 years before becoming Senior Vice President of Strategy at OptumRx in 2013.

E. The Insulin Pricing Scheme

302. The market for the at-issue diabetes medications is unique in that it is highly concentrated with no true generics and few biosimilar options. The drugs and biosimilars have similar efficacy and risk profiles.

303. This affords the PBMs great leverage that, in theory, could be used to negotiate with the Manufacturer Defendants to drive down list prices for the at-issue drugs through open competition.

304. But the PBMs do not want the prices for diabetes medications to go down. A 2022 report by the Community Oncology Alliance put it this way:

> Among the different sources of revenue, the most prolific by far is in the form of rebates from pharmaceutical manufacturers that PBMs extract in exchange for placing the manufacturer's product drug on a plan sponsor's formulary or encouraging utilization of the manufacturer's drugs . . . . [T]he growing number and scale of rebates is the primary fuel of today's high drug prices. The truth is that PBMs have a vested interest to have drug prices remain high, and to extract rebates

> off of these higher prices. PBM formularies tend to favor drugs that offer higher rebates over similar drugs with lower net costs and lower rebates.[34]

305. The Manufacturer Defendants understand that PBM Defendants make more money as prices increase. This is confirmed by the January 2021 Senate Insulin Report after review of internal documents produced by the Manufacturers: [B]oth Eli Lilly and Novo Nordisk executives, when considering lower list prices, were sensitive to the fact that PBMs largely make their money on rebates and fees that are based on a percentage of a drug's list price.[35]

306. The documents eventually released by the Senate also show how the Manufacturers' pricing strategy focuses on *the PBMs' profitability*. In an internal August 6, 2015, email, Novo Nordisk executives debated delaying increasing the price of an at-issue drug in order to make the increase more profitable for *CVS Caremark*, stating:

> Should we take 8/18 [for a price increase], as agreed to by our [pricing committee], or do we recommend pushing back due to the recent CVS concerns on how we take price? . . . We know CVS has stated their disappointment with our price increase strategy (ie taking just after the 45th day) and how it essentially results in a lower price protection, admin fee and rebate payment for that quarter/time after our increase . . . it has been costing CVS a good amount of money. [36]

307. The Manufacturer Defendants also understand that because of the PBMs' market dominance, most payors, including Plaintiff Hamblen County and its Beneficiaries, accept the baseline national formularies offered by the PBMs with respect to the at-issue drugs.

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[34] Community Oncology Alliance & Frier Levitt, *Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers* (Feb. 2022), https://communityoncology.org/wpcontent/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf (last visited Jan. 14, 2023).

[35] Grassley & Wyden, *supra* note 2 at 89.

[36] Letter from Raphael A. Prober, Counsel for Novo Nordisk Inc., to Charles E. Grassley & Ron Wyden, S. Fin. Comm. (Mar. 8, 2019), https://www.finance.senate.gov/imo/media/doc/Novo_ Redacted.pdf (last visited Jan. 15, 2023).

308. The Insulin Pricing Scheme was borne from these understandings. Both sets of Defendants realized that if the Manufacturers artificially inflate their list prices while paying large, undisclosed Manufacturer Payments back to the PBMs, both the PBMs and Manufacturers would generate billions of unearned dollars. The plan worked.

309. Over the past several years the Manufacturers have raised prices in unison and have paid correspondingly larger Manufacturer Payments to the PBMs.

310. In exchange for the Manufacturers artificially inflating their prices and paying the PBMs substantial amounts in Manufacturer Payments, the PBM Defendants grant the Manufacturer Defendants' diabetes medications elevated prices and preferred status on their national formularies. During the relevant period, the rebate amounts (as a proportion of the list price) grew year-over-year while list prices themselves increased.

311. Beyond increased rebate demands, the PBMs also have sought and received larger and larger administrative fee payments and other Manufacturer Payments from the Manufacturers during the relevant period.

312. A recent study by the Pew Charitable Trust estimated that, between 2012 and 2016, the amount of administrative and other fees that the PBMs requested and received from the Manufacturers tripled, reaching more than $16 billion. The study observed that, although rebates were sent to payors during this period, PBMs retained the same volume of rebates in pure dollars, given the overall growth in rebate volume while administrative fees and spread pricing (charging a client payor more for a drug than the PBM pays the pharmacy) further offset reductions in retained rebate volumes.

313. Thus—and contrary to their public representations—the PBM Defendants' negotiations and agreements with the Manufacturer Defendants (and the formularies that result

from these agreements) have caused and continue to cause precipitous price increases for the at-issue drugs.

314. As a result of the Insulin Pricing Scheme, every payor, including Plaintiff, that pays for and/or reimburses for the at-issue drugs has been overcharged.

315. Moreover, the PBMs use this false price to misrepresent the amount of "savings" they generate for diabetics, payors, and the healthcare system. For example, in January 2016, Express Scripts' president Tim Wentworth stated at the 34th annual JP Morgan Healthcare Conference that Express Scripts "saved our clients more than $3 billion through the Express Scripts National Preferred Formulary."[37] Likewise, in April 2019, CVS Caremark President Derica Rice stated: "Over the last three years . . . CVS Caremark has helped our clients save more than $141 billion by blunting drug price inflation, prioritizing the use of effective, lower-cost drugs and reducing the member's out-of-pocket spend."[38]

316. In making these representations, the PBMs fail to disclose that the amount of "savings" generated is calculated based on the false list price, which is not paid by any entity in the pharmaceutical pricing chain and which all Defendants are directly responsible for artificially inflating.

317. The Insulin Pricing Scheme is a coordinated effort among the Manufacturer and PBM Defendants in which each agreed to, and did, participate, and which created enormous profits for all. For example:

a. The Manufacturers and the PBMs are in constant communication and regularly meet and exchange information to construct and refine the PBM formularies that

[37] Surabhi Dangi-Garimella, *PBMs Can Help Bend the Cost Curve: Express Scripts' Tim Wentworth*, AJMC (Jan. 12, 2016), https://www.ajmc.com/view/pbms-can-help-bendthe-cost-curve-express-scripts-tim-wentworth (last visited Jan. 15, 2023).

[38] CVS Health, *CVS Health PBM Solutions Blunted the Impact of Drug Price Inflation, Helped Reduce Member Cost, and Improved Medication Adherence in 2018* (Apr. 11, 2019), https://www.cvshealth.com/news-and-insights/press-releases/cvs-health-pbmsolutions-blunted-the-impact-of-drug-price (last visited Jan. 11, 2023).

form and fuel the scheme. As part of these communications, the Manufacturers are directly involved in determining not only where their own diabetes medications are placed on the PBMs' formularies and with what restrictions, but also in determining the same for competing products;

b. The Manufacturers and the PBMs share confidential and proprietary information with each other in furtherance of the Insulin Pricing Scheme, such as market data gleaned from the PBMs' drug utilization tracking efforts and mail-order pharmacy claims, internal medical efficacy studies, and financial data. Defendants then use this information in coordination to set the false prices for the at-issue medications and to construct their formularies in the manner that is most profitable for both sets of Defendants. The data that is used to further this coordinated scheme is compiled, analyzed, and shared either by departments directly housed within the PBM or by subsidiaries of the PBM, as is the case with OptumRx, which utilizes OptumInsight and Optum Analytics; and

c. The Manufacturers and the PBMs engage in coordinated outreach programs directly to patients, pharmacies, and prescribing physicians to convince them to switch to the diabetes medications that are more profitable for the PBMs and Manufacturers, even drafting and editing letters in tandem to send out to diabetes patients on behalf of the PBMs' clients. For example, the Grassley-Wyden Senate committee recently released an email where Eli Lilly discussed paying Defendant UnitedHealth Group and OptumRx additional rebates for every client that was converted to formularies that exclusively preferred Eli Lilly's at-issue drugs, including Humalog. The email continued: "United's leadership committee made one ask of Lilly – that we are highly engaged in the communication/pull through plan.[39] I of course indicated we fully expect to support this massive patient transition [to Eli Lilly's at-issue drugs favored by United] and provider education with the full breadth of Lilly resources. UHC also proactively thanked Lilly for our responsiveness, solution generation and DBU execution."

318. Rather than using their prodigious bargaining power to lower drug prices as they claim, Defendants instead used their dominant positions to conspire to generate billions of dollars in illicit profits at the expense of payors like Plaintiff.

F. Defendants Play Down the Insulin Pricing Scheme and Its Harms

319. On April 10, 2019, the United States House of Representatives Committee on Energy and Commerce held a hearing on industry practices titled, "Priced Out of a Lifesaving

[39] "Pull through" is an industry term that refers to an integrated process between PBMs and Manufacturers aimed at moving market share and increasing sales for a certain product following the PBM granting that product preferred placement on its formulary.

Drug: Getting Answers on the Rising Cost of Insulin."[40]

320. Representatives from all Defendants testified at the hearing, and each acknowledged before Congress that the price for insulin has increased exponentially in the past 15 years.

321. Further, each Defendant conceded that the price that diabetics pay out-of-pocket for insulin is too high. For example:

- Dr. Sumit Dutta, SVP and Chief Medical Officer of OptumRx since 2015, stated: "A lack of meaningful competition allows the [M]anufacturers to set high [list] prices and continually increase them which is odd for a drug that is nearly 100 years old and which has seen no significant innovation in decades. These price increases have a real impact on consumers in the form of higher out-of-pocket costs."

- Thomas Moriarty, Chief Policy and External Affairs Officer and General Counsel for CVS Health testified: "A real barrier in our country to achieving good health is cost, including the price of insulin products which are too expensive for too many Americans. Over the last several years, [list] prices for insulin have increased nearly 50 percent. And over the last ten years, [list] price of one product, Lantus, rose by 184 percent."

- Mike Mason, Senior Vice President of Eli Lilly when discussing how much diabetics pay out-of-pocket for insulin stated: "it's difficult for me to hear anyone in the diabetes community worry about the cost of insulin. Too many people today don't have affordable access to chronic medications . . ."

- Kathleen Tregoning, Executive Vice President External Affairs at Sanofi, testified: "Patients are rightfully angry about rising out-of-pocket costs and we all have a responsibility to address a system that is clearly failing too many people. . . we recognize the need to address the very real challenges of affordability . . . Since 2012, average out-of-pocket costs for Lantus have risen approximately 60 percent for patients . . ."

- Doug Langa, Executive Vice President of Novo Nordisk, stated: "On the issue of affordability . . . I will tell you that at Novo Nordisk we are accountable for the [list] prices of our medicines. We also know that [list] price matters to many, particularly those in high-deductible health plans and those that are uninsured."

[40] https:// www.congress.gov/event/116th-congress/house-event/109299?s=1&r=3 (last visited Jan. 9, 2023) (hereinafter *Priced Out of a Lifesaving Drug*).

322. None of the testifying Defendants claimed that the significant increase in the price of insulin was related to competitive factors such as increased production costs or improved clinical benefit.

323. Instead, Novo Nordisk's President Doug Langa's written testimony for the April 2019 hearing recognized "misaligned incentives" that have led to higher drug costs, including for insulin: "Chief among these misaligned incentives is the fact that the rebates pharmaceutical companies pay to PBMs are calculated as a percentage of WAC [list] price. That means a pharmaceutical company fighting to remain on formulary is constrained from lowering WAC price, or even keeping the price constant, if a competitor takes an increase. This is because PBMs will then earn less in rebates and potentially choose to place a competitor's higher-priced product on their formulary to the exclusion of others." Likewise, Mr. Langa's responses to questions for the record conceded that "[t]he disadvantage of a system in which administrative fees are paid as a percentage of the list price is that there is increased pressure to keep list prices high. . . ." The hearing transcript records Mr. Langa's further comments in this regard:

> So as you heard from Dr. Cefalu last week of the ADA [American Diabetes Association], there is this perverse incentive and misaligned incentives and this encouragement to keep list prices high. And *we've been participating in that system* because the higher the list price, the higher the rebate . . . There is a significant demand for rebates…. *We're spending almost $18 billion a year in rebates*, discount, and fees, and *we have people with insurance with diabetes that don't get the benefit of that*. (emphasis added)

324. Eli Lilly admitted that it raises list prices as a quid pro quo for formulary positions. At the April 2019 Congressional hearing, Mike Mason, Senior Vice President of Eli Lilly, testified:

> Seventy-five percent of our list price is paid for rebates and discounts . . . . $210 of a vial of Humalog is paid for discounts and rebates. . . . We have to provide rebates [to PBMs] in order to provide and compete for that [formulary position] so that people can use our insulin. In the very next question, Mr. Langa of Novo Nordisk was asked, "[H]ave you ever lowered a list price? His answer: "We have not."

325. Sanofi's Executive Vice President for External Affairs, Kathleen Tregoning, testified:

> The rebates is [sic] how the system has evolved. . . . I think the system became complex and rebates generated through negotiations with PBMs are being used to finance other parts of the healthcare system and not to lower prices to the patient.

Her written response to questions for the record acknowledged that "it is clear that payments based on a percentage of list price result in a higher margin [for PBMs] for the higher list price product than for the lower list price product."

326. The PBM Defendants also conceded at the April 2019 Congressional hearing that they grant preferred, or even exclusive, formulary position because of higher Manufacturer Payments paid by the Manufacturer Defendants.

327. In her responses to questions for the record, Amy Bricker, former SVP of Express Scripts and PCMA board member, confirmed that "manufacturers lowering their list prices" would give patients "greater access to medications;" yet when asked to explain why Express Scripts did not grant an insulin with a lower list price preferred formulary status, answered, "Manufacturers do give higher discounts [i.e., payments] for exclusive [formulary] position . . ." When asked why the PBM would not include both costly and lower-priced insulin medications on its formulary, Ms. Bricker stated plainly, "We'll receive less discount in the event we do that."[41]

328. As Dr. Dutta, SVP of OptumRx, perversely reasoned, the cheaper list-priced alternative Admelog is not given preference on the formulary because "it would cost the payer more money to do that . . . because the list price is not what the payer is paying. They are paying

[41] Buried in Express Scripts' 2017 10-K is the following: "We maintain contractual relationships with numerous pharmaceutical manufacturers, which provide us with, among other things administrative fees for managing rebate programs, including the development and maintenance of formularies that include particular manufacturer's products . . . ." That is, the Manufacturers pay the PBMs to effectively participate in the creation of formularies that payors are required to adopt as a condition for obtaining PBM services. Express Scripts Annual Report (Form 10-K) (FYE Dec. 31, 2017) at 24. It also notes that its business would be "adversely affected" if it were to "lose [its] relationship with one or more key pharmaceutical manufacturers." *Id.*

the net price."[42] In other words, under the pricing scheme, PBMs and manufacturers can make a drug with a lower list price effectively more expensive for payors and then ostensibly save payors from that artificially inflated price by giving preference to drugs that had higher list prices to begin with (yielding higher Manufacturer Payments to the PBMs).

329. While all Defendants acknowledged before Congress their participation in conduct integral to the Insulin Pricing Scheme, none revealed its inner workings or the connection between their coordination and the economic harm that payors, like Plaintiff, and Beneficiaries were unwittingly suffering. Instead, in an effort to obscure the true reason for precipitous price increases, each Defendant group pointed the finger at the other as the more responsible party.

330. The PBM Defendants testified to Congress that the Manufacturer Defendants are solely responsible for their list price increases and that the Manufacturer Payments that the PBMs receive are not correlated to rising insulin prices.

331. This testimony is false. The amounts Manufacturers pay back to the PBMs is *directly correlated* to an increase in list prices. On average, a $1 increase in Manufacturer Payments is associated with a $1.17 increase in list price. Reducing or eliminating Manufacturer Payments would lower prices and reduce out-of-pocket expenditures.

332. Further, in large part because of the increased list prices and related Manufacturer Payments, the PBMs' profit per prescription has grown substantially over the same time period that insulin prices have steadily increased. For example, since 2003, Defendant Express Scripts has seen its profit per prescription increase more than 500% per adjusted prescription.[43]

[42] *Id.* As noted in the hearing, even the "cheaper" alternative Admelog "costs over $200 a bottle."

[43] David Balto, *How PBMs Make the Drug Price Problem Worse*, Hill (Aug. 31, 2016, 5:51 PM), https://thehill.com/blogs/pundits-blog/healthcare/294025-how-pbms-make-thedrug-price-problem-worse (last visited Jan. 15, 2023).

333. Novo Nordisk's President, Doug Langa, submitted written testimony to Congress acknowledging "there is no doubt that the WAC [list price] is a significant component" of "what patients ultimately pay at the pharmacy counter." Yet, the Manufacturers urged upon Congress the fiction that the PBMs were solely to blame for insulin prices because of their demands for rebates in exchange for formulary placement. The Manufacturers claimed their hands were tied and sought to conceal their misconduct by suggesting that they have not profited off rising insulin prices.

334. Given the Manufacturers' claims that rebates were the sole reason for rising prices, each was asked directly during the Congressional hearing to guarantee it would decrease list prices if rebates were restricted or eliminated. The spokespersons for Eli Lilly, Novo Nordisk and Sanofi all said only that they would "consider it."

335. In addition, a 2020 study from the Institute of New Economic Thinking titled, "Profits, Innovation and Financialization in the Insulin Industry," demonstrates that during the time insulin price increases were at their steepest, distributions to the Manufacturers' shareholders in the form of cash dividends and share repurchases totaled $122 billion. In fact, during this period the Manufacturers spent a significantly lower proportion of profits on R&D compared to shareholder payouts. The paper also notes that "[t]he mean price paid by patients for insulin in the United States almost tripled between 2002 and 2013" and that "per-person spending on insulin by patients and insurance plans in the United States doubled between 2012 and 2016, despite only a marginal increase in insulin use."[44]

336. The 2022 Community Oncology Alliance report found:[45]

[44] Rosie Collington, *Profits, Innovation and Financialization in the Insulin Industry*, Inst. for New Econ. Thinking (Apr. 2020), https://www.ineteconomics.org/research/research-papers/ profits-innovation-and-financialization-in-the-insulin-industry (last visited Jan. 15, 2023).

[45] Community Oncology Alliance, *supra* note 29.

> [T]here are several important ways that PBM rebates increase the costs of drugs for both plan sponsors and patients. . . . PBMs employ exceedingly vague and ambiguous contractual terms to recast monies received from manufacturers outside the traditional definition of rebates, which in most cases must be shared with plan sponsors. Rebate administration fees, *bona fide* service fees, and specialty pharmacy discounts/fees are all forms of money received by PBMs and rebate aggregators which may not be shared with (or even disclosed to) the plan sponsor. These charges serve to increase the overall costs of drugs, while providing no benefit whatsoever to plan sponsors. . . . The total drug spend of a plan sponsor, regardless of whether it is a federal or state governmental program or a self-funded employer, will inevitably increase because PBMs are incentivized to favor expensive drugs that yield high rebates. . . .

337. In January 2021, the Senate Finance Committee (Grassley-Wyden) issued a report titled "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug,"[46] which detailed Congress's findings after reviewing more than 100,000 pages of internal company documents from Sanofi, Novo Nordisk, Eli Lilly, CVS Caremark, Express Scripts, OptumRx, and Cigna. The report concluded, among other things:

- The Manufacturer Defendants retain more revenue from insulin than in the 2000s—for example, Eli Lilly has reported a steady increase in Humalog revenue for more than a decade—from $1.5 billion in 2007 to $3 billion in 2018;
- The Manufacturer Defendants have aggressively raised the list price of their Insulin products absent significant advances in the efficacy of the drugs; and
- The Manufacturer Defendants only spend a fraction of their revenue related to the at-issue drugs on research and development—Eli Lilly spent $395 million on R&D costs for Humalog, Humulin, and Basaglar between 2014-2018, during which time the company generated $22.4 billion in revenue on these drugs.

[46] Grassley & Wyden, *supra* note 2 at 5, 7.

338. The truth is that, despite their finger pointing in front of Congress, the Manufacturers and PBMs are *both* responsible for their concerted efforts in creating the Insulin Pricing Scheme.

G. Defendants Profit from the Insulin Pricing Scheme

339. The Insulin Pricing Scheme affords the Manufacturer Defendants the ability to pay the PBM Defendants secret but significant Manufacturer Payments in exchange for formulary placement, which garners the Manufacturer Defendants greater revenues from sales without decreasing their profit margins. During the relevant period, the PBM Defendants granted national formulary position to each at-issue drug in exchange for large Manufacturer Payments and inflated prices.

340. The Manufacturer Defendants also use the inflated price to earn hundreds of millions of dollars in additional tax breaks by basing their deductions for donated insulins on the inflated list price.

341. Because of the increased list prices and related Manufacturer Payments, the PBMs' profit per prescription has grown exponentially during the relevant period as well. A recent study published in the Journal of the American Medical Association concluded that the amount of money that goes to the PBM Defendants for each insulin prescription increased more than 150% from 2014 to 2018. In fact, for transactions where the PBM Defendants control the PBM and the pharmacy (e.g., Caremark-CVS pharmacy) these Defendants were capturing an astonishing 40% of the money spent on each insulin prescription (up from only 25% just four years earlier), despite the fact that they do not contribute to the development, manufacture, innovation or production of the product.[47]

[47] Karen Van Nuys, et al., *Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans From 2014 to 2018*,

342. The PBM Defendants profit from the artificially inflated prices created by the Insulin Pricing Scheme in a number of ways, including by: (1) retaining a significant, yet undisclosed, percentage of the Manufacturers Payments, (2) using the inflated list price to generate profits from pharmacies, and (3) relying on the inflated list price to drive up the PBMs' margins through their own mail-order pharmacies.

The PBMs Pocket a Substantial Share of Manufacturer Payments

343. The first way in which the PBMs profit from the Insulin Pricing Scheme is by keeping a significant portion of the secret Manufacturer Payments.

344. The amount that the Manufacturers pay back to the PBMs has increased over time both in real dollars and as a proportion of the ever-increasing list prices.

345. Historically, contracts between PBMs and payors allowed the PBMs to keep most or all of the rebates they received, rather than forwarding them to the payor.

346. Over time, payors secured contract provisions guaranteeing payment to them of all or some portion of the rebates paid by the Manufacturers to the PBMs. Critically, however, "rebates" are only one aspect of the total Manufacturer Payments, particularly as "rebates" are narrowly defined and qualified by vague exceptions in the PBM contracts with payors.

347. Indeed, as described in the January 2021 Senate Insulin Report, the PBMs and Manufacturers coordinate to determine the contract options made available to payors: "Contracts between PBMs and manufacturers provide a menu of options from which their health plan clients can choose certain terms and conditions."[48] The contracts between the PBMs and Manufacturers also "stipulate terms the plans must follow regarding factors such as formulary placement and

JAMA Network (Nov. 5, 2021), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2785932 (last visited Aug. 23, 2023).

[48] Grassley & Wyden, *supra* note 2 at 40.

competition from other drugs in the therapeutic class."[49] Thus, the Manufacturers ultimately played a role in dictating the terms and conditions of the contracts that payors like Plaintiff entered into with PBMs. Of course, the payors were not involved in the coordination or the negotiation of the contracts between the PBMs and Manufacturers and the PBMs disclosed only the fact that such relationships may exist—the terms of the contracts, the consideration exchanged between the PBMs and Manufacturers, and the means of reaching these determinations all were and remain shrouded in secrecy.

348. The PBM and Manufacturer Defendants thus created a "hide-the-ball" system where payors like Plaintiff are not privy to rebate negotiations or contracts between the Manufacturers and the PBMs. The consideration exchanged between them (and not shared with payors) is labeled and relabeled. As more payors moved to contracts that required PBMs to remit some or all of the manufacturer "rebates" through to the payor, the PBMs rechristened Manufacturer Payments to shield them from scrutiny and from their payment obligations. Payments once called "rebates" now include administrative fees, volume discounts, service fees, inflation fees, or other industry monikers designed to obfuscate the substantial sums being secretly exchanged between the PBMs and the Manufacturers.

349. Just last year, the Senate Commerce, Science and Transportation Committee released testimony from David Balto—a former antitrust attorney with the DOJ and Policy Director for the FTC's Bureau of Competition—from a hearing on fairness and transparency in drug pricing:

> The PBM rebate system turns competition on its head with PBMs seeking higher, not lower prices to maximize rebates and profits. In the past decade, PBM profits have increased to $28 billion annually. . . . PBMs establish tremendous roadblocks to prevent payors from knowing the amount of rebates they secure. Even sophisticated buyers are unable to secure specific drug by drug rebate information.

[49] *Id.* at 44.

> PBMs prevent payors from being able to audit rebate information. As the Council of Economic Advisors observed, the PBM market lacks transparency as "[t]he size of manufacturer rebates and the percentage of the rebate passed on to health plans and patients are secret." Without adequate transparency, plan sponsors cannot determine if the PBMs are fully passing on any savings, or whether their formulary choices really benefit the plan and subscribers.

350. The renamed, undisclosed Manufacturer Payments are substantial. "Administrative fees" are one example. A heavily redacted complaint filed by Defendant Express Scripts in 2017 revealed that Express Scripts retains up to 13 times more in "administrative fees" than it remits to payors in rebates.[50]

351. These so-called administrative fees typically are based on a percentage of the drug price—as opposed to a flat fee—such that even if the actual "administrative" cost associated with processing two drugs is the same, the "administrative fee" would be correspondingly higher for the higher-priced drug, which creates (by design) a perverse incentive to give preference to more expensive drugs. Moreover, the PBM Defendants' contracts with payors, including those with Plaintiff, narrowly define "rebates" by tying them to patient drug utilization, so rebates for formulary placement are characterized as "administrative fees" that are not remitted to payors and are beyond a payor's contractual audit right to verify the accuracy of "rebate" payments under the contracts.

352. The opaque nature of these arrangements between the Manufacturers and PBM Defendants also makes it impossible for a given payor to discover, much less assess or confront, conflicts of interest that may affect it or its members. The January 2021 Senate Insulin Report observed with respect to these arrangements: "Relatively little is publicly known about these financial relationships and the impact they have on insulin costs borne by consumers."[51]

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[50] *Express Scripts, Inc. v. Kaleo, Inc.*, No. 4:17-cv-01520-RLW (E.D. Mo. 2017).
[51] Grassley & Wyden, *supra* note 2 at 4.

353. Unsurprisingly, the PBMs have gone to great lengths to obscure these renamed Manufacturer Payments in order keep them for themselves and to avoid scrutiny from payors and others.

354. For example, with regard to the Manufacturer Payments now known as "inflation fees," the PBMs often create a hidden gap between how much the Manufacturers pay them to increase their prices and the amount in "price protection guarantees" that the PBMs agree to pay back to their client payors.

355. In particular, the Manufacturer Defendants often pay the PBM Defendants "inflation fees" in order to increase the price of their diabetes medications. The thresholds for these payments are typically set at around 6% to 8%—if the Manufacturer Defendants raise their prices by more than the set percentage during a specified time period, they pay the PBM Defendants an additional "inflation fee" (based on a percentage of the list prices).

356. For many of their clients, the PBMs have separate "price protection guarantees" that state that if the overall drug prices for that payor increase by more than a set amount, then the PBMs will remit a portion of the amount to the client.

357. The PBMs set these "price protection guarantees" at a higher rate than the thresholds that trigger the Manufacturers' "inflation fees," usually around 10%-15%.

358. Thus, if the Manufacturers increase their list prices more than the 6% (or 8%) inflation fee rate but less than the 10%-15% client price protection guarantee rate, then the PBMs keep all of these "inflation fee" payments. This is a win-win for the Manufacturers and PBMs—they share and retain the entire benefit of these price increases while the PBM contracts with payors imply that payors are protected from price hikes by their price protection guarantees.

359. The PBMs also hide the renamed Manufacturer Payments with "rebate aggregators." Rebate aggregators, sometimes referred to as rebate group purchasing organizations ("GPOs"), are entities that negotiate for and collect payments from drug manufacturers, including the Manufacturer Defendants, on behalf of a large group of pharmacy benefit managers (including the PBM Defendants) and different entities that contract for pharmaceutical drugs.

360. These rebate aggregators are often affiliated with or owned by the PBM Defendants, such as Ascent Health Services (Express Scripts), Coalition for Advanced Pharmacy Services and Emisar Pharma Services (OptumRx), and Zinc (CVS Caremark).

361. The PBMs carefully guard the revenue streams from their rebate aggregator activities, hiding them in complex contractual relationships and not reporting them separately in their quarterly SEC filings.

362. Certain rebate-aggregator companies are located offshore, for example, in Switzerland (Express Scripts' Ascent Health) and Ireland (Emisar Pharma Services), making oversight even more difficult.

363. As summarized by the recent Community Oncology Alliance report:[52]

> PBMs have increasingly "delegated" the collection of manufacturer rebates to "rebate aggregators," which are often owned by or affiliated with the PBMs, without seeking authorization from plan sponsors and without telling plan sponsors. . . . Even some of the major PBMs (i.e., the "Big Three" PBMs) sometimes find themselves contracting with other PBMs' rebate aggregators for the collection of manufacturer rebates. . . . In both the private sector and with respect to government health care programs, the contracts regarding manufacturer rebates (i.e., contracts between PBMs and rebate aggregators, as well as contracts between PBMs/rebate aggregators and pharmaceutical manufacturers) are not readily available to plan sponsors.

364. For example, a 2017 audit conducted by a local governmental entity on Defendant OptumRx related to its PBM activities from 2013 to 2015 concluded that the auditor was unable

[52] Community Oncology Alliance, *supra* note 29.

to verify the percentage of rebates OptumRx remitted to its client payor because OptumRx would not allow the auditor access to its rebate contracts. The audit report explained:

> Optum[Rx] has stated that it engaged the services of an aggregator to manage its rebate activity. Optum[Rx] shared that under this model, they are paid by their aggregator a certain amount per prescription referred. Then, the aggregator, through another entity, seeks rebates from the drug manufacturers, based upon the referred [Payor Client] prescription utilization, and retains any rebate amounts that may be received. Optum[Rx] states that they have paid [Payor Client] all amounts it has received from its aggregator, and that they do not have access to the contracts between the aggregator (and its contractors) and the manufacturer. However, our understanding is that Optum[Rx] has an affiliate relationship with its aggregator.[53]

365. A footnote in the audit report clarifies that "Optum[Rx] contracted with Coalition for Advanced Pharmacy Services (CAPS), and CAPS in turn contracted with Express Scripts, Inc."

366. In other words, according to this report, OptumRx contracts with its own affiliate aggregator Coalition for Advanced Pharmacy Services, who then contracts with OptumRx's co-conspirator Express Scripts, who then contracts with the Manufacturers for rebates related to OptumRx's client's drug utilization. OptumRx then uses this complex relationship to obscure the amount of Manufacturer Payments that are being generated from its client's utilization.

367. A subsequent audit by the same local entity—covering the period September 2017 to September 2018, concluded:[54]

> Several material weaknesses in Broward's agreement with Optum were identified, many of which are commonplace across pharmacy benefit manager agreements in general. Due to contract weaknesses, comparison of Broward's PBM agreement, including rebate amounts received, to the Consultant's marketplace data is not feasible. Broward could save an estimated $1,480,000 per year in net prescription drug benefit expenses (based upon minimum rebate guarantees) by switching from

[53] Laura Rogers & Stacey Thomas, Broward County Florida, Audit of Pharmacy Benefit Management Services Agreement, No. 18-13 (Dec. 7, 2017), https://www.broward.org/Auditor/Reports/Documents/2017_1212%20Agenda%20Review%20of%20Pharmacy%20Benefit%20Management%20Services%20by%20StoneBridge/2017_1212%20Exh1_OptumRx.pdf (last visited Jan. 15, 2023).

[54] Broward County, Florida, *Analysis of Broward County's Prescription Drug Coverage*, https://www.broward.org/Auditor/Reports/Reports/082019_Exh1_BCRxDrug_19-15.pdf (last visited Aug. 23, 2023).

> its current flawed agreement with Optum, to an agreement with its Coalition, which offers clearly defined terms, increased rebate guarantees and cost saving requirements.

Among other "loopholes" discovered in the contract were a number of "flawed" (i.e., vague and manipulable) definitions—including the definition of Rebates, which "allows the exclusion of monies that should be included—and limitation with respect to "Pass Through Transparency Pricing."

368. The January 2021 Grassley-Wyden Senate Report summarizing findings of their two-year probe into the Insulin Pricing Scheme contained the following observation on these rebate aggregators[55]:

> [T]he recent partnership between Express Scripts and Prime Therapeutics may serve as a vehicle to avoid increasing legislative and regulatory scrutiny related to administrative fees by channeling such fees through a Swiss based group purchasing organization (GPO), Ascent Health. While there are several regulatory and legislative efforts underway to prohibit manufacturers from paying administrative fees to PBMs, there is no such effort to change the GPO safe harbor rules. New arrangements used by PBMs to collect fees should be an area of continued investigative interest for Congress.

369. Federal regulations governing Medicare attempt to capture all possible forms of Direct or Indirect Remuneration (DIR) to PBMs (and plan sponsors), defining DIR as "any form of price concession" received by a plan sponsor or PBM "from any source," including "discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, legal judgment amounts, settlement amounts from lawsuits or other legal action, and other price concessions or similar benefits. DIR also includes price concessions from and additional contingent payments to network pharmacies that cannot reasonably be determined at the point of sale."[56]

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[55] Grassley & Wyden, *supra* note 2 at 83.

[56] CMS, *Final Medicare Part D DIR Reporting Guidance for 2021* at 7, https://www.cms.gov/files/document/final2021dirreportingreqsmemo508v3.pdf (last visited Jan. 15, 2023).

370. The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) considers all of the following as DIR: rebates, grants, reduced price administrative services, PBM-retained rebates, PBM rebate guarantee amounts, all post-point of sale payments by pharmacies that are not included in the negotiating price including dispensing incentive payments, prompt pay discounts, and payment adjustments. On the other hand, "bona fide service fees from pharmaceutical manufacturers" and "remuneration for administrative services with no impact on the sponsor's or PBM's drug cost (e.g., PBM incentive payments)" are not considered DIR, but only to the extent they reflect fair market value for services rendered.[57]

371. Because the PBMs retain and conceal a majority of the secret Manufacturer Payments that they receive, they are able to reap significant profits on the Insulin Pricing Scheme.

372. Even where payor clients receive a portion of the Manufacturer Payments from their PBM, those payors still are significantly overcharged as a direct result of the Insulin Pricing Scheme given the extent to which Defendants have deceptively and egregiously inflated the prices of the at-issue drugs.

The Insulin Pricing Scheme Allows the PBMs to Profit Off Pharmacies

373. A second way the PBM Defendants profit off the Insulin Pricing Scheme is by using the Manufacturers' inflated price to derive profit from the pharmacies with whom they contract, including those in Hamblen County.

374. Each PBM Defendant decides which pharmacies are included in the PBM's network and how much it will reimburse these pharmacies for each drug dispensed.

375. The PBM Defendants, in coordination with the Manufacturers, directly reach out to patients, pharmacies, and prescribing physicians to convince them to switch to the diabetes

[57] *Id.* at 6-7.

medications that are more profitable for the PBMs and Manufacturers, even drafting and editing letters together to send to diabetes patients on behalf of the PBMs' clients [58]. The Defendants also petition these recipients to use the PBM Defendants' mail-order pharmacies and have succeeded in convincing patients, pharmacies, and prescribing physicians to do so.

376. The PBMs pocket the spread between the amount that the PBMs are paid by their clients for the at-issue drugs (which are based on the prices generated by the Insulin Pricing Scheme) and the amount the PBM reimburses the pharmacy (which often is less). In other words, the PBMs charge a client like Hamblen County more for a drug than the PBM pays the pharmacy and pockets the difference.

377. A bipartisan bill introduced in the Senate in 2022 (the Pharmacy Benefit Manager Transparency Act—S. 4293)—would have, criminalized spread pricing, which the bill defined as "[c]harg[ing] a health plan or payer a different amount for a prescription drug's ingredient cost or dispensing fee than the amount the pharmacy benefit manager reimburses a pharmacy for the prescription drug's ingredient cost or dispensing fee where the pharmacy benefit manager retains the amount of any such difference." The bill has not yet been enacted.[59]

378. Not coincidentally, the PBMs' industry-funded trade association PCMA spent $7.8 million on federal lobbying in 2021 and more $6 million through the third quarter of 2022.[60]

379. The PBMs often disclose the concept of spread pricing to payors, but only in vague terms that require no accountability and are not subject to the payors' audit rights because the revenue is not defined as a "rebate" in the PBM contracts with payors.

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[58] See supra 326(c).

[59] https://www.govtrack.us/congress/bills/117/s4293 (last visited Jan. 10, 2023).

[60] https://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2021&id=D000028342 (2021); https://www.opensecrets.org/federallobbying/clients/summary?cycle= 2022&id=D000028342 (2022) (last visited Jan. 10, 2023).

380. This spread pricing, like the secret Manufacturer Payment negotiation, happens behind closed doors. There is no transparency, no commitment from the PBM Defendants to account for the cost effectiveness of a drug, and no communication to either the payor or the pharmacy to let them know if they are getting a fair deal.

381. The higher the Manufacturers' list prices, the more money the PBMs make off this spread. At the same time, a Beneficiary's out-of-pocket co-pay or deductible cost often is more than if the client had simply paid cash outside of his or her plan. On top of this, the PBM contracts generally allow no rebates to payors where the Beneficiary is responsible for 100% of the drug cost, e.g., under his or her deductible.

382. The PBMs also use the Insulin Pricing Scheme to generate additional profits from pharmacies by charging the pharmacies post-purchase fees, including DIR (Direct or Indirect Remuneration) fees, based on the list prices—and again, the higher the list price for each diabetes medication sold, the more fees the PBMs generate—or by applying "retrospective" discounts. So, for example, a payor's (and member's co-pay or deductible) cost may be $100, but the price is discounted post-purchase (between the PBM and the (often self-owned) pharmacy) to $90 with the spread going to the PBM.

383. CMS addressed these and similar DIR issues in a proposed rule in 2017. While noting the growth of "pharmacy price concessions" that "are negotiated between pharmacies and their sponsors or PBMs," CMS nevertheless concluded:[61]

> When manufacturer rebates and pharmacy price concessions are not reflected in the price of a drug at the point of sale, beneficiaries might see lower premiums, but they do not benefit through a reduction in the amount they must pay in cost-sharing, and thus, end up paying a larger share of the actual cost of a drug. Moreover, given the increase in manufacturer rebates and pharmacy price concessions in recent

[61] Medicare Program; Contract Year 2019 Policy and Technical Changes, 82 Fed. Reg. 56336 (Nov. 29, 2017), https://www.govinfo.gov/content/pkg/FR-2017-11-28/pdf/2017-25068.pdf. Last visited Aug 23, 2023.

> years, the point-of-sale price of a drug that a Part D sponsor reports on a PDE record as the negotiated price is rendered less transparent . . . .

CMS expressed further concern that when rebates and other price concessions are not reflected in the negotiated point-of-sale drug price, it "can impede beneficiary access to necessary medications, which leads to poorer health outcomes and higher medical care costs for beneficiaries . . . ."

384. PBMs thus make money coming and going. In a pre-PBM world, a competitively priced drug might have a (hypothetical) net cost to a health plan $50 and that is what it paid. PBMs enter the picture and coordinate with Manufacturers to increase the list price to $150. The PBMs then "negotiate" the inflated price down to $100 and take a $50 rebate, some of which may be forwarded to the payor, whose net cost is less than the inflated list price, but whose real-world cost is considerably more than if the PBMs were not involved.

385. At the same time, the PBM receives "administrative fees" for including certain drugs on its formularies, which are not considered "rebates." The PBM also receives "service fees" or other payment for "administrative services" provided to the Manufacturers such as "formulary compliance initiatives," "education services," or "the sale of non-patient identifiable claim information." All of these revenues are outside the definition of "rebates."

386. The PBM then charges payors like the County for administrative fees for providing pharmacy benefit management services and charges for drug costs (i.e. ingredient costs) and per-prescription dispensing fees, as well as additional administrative fees for services not included in the PBM's general administrative obligations. The PBM also receives rebates and/or discounts (pre-purchase or post-purchase) from the pharmacies, which it often owns. These too are excluded from the definition of "rebates." These and other vaguely described revenue streams are sometimes disclosed but only in hazy, overly generalized terms. And they are beyond a payor's contractual

rights to audit for "transparency" purposes because they are not defined "rebates." Additionally, the PBM may take months to pay rebates to payors and the PBM retains all interest on, and the time-value of, the rebates pending payment.

387. Payors have no access to, and no knowledge of, the intricacies of the dealings between the PBM Defendants and the Manufacturers that are shrouded by such vague "disclosures" (which vary in detail, but not in substance, in all three of the PBM Defendants' adhesive contracts).

The Insulin Pricing Scheme Increases PBM Mail-Order Profit

388. Another way PBMs profit from the Insulin Pricing Scheme is through the PBM Defendants' own mail-order pharmacies. The higher the price that PBM Defendants are able to get customers, such as Plaintiff, to pay for diabetes medications, the higher the profits PBM Defendants realize through their mail-order pharmacies.

389. Because the PBMs base the price they charge for the at-issue diabetes medications on the Manufacturers' price, the more the Manufacturers inflate their prices, the more money the PBMs make. For example, the PBMs have colluded with the Manufacturers so that the PBMs often know when the Manufacturers are going to raise their prices. The PBMs use this opportunity to purchase a significant amount of the at- issue drugs prior to the price increase, at the lower rate. Then, after the Manufacturers raise their price, the PBMs charge their mail-order customers based on the higher, increased prices and pocket the difference. The PBMs make significant amounts of money through this arbitrage scheme.

390. The PBMs also charge the Manufacturer Defendants fees related to their mail-order pharmacies, such as pharmacy supplemental discount fees, that are directly tied to the

Manufacturers' price. Thus, once again, the higher the price, the more money the PBMs make on these fees.

391. In sum, every way in which the PBMs make money on diabetes medications is tied directly to creating higher prices and inducing larger secret Manufacturer Payments. The PBMs are not lowering the price of diabetes medications as they publicly represent; they are making billions of dollars by fueling these skyrocketing prices.

H. Plaintiff Purchases the At-Issue Drugs Directly from Defendants

392. As a government employer, Plaintiff serves its residents by providing public safety, emergency management, and health services, among other vital roles. As more federal and state responsibilities are mandated to local government, Plaintiff has a growing list of demands on a limited budget. Consequently, any significant increase in spending can have a severe detrimental effect on Plaintiff's overall budget and, in turn, negatively impact its ability to provide necessary services to the community.

393. One benefit Plaintiff provides the Beneficiaries of its healthcare plan is payment for a large portion of their pharmaceutical purchases. In this role, Plaintiff spent significant amounts on the at-issue diabetes medications during the relevant period.

394. Because Plaintiff maintains a self-funded plan for County employees, Plaintiff does not rely on a third-party insurer to pay for insured employees' medical care, pharmaceutical benefits, or prescription drugs. Rather, Plaintiff directly contracts with, and directly pays, PBMs (and their affiliated pharmacies) for pharmaceutical benefits and prescription drugs, including the at-issue medications.

395. Plaintiff also purchased, and still purchases, the at-issue drugs directly from these PBMs (and their affiliated pharmacies) for use in Plaintiff's county-run facilities.

396. In the context of Plaintiff's purchases of the at-issue drugs, Plaintiff and its Beneficiaries are the only victims of the Insulin Pricing Scheme. Plaintiff is the only named party that pays the full purchase price for the at-issue drugs, and the only named party that has not knowingly participated in the Insulin Pricing Scheme. Neither the PBM Defendants nor the Manufacturers Defendants suffer losses from the Insulin Pricing Scheme.

397. As part of purchasing the at-issue drugs from the PBMs, Plaintiff directly pays the PBMs artificially inflated costs resulting from the Insulin Pricing Scheme, including "administrative fees," "inflation fees," "discount fees," and more—all of which are associated with Plaintiff's purchase of the at-issue drugs from the PBM Defendants. Because the at-issue medications are potentially life-saving drugs, and because the Manufacturers control the market for these drugs, Plaintiff has no choice but to pay these exorbitant, artificially inflated prices directly to PBM Defendants.

398. Plaintiff also relies (and has relied) on CVS Caremark and Express Scripts as administrative agents, for the alleged purposes of limiting its administrative burden and controlling pharmaceutical drugs costs.

399. In providing PBM services to the County, including developing and offering formularies for Plaintiff's prescription plan, constructing and managing Plaintiff's pharmacy network (which included the PBMs' retail and mail-order pharmacies), processing pharmacy claims, and providing mail-order pharmacy services, Express Scripts and CVS Caremark set the amount Plaintiff paid in coordination with the Manufacturer Defendants and, utilizing the false prices, generated by the Insulin Pricing Scheme. Plaintiff paid Express Scripts and CVS Caremark directly for the at-issue drugs.

I. Defendants Deceived Plaintiff

400. At no time has either Defendant group disclosed the Insulin Pricing Scheme or the reasons for the false list prices produced by it.

The Manufacturer Defendants Deceived Plaintiff

401. At all times during the relevant period, the Manufacturer Defendants knew that the list prices, net prices, and payors' net costs (purchase prices) generated by the Insulin Pricing Scheme were false, excessive, and untethered to any legal, competitive, or fair market price.

402. The Manufacturer Defendants knew that these prices did not bear any rational relationship to the actual costs incurred or prices realized by Defendants, did not result from transparent or competitive market forces, and were artificially and arbitrarily inflated for the sole purpose of generating profits for Defendants.

403. The insulin market, and Defendants' business arrangement relating thereto, exhibit the key features of oligopolies (see Fig. 14)—concentration of numerous competitors into a small group of firms that dominates the market, high barriers to entry, ability to set and control prices, firm interdependence, and maximal revenues.

404. The Manufacturer Defendants also knew that payors, including Plaintiff, relied on the false list prices generated by the Insulin Pricing Scheme to pay for the at-issue drugs.

405. The Manufacturer and PBM Defendants further knew that Plaintiff—like any reasonable consumer, and particularly one with fiduciary obligations to its Beneficiaries—wanted and expected to pay a price reflecting the lowest fair market value for the drugs (which was not necessarily the same as the lowest price in the market, given that all prices were inflated due to the Insulin Pricing Scheme).

406. Despite this knowledge, the Manufacturer Defendants published the prices generated by the Insulin Pricing Scheme throughout the United States and Tennessee through

publishing compendia, in various promotional and marketing materials distributed by entities downstream in the drug supply chain, and directly to pharmacies which then used these prices to set the amount that the pharmacies charged for the at-issue drugs.

407. The Manufacturer Defendants also publish these prices to the PBMs and pharmacies, which then use them to charge diabetics and payors like Plaintiff for the at-issue drugs.

408. By publishing their prices throughout Tennessee, the Manufacturer Defendants held these prices out as a reasonable price upon which to base the prices that payors actually pay for the at-issue drugs.

409. These representations are false. The Manufacturer Defendants knew that their artificially inflated list prices were not remotely related to their cost, their fair market value in a competitive market, or the net price received for the at-issue drugs.

410. During the relevant period, the Manufacturer Defendants published prices in Tennessee at hundreds of dollars per dose for the same at-issue drugs that would have been profitable to Manufacturers at prices less than $10 per dose.

411. The Manufacturer Defendants also have publicly represented that they price the at-issue drugs according to each drug's value to the health care system and the need to fund innovation. For example, briefing materials prepared for Dave Ricks, Eli Lilly's CEO, as a panelist at the 2017 Forbes Healthcare Summit included "Reactive Key Messages" on pricing that emphasized the significant research and development costs for insulin. During the relevant period, executives from Sanofi and Novo Nordisk also falsely represented that research and development costs were key factors driving the at-issue price increases.[62]

[62] Drug Pricing Investigation, H.R. Comm. On Oversight and Reform, 117th Cong. (2021), https://web.archive.org/web/20211215170722/https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf (last visited Jan. 10, 2023).

412. To the contrary, between 2005 and 2018, Eli Lilly spent $680 million on R&D costs related to Humalog while earning $31.35 billion in net sales during that same time period. In other words, Eli Lilly made more than 46 times its reported R&D costs on Humalog during this portion of the relevant period, i.e., R&D costs amounted to about 2% of net sales (whereas R&D costs for pharmaceuticals typically amount to around 20% of total revenues). Novo Nordisk has spent triple the amount it spends on R&D on stock buyouts and shareholder dividend payouts in recent years.[63]

413. The January 2021 Senate Insulin Report found that the PBMs consider insulins to be "interchangeable" from "a clinical perspective" and that Manufacturers focus their R&D efforts on new insulin-related device, equipment, and other mechanical parts which are separate from insulin's formulation."[64]

414. A House Oversight Committee staff report concluded that "drug companies' claims that reducing U.S. prescription drug prices will harm innovation is overblown" and that "[m]any drug companies spent a significant portion of their R&D budget on finding ways to suppress generic and biosimilar competition while continuing to raise prices, rather than on innovative research."[65]

415. In sum, the Manufacturer Defendants affirmatively withheld the truth from Plaintiff and specifically made these misrepresentations in furtherance of the Insulin Pricing Scheme and

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[63] *Id.*

[64] Grassley & Wyden, *supra* note 2 at 5, 17.

[65] U.S. House of Reps., *Drug Pricing Investigation: Industry Spending on Buybacks, Dividends and Executive Compensation* (July 2021), https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/COR%20Staff%20Report%20-%20Pharmaceutical%20Industry%20Buybacks%20Dividends%20Compared%20to%20Research.pdf (last visited Aug. 23, 2023).

to induce Plaintiff's reliance to purchase the at-issue drugs. The PBM Defendants Deceived Plaintiff

416. The PBM Defendants ensured that the Manufacturer Defendants' artificially inflated list prices harmed diabetics and payors by selecting the highest price at-issue drugs for preferred formulary placement and by requiring that their contracts with both pharmacies and with payors include such prices as the basis for payment.

417. The PBM Defendants perpetuate the use of the artificially inflated insulin prices because it allows them to obscure the actual price any entity in the drug pricing chain is paying for the at-issue drugs. This lack of transparency affords Defendants the opportunity to construct and perpetuate the Insulin Pricing Scheme and to profit therefrom at the expense of Tennessee payors, including Plaintiff.

418. At all times throughout the relevant period, the PBMs have purposefully, consistently, and routinely misrepresented that they negotiate with Manufacturer Defendants and construct formularies for the benefit of payors and patients by lowering the price of the at-issue drugs and by promoting the health of diabetics. Representative examples include: [66]

- Defendant CVS Caremark has for the past decade consistently stated in its annual reports that its design and administration of formularies are aimed at reducing the costs and improving the safety, effectiveness, and convenience of prescription drugs. CVS Caremark has further stated that it maintains an independent panel of doctors, pharmacists, and other medical experts to review and approve the selection of drugs based on safety and efficacy for inclusion on one of Caremark's template formularies and that CVS Caremark's formularies lower the cost of drugs.

- Likewise, Defendant Express Scripts has consistently represented that it works with clients, manufacturers, pharmacists, and physicians to increase efficiency in the drug distribution chain, to manage costs in the pharmacy benefit chain, and to improve members' health outcomes. Its annual reports consistently claim that in making formulary recommendations, Express Scripts' Pharmacy & Therapeutics Committee considers the drug's safety and efficacy, without any information on or

[66] CVS Health Annual Reports (Form 10-K) (FY 2010-2019); OptumRx Annual Reports (Form 10-K) (FY 2010-2019); Express Scripts Annual Reports (Form 10-K) (FY 2010-2019).

consideration of the cost of the drug, including any discount or rebate arrangement that Express Scripts negotiates with the Manufacturer, and that Express Scripts fully complies with the P&T Committee's clinical recommendations regarding drugs that must be included or excluded from the formulary based on their assessment of safety and efficacy.

- Similarly, Defendant OptumRx has consistently stated in its annual reports over the past decade that OptumRx's rebate contracting and formulary management assist customers in achieving a low-cost, high-quality pharmacy benefit. It has consistently claimed that it promotes lower costs by using formulary programs to produce better unit costs, encouraging patients to use drugs that offer improved value and that OptumRx's formularies are selected for health plans based on their safety, cost and effectiveness.

419. In addition to these general misrepresentations, the PBM Defendants have during the relevant period purposefully, consistently, and routinely made misrepresentations about the at-issue diabetes medications. Representative examples include:

- In a public statement issued in November 2010, CVS Caremark represented that it was focused on diabetes to "help us add value for our PBM clients and improve the health of plan members . . . a PBM client with 50,000 employees whose population has an average prevalence of diabetes could save approximately $3.3 million a year in medical expenditures."[67]

- In 2010, Andrew Sussman, Chief Medical Officer of CVS Caremark, stated on national television that "CVS is working to develop programs to hold down [diabetes] costs."[68]

- In a public statement issued in November 2012, CVS Caremark represented that formulary decisions related to insulin products "is one way the company helps manage costs for clients."[69]

- In 2016, Glen Stettin, Senior Vice President and Chief Innovation Officer at Express Scripts, said in an interview with a national publication that "[d]iabetes is wreaking havoc on patients, and it is also a runaway driver of costs for payors . . .

[67] Chain Drug Review, *CVS Expands Extracare for Diabetes Products* (May 11, 2010), https://www.chaindrugreview.com/cvs-expands-extracare-for-diabetes-products/ (last visited Jan. 15, 2023).

[68] CBS News, Diabetes Epidemic Growing (June 22, 2010, 11:29 AM), https://www.cbsnews.com/news/diabetes-epidemic-growing/ (last visited Aug. 23, 2023).

[69] Jon Kamp & Peter Loftus, *CVS' PBM Business Names Drugs It Plans to Block Next Year*, WSJ (Nov. 8, 2012), https://www.wsj.com/articles/SB10001424127887324439804578 107040729812454 (last visited Jan. 15, 2023).

[Express Scripts] helps our clients and diabetes patients prevail over cost and care challenges created by this terrible disease."[70] Mr. Stettin also claimed that Express Scripts "broaden[s] insulin options for patients and bend[s] down the cost curve of what is currently the costliest class of traditional prescription drugs."[71]

- In a 2018 Healthline interview, Mark Merritt, longtime President of the PBM trade association PCMA, stated: "[Through their formulary construction], PBMs are putting pressure on drug companies to reduce insulin prices."[72]

- CVS Caremark's Chief Policy and External Affairs Officer claimed in the April 2019 hearings that CVS Caremark "has taken a number of steps to address the impact of insulin price increases. We negotiate the best possible discounts off the manufacturers' price on behalf of employers, unions, government programs, and beneficiaries that we serve."[73]

- Dr. Sumit Dutta, SVP and Chief Medical Officer of OptumRx, testified before the U.S. Congress in the April 2019 hearing that for "insulin products . . . we negotiate with brand manufacturers to obtain significant discounts off list prices on behalf of our customers."[74]

- The PBM-funded trade association PCMA's website acknowledges, "the insulin market is consolidated, hindering competition and limiting alternatives, leading to higher list prices on new and existing brand insulins," but then misleadingly claims that "PBMs work hard to drive down costs using formulary management and rebates."[75]

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[70] https://www.bizjournals.com/stlouis/news/2016/08/31/express-scripts-launchesprogram-to-control.html (last visited Jan. 15, 2023).

[71] Angela Mueller, *Express Scripts Launches Program to Control Diabetes Costs*, St. Louis Bus. J. (Aug. 31, 2016), https://drugstorenews.com/pharmacy/express-scriptsimplements-latest-diabetes-care-value-program (last visited Jan. 15, 2023).

[72] Dave Muoio, *Insulin Prices: Are PBMs and Insurers Doing Their Part?*, Population Health Learning Network (Dec. 2016), https://www.hmpgloballearningnetwork.com/site/frmc/ article/insulin-prices-are-pbms-and-insurers-doing-their-part (last visited Jan. 15, 2023).

[73] *Priced Out of a Lifesaving Drug*, *supra* note 35.

[74] *Id*.

[75] PCMA, *PCMA on National Diabetes Month: PBMs Lowering Insulin Costs, Providing Support to Patients* (Nov. 16, 2020), https://www.pcmanet.org/pcma-on-nationaldiabetes-month-pbms-lowering-insulin-costs-providing-support-to-patients/ (last visited Aug. 23, 2023); Visante, *Insulins: Managing Costs with Increasing Manufacturer Prices* (2020), https://www. pcmanet.org/ wpcontent/uploads/2020/08/PCMA_Visante-Insulins-Prices-and-Costs-.pdf.

420. The PBM Defendants not only falsely represent that they negotiate with the Manufacturer Defendants to lower the price of the at-issue diabetes medications for *payors*, but also for diabetic *patients* as well. Representative examples include:

- Express Scripts' code of conduct, effective beginning in 2015, states: "At Express Scripts we're dedicated to keeping our promises to *patients and clients* . . . This commitment defines our culture, and all our collective efforts are focused on our mission to make the use of prescription drugs safer and more affordable."[76] (emphasis added)

- Amy Bricker, former President of Express Scripts and PCMA board member, testified before Congress in April 2019: "At Express Scripts we negotiate lower drug prices with drug companies on behalf of our clients, *generating savings that are returned to patients* in the form of lower premiums and reduced out-of-pocket costs."[77] (emphasis added)

- Ms. Bricker of Express Scripts also testified that "Express Scripts remains committed to . . . *patients* with diabetes and creating affordable access to their medications."[78] (emphasis added)

- OptumRx CEO John Prince testified to the Senate: "We *reduce the costs of prescription drugs* [and] we are leading the way to ensure that *those discounts directly benefit consumers*. . . . OptumRx's pharmacy care services business is *achieving better health outcomes for patients, lowering costs* for the system, and *improving the healthcare experience for consumers*. . . . OptumRx negotiates better prices with drug manufacturers *for our customers and for consumers*.[79] (emphasis added)

- In its 2017 Drug Report, CVS Caremark stated that the goal of its pharmacy benefit plans is to ensure "that the cost of a drug is aligned with the value it delivers in terms of *patient* outcomes . . . in 2018, we are doing even more to help keep drugs affordable with our new Savings *Patients* Money initiative." (emphasis added)[80]

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[76] Express Scripts, *Code of Conduct*, https://www.expressscripts.com/aboutus/codeconduct/ExpressScriptsCodeOfConduct.pdf (last visited Jan. 10, 2023).

[77] *Priced Out of a Lifesaving Drug*, *supra* note 35.

[78] *Id.*

[79] Grassley & Wyden, *supra* note 2—*Hearing Transcript* at 174, https://www.finance.senate.gov/imo/media/doc/435631.pdf (last visited Aug. 23, 2023).

[80] CVS Health, *2017 Drug Trend Report* (Apr. 5, 2018), https://payorsolutions.cvshealth.com/insights/2017-drug-trend-report (last visited Aug. 23, 2023).

- The PCMA website touts PBMs as "the only entity in the prescription drug supply and payment chain dedicated to reducing drug costs" and (contradicting the PBM representatives' Congressional testimony), that "when new manufacturers enter the market at a lower list price, PBMs use the competition to drive costs down."[81]

421. Not only have PBM Defendants intentionally misrepresented that they use their market power to save payors money, but they have specifically and falsely disavowed that their conduct drives prices higher. Representative examples include:

- On an Express Scripts' earnings call in February 2017, CEO Tim Wentworth stated: "Drugmakers set prices, and we exist to bring those prices down."[82]

- Larry Merlo, head of CVS Caremark sounded a similar refrain in February 2017: "Any suggestion that PBMs are causing prices to rise is simply erroneous."[83]

- In 2017, Express Scripts' Wentworth went on CBS News to argue that PBMs play no role in rising drug prices, stating that PBMs work to "negotiate with drug companies to get the prices down."[84]

- During the April 2019 Congressional hearings, when asked if PBM-negotiated rebates and discounts were causing the insulin price to increase, OptumRx's Chief Medical Officer Sumit Dutta answered: "we can't see a correlation when rebates raise list prices."[85]

- In 2019, when testifying under oath before Congress on the rising price of insulins, Amy Bricker—former President of Express Scripts and PCMA board member—testified: "I have no idea why the prices [for insulin] are so high none of it is the fault of rebates."[86]

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[81] PCMA, *PBMs Reduce Insulin Costs: PBMs are working to improve the lives of patients living with diabetes and their families*, https://www.pcmanet.org/insulin-managingcosts-with-increasing-manufacturer-prices/ (last visited Jan. 10, 2023).

[82] Samantha Liss, *Express Scripts CEO Addresses Drug Pricing 'Misinformation'*, St. Louis Post-Dispatch (Feb. 17, 2017), https://www.stltoday.com/business/local/expressscripts-ceo-addresses-drug-pricing-misinformation/article_8c65cf2a-96ef-5575-8b5c-95601ac51840.html (last visited Jan. 11, 2023).

[83] Lynn R. Webster, *Who Is To Blame For Skyrocketing Drug Prices?*, The Hill (July 27, 2017, 11:40 AM), https://thehill.com/blogs/pundits-blog/healthcare/344115-who-is-toblame-for-skyrocketing-drug-prices (last visited Jan. 11, 2023).

[84] CBS News, *Express Scripts CEO Tim Wentworth Defends Role of PBMs in Drug Prices* (Feb 7, 2017), https://www.cbsnews.com/news/express-scripts-tim-wentworth-pbmrising-drug-prices-mylan-epipen-heather-bresh/ (last visited Jan. 11, 2023).

[85] *Priced Out of a Lifesaving Drug*, *supra* note 35.

[86] *Id.*

422. All of Defendants' public statements regarding insulin pricing have been consistent with the misrepresentations above and those detailed below. None have contradicted those misrepresentations or revealed the Insulin Pricing Scheme.

423. The PBM Defendants understand that payors like Plaintiff rely on the PBMs to achieve the lowest prices for the at-issue drugs and to construct formularies designed to improve access to medications. Plaintiff did so rely.

424. Throughout the relevant period, the PBM Defendants also falsely claimed they are transparent about the Manufacturer Payments and that the amounts they remit (or not) to payors. In fact, the PBM Defendants' disclosures of their ties to the Manufacturer Defendants were vague, equivocal, and misleading. Their manner of defining "rebates" in payor contracts was illusory and subject to indeterminate conditions and exceptions. The PBM Defendants thereby facilitated and obtained secret Manufacturer Payments far above and beyond the amount of "rebates" remitted to payors.

425. The PBMs' internal processes and accounting were and are abstruse and opaque, allowing them to overtly mislead the public and payors like Plaintiff.

426. In 2011, for example, OptumRx's President stated: "We want our clients to fully understand our pricing structure . . . [e]very day we strive to show our commitment to our clients, and one element of that commitment is to be open and honest about our pricing structure."[87]

[87] UnitedHealth Group, *Prescription Solutions by OptumRx Receives 4th Consecutive TIPPS Certification for Pharmacy Benefits Transparency Standards* (Sept. 13, 2011), https://web.archive.org/web/20210805182422/https://www.unitedhealthgroup.com/newsroom/2011/0913tipps.html (last visited Jan. 11, 2023). *See also, e.g.*, published version of press release at https://www.businesswire.com/news/home/20110913006224/en/Prescription-Solutions-by-OptumRx-Receives-4th-Consecutive-TIPPSSM-Certification-for-Pharmacy-Benefits-Transparency-Standards (last visited Aug. 23, 2023).

427. In a 2017 CBS News interview, Express Scripts' CEO represented, among other things, that Express Scripts was "absolutely transparent" about the Manufacturer Payments they receive and that payors "know exactly how the dollars flow" with respect to these Manufacturer Payments.[88]

428. When testifying before the Senate Finance Committee, CVS Executive Vice President Derica Rice stated: "[A]s it pertains to transparency overall, we at CVS Caremark are very supportive. We provide full visibility to our clients of all our contracts and the discounts that we negotiate on their behalf. . . . And transparency—today we report and fully disclose not only to our clients, but to CMS [Medicare]."[89]

429. At the same hearing, Steve Miller of Cigna (Express Scripts) testified: "we are a really strong proponent for transparency for those who pay for health care. So the patient should know exactly what they are going to pay. Our plan sponsors should know exactly what is in their contract."[90]

430. John Prince of OptumRx chimed in: "Senator, if our discounts were publicly available, it would hurt our ability to negotiate effectively. Our discounts are transparent to our clients."[91]

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[88] CBS News, *supra* note 79.

[89] Grassley & Wyden, *supra* note 2—*Hearing Transcript* at 28, 32, https://www.finance.senate.gov/imo/media/doc/ 435631.pdf (last visited Jan. 11, 2023).

[90] *Id.* at 32.

[91] *Id.*

431. When testifying before Congress in April 2019, Amy Bricker, then a Senior Vice President of Defendant Express Scripts, claimed transparency with payors and echoed Mr. Prince's need for confidentiality around discounts:[92]

> Ms. Bricker. The rebate system is 100 percent transparent to the plan sponsors and the customers that we service. To the people that hire us, employers of America, the government, health plans, what we negotiate for them is transparent to them. . . The reason I'm able to get the discounts that I can from the manufacturer is because it's confidential [to the public].
>
> ***
>
> Mr. Sarbanes. Yeah, because it's a secret. What about if we made it completely transparent? Who would be for that?
>
> ***
>
> Ms. Bricker. Absolutely not . . . [i]t will hurt the consumer. . . . prices will be held high.

432. As recently as May 2022, JC Scott—President of the PBM trade group PCMA—testified as follows before the Senate Commerce Committee:

> PBMs are proud of the work they do to reduce prescription drug costs, expand affordable access to medications, and improve patient outcomes. PBMs negotiate with drug companies to lower prescription drug costs PBMs advocate for patients in the fight to keep prescription drugs accessible and affordable.

433. Mirroring the PCMA website (¶¶ 429, 430, *supra*), Mr. Scott also testified, "The PBM industry is the only stakeholder in the chain dedicated to seeking lower costs."

434. During the relevant period—as seen above—PBM Defendants represented to Plaintiff that they constructed formularies and negotiated with the Manufacturer Defendants for the benefit of payors and patients to maximize drug cost savings while promoting the health of diabetics.

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[92] *Priced Out of a Lifesaving Drug, supra* note 35.

435. Throughout the relevant period, the PBMs made the foregoing and similar misrepresentations consistently and directly to Tennessee payors, including Hamblen County, through bid proposals, member communications, invoices, formulary change notifications, and through extensive direct-to-consumer pull through efforts engaged in with the Manufacturers.

436. All of these representations are false. The Manufacturer and PBM Defendants in fact coordinated to publish the false prices and to construct the PBM formularies, causing the price of the at-issue drugs to skyrocket. For example:

a. In 2018, the US spent $28 billion (USD) on insulin compared with $484 million in Canada. The average American insulin user spent $3,490 on insulin in 2018 compared with $725 among Canadians.

b. Diabetics who receive their medications from federal programs that do not utilize PBMs also pay significantly less. For example, in December 2020, the United States House of Representatives Committee on Oversight and Reform issued a Drug Pricing Investigation Report finding that federal health care programs that negotiate directly with the Manufacturers (such as the Department of Veterans Affairs), and are thus outside the PBM Defendants' scheme, paid $16.7 billion less from 2011 through 2017 for the at-issue drugs than the Medicare Part D program, which relies on the PBM Defendants to set their at-issue drug prices (and are thus victims of the PBMs' concerted efforts to drive up the list prices).

437. Defendants knew their representations were false when they made them and coordinated to affirmatively withhold the truth from payors, including Plaintiff.

438. Defendants concealed the falsity of their representations by closely guarding their pricing negotiations, structures, agreements, sales figures, and the flow of money and other consideration between them.

439. The Defendants have never revealed the full amount of any drug-specific Manufacturer Payments exchanged between them.

440. The PBM Defendants do not disclose the terms of their agreements with the Manufacturers or the Manufacturer Payments they receive. Nor do they disclose the details related

to their agreements (formal or otherwise) with pharmacies. All of these revenue streams are beyond the scope of the payors' contractual audit rights.

441. Further, although PBMs negotiate drug-specific rebates with Manufacturers,[93] the PBM rebate payments to payor clients and summaries of such payments are in the aggregate, rather than on a drug-by-drug basis. It is impossible for payors like Plaintiff to tease out drug-specific rebates, much less the other undisclosed Manufacturer Payments. This allowed the PBM Defendants to hide the large Manufacturer Payments that they receive for the at-issue diabetes medications.

442. The PBM Defendants have gone so far as to sue governmental entities to block the release of details on their pricing agreements with the Manufacturers and pharmacies.

443. Even when audited by payors, the PBM Defendants routinely refuse to disclose their agreements with the Manufacturers and pharmacies, relying on overly broad confidential agreements, claims of trade secrets, and erecting other unnecessary roadblocks and restrictions.

444. Beneficiaries of the Plaintiff's health plans have no choice but to pay prices flowing from Defendants' inflated list prices because Beneficiaries need these medications to survive and the Manufacturer Defendants make virtually all diabetes medications available in the United States. The list prices generated by the Defendants' coordinated efforts directly impact out-of-pocket costs at the point of sale.

445. In sum, the entire insulin pricing structure created by the Defendants—from the false prices to the Manufacturers' misrepresentations related to the reason behind the price, to the inclusion of the false prices in payor contracts, to the non-transparent Manufacturer Payments, to

[93] Grassley & Wyden, *supra* note 2 at 40.

the misuse of formularies, to the PBMs' representations that they work to lower prices and promote the health of diabetics—is unconscionable, deceptive, and immensely lucrative.

446. Plaintiff did not know, because the Defendants affirmatively concealed, that (1) the Manufacturers and PBMs coordinated to create the PBM formularies in exchange for money and other consideration; (2) the list prices were falsely inflated; (3) the list prices were manipulated to satisfy PBM profit demands; (4) the list prices and net costs (purchase prices) paid by Plaintiff bore no relationship to the fair market value of the drugs themselves or the services rendered by the PBMs in coordinating their pricing; or (5) the entire insulin pricing structure Defendants created was false.

J. The Insulin Pricing Scheme Has Damaged Plaintiff

447. Plaintiff Hamblen County provides health and pharmacy benefits to its Beneficiaries, including employees, retirees, and their dependents, who have numbered in the thousands throughout the relevant period.

448. One benefit Plaintiff provides the Beneficiaries of its healthcare plan is paying for their pharmaceutical needs.

449. Plaintiff entered into an agreement with CVS Caremark, whereby CVS Caremark agreed to provide Plaintiff prescription drug benefits and other at-issue services.

450. Plaintiff and Medco entered into an agreement whereby Medco agreed to provide Plaintiff prescription drug benefits and other at-issue services.

451. Plaintiff has renewed and had an active agreement in place with either Express Scripts or Medco or CVS Caremark.

452. Express Scripts acquired Medco in 2012.

453. Plaintiff requested proposals from the PBM Defendants for the at issue services.

454. In response to Plaintiff's requests, all PBM Defendants submitted proposals.

455. Plaintiff was unaware of the Insulin Pricing Scheme. Plaintiff relied on Defendants' public statements and material omissions.

456. Plaintiff contracted with Defendant Express Scripts, Inc. and CVS Caremark for PBM services.

457. Defendants' Insulin Pricing Scheme has cost Plaintiff millions of dollars in overcharges.

458. Indeed, since 2003 Hamblen County has spent exorbitant amounts of money on the at-issue diabetes medications.

459. CVS Caremark's and Express Scripts' respective relationships with Plaintiff were inherently unbalanced and their contracts adhesive. Both Defendants had superior bargaining power and superior knowledge of their relationships with the Manufacturer Defendants, including those that ultimately dictate the drug costs Plaintiff incurred. Although Defendants were supplying a vital service of a quasi-public nature, they both exploited their superior positions to mislead Plaintiff and thwart its expectations, all at great expense to Hamblen County.

460. The Defendants' misrepresentations, omissions, and misconduct—including and as manifested in the Insulin Pricing Scheme—directly and proximately caused economic damage to Plaintiff as a payor/purchaser of Defendants' at-issue diabetes medications.

461. A substantial proportion of the money Plaintiff spent on diabetes medications is attributable to Defendants' inflated prices, which did not arise from competitive market forces but, instead, exist solely by virtue of the Insulin Pricing Scheme.

462. Because of Defendants' success in concealing the Insulin Pricing Scheme through act and omission, no payor, including Plaintiff, knew (or should have known) during the relevant

period that the prices for the at-issue diabetes medications were (and are) artificially inflated due to the Insulin Pricing Scheme.

463. As a result, despite receiving some rebates and incurring drug costs based on discounts off list prices, Plaintiff has unknowingly overpaid for the Manufacturer Defendants' diabetes medications, which would have cost far less but for the Insulin Pricing Scheme.

464. In short, the Insulin Pricing Scheme has directly and proximately caused Plaintiff to substantially overpay for diabetes medications.

465. Because Defendants continue to generate exorbitant, unfair, and deceptive prices for the at-issue drugs through the Insulin Pricing Scheme, the harm to Plaintiff is ongoing.

K. Defendants' Recent Efforts in Response to Rising Insulin Prices

466. In reaction to mounting political and public outcry, Defendants have taken action both on Capitol Hill and in the public relations space.

467. First, in response to public criticism, Defendants have increased their spending to spread their influence in Washington D.C.

468. For example, in recent years Novo Nordisk's political action committee ("PAC") has doubled its spending on federal campaign donations and lobbying efforts. In 2017 alone, Novo Nordisk spent $3.2 million lobbying Congress and federal agencies, its biggest ever investment in directly influencing U.S. policymakers. Eli Lilly and Sanofi also have contributed millions of dollars through their PACs in recent years.

469. Second, Defendants have recently begun publicizing programs ostensibly aimed at lowering the cost of insulins.

470. These affordability measures fail to address the structural issues that caused the price hikes. Rather, these are public-relations measures that do not solve the problem.

471. For example, in March 2019, Defendant Eli Lilly announced that it would produce an authorized generic version of Humalog, "Insulin Lispro," and promised that it would "work quickly with supply chain partners to make [the authorized generic] available in pharmacies as quickly as possible."

472. However, in the months after Eli Lilly's announcement, reports raised questions about the availability of "Insulin Lispro" in local pharmacies.

473. Following this the staff of the Offices of U.S. Senators Elizabeth Warren and Richard Blumenthal prepared a report examining the availability of this drug. The investigative report, *Inaccessible Insulin: The Broken Promise of Eli Lilly's Authorized Generic*, concluded that Eli Lilly's lower-priced, authorized generic insulin is widely unavailable in pharmacies across the country, and that the company has not taken meaningful steps to increase insulin accessibility and affordability.[94]

474. Eli Lilly did lower the price of Lispro by 40% effective January 1, 2022; but it is not included in any of the PBM Defendants' formularies as of January 2023.

475. In 2019, Novo Nordisk partnered with Walmart to offer ReliOn brand insulins for a discounted price at Walmart. However, experts have warned that the Walmart/Novo Nordisk insulins are not substitutes for most diabetics' regular insulins and should only be used in an emergency or when traveling. In particular, for many diabetics, especially Type 1 diabetics, these insulins can be dangerous. In any event, ReliOn is not included in any of the PBM Defendants' formularies as of January 2023.

[94] Sen. Elizabeth Warren & Sen. Richard Blumenthal, *Inaccessible Insulin: The Broken Promise of Eli Lilly's Authorized Generic*, (Dec. 2019), https://www.warren.senate.gov/imo/media/doc/Inaccessible%20Insulin%20report.pdf (last visited Aug. 23, 2023).

476. Thus, Defendants' "lower priced" insulin campaigns have not addressed the problem, and the PBMs continue to exclude drugs with lower list prices despite their assurances of cost-savings for payors and Beneficiaries. Plaintiff continues to suffer harm caused by the Insulin Pricing Scheme.

477. Likewise, FDA in 2020 approved the biosimilar Insulin Glargine-yfgn (branded as Semglee), which is manufactured and sold by newcomers to the market—Viatris and Biocon Biologics.[95] Insulin Glargine-yfgn (Semglee) is interchangeable with Defendant Sanofi's Lantus product and, according Viatris, its list price is three times cheaper than Lantus. It is not included in any of the PBM Defendants' formularies as of January 2023.

[95] As explained in n.3, insulin now is regulated as a biologic rather than a drug. Biosimilars are analogous to generic drugs—approved versions of original products that are virtually identical to, and interchangeable with, the original product.

CLAIMS FOR RELIEF

First Cause of Action (Count I)
Violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962(c)
(against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark)

478. Plaintiff Hamblen County re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

479. Plaintiff brings this count against Express Scripts, CVS Caremark, and the Manufacturer Defendants (Eli Lilly, Novo Nordisk and Sanofi) for violations of 18 U.S.C. § 1962(c).

480. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark are (1) culpable "persons" who (2) willfully and knowingly (3) committed and conspired to commit two or more acts of mail and wire fraud (4) through a "pattern" of racketeering activity that (5) involves an "association in fact" enterprise, (6) the results of which had an effect on interstate commerce.

A. Defendants Are Culpable "Persons" Under RICO.

481. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark, separately, are "persons" as that term is defined in 18 U.S.C. § 1961(3) because each is capable of holding a legal or beneficial interest in property.

482. Each one of Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark are separate entities and "persons" that are distinct from the RICO enterprises alleged below.

B. The Manufacturer-PBM RICO Enterprise

483. For the purposes of this claim, the RICO enterprises are six separate associations-in-fact consisting of one of each of CVS Caremark and Express Scripts and one of each of the Manufacturer Defendants, including those entities' directors, employees, and agents: the Eli Lilly-CVS Caremark Enterprise; the Eli Lilly-Express Scripts Enterprise; the Novo Nordisk-CVS Caremark Enterprise; the Novo Nordisk-Express Scripts Enterprise; the Sanofi-CVS Caremark Enterprise; and the Sanofi-Express Scripts Enterprise.

484. These association-in-fact enterprises are collectively referred to herein as the "Manufacturer-PBM Enterprises."

485. Each Manufacturer-PBM Enterprise is a separate, ongoing, and continuing business organization consisting of corporations and individuals associated for the common purpose of manufacturing, selling, and facilitating the purchase of the Manufacturer Defendants' products, including the at-issue drugs. For example:

(a) The Eli Lilly-CVS Caremark Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Eli Lilly medications including Prozac, Cymbalta, and Zyprexa, as well as the at-issue Eli Lilly insulin and insulin-analog medications (Trulicity, Humulin N, Humulin R, Humalog, and Basaglar), which are Eli Lilly's primary source of revenue.

(b) The Eli Lilly-Express Scripts Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Eli Lilly medications including Prozac, Cymbalta, and Zyprexa, as well as the at-issue Eli Lilly insulin and insulin-analog medications (Trulicity, Humulin N, Humulin R, Humalog, and Basaglar), which are Eli Lilly's primary source of revenue.

(c) The Novo Nordisk-CVS Caremark Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Novo Nordisk medications for the treatment of obesity, hemophilia, and hormone imbalance, as well as the at-issue Novo Nordisk insulin and insulin analog medications (Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic), which account for more than three-quarters of Novo Nordisk's revenue.

(d) The Novo Nordisk-Express Scripts Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Novo Nordisk medications for the treatment of obesity, hemophilia, and hormone imbalance, as well as the at-issue Novo Nordisk insulin and insulin-analog medications (Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic), which account for more than three-quarters of Novo Nordisk's revenue.

(e) The Sanofi-CVS Caremark Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Sanofi medications including Ambien, Plavix, and Dupixent, as well as the at-issue Sanofi insulin and insulin-analog medications (Lantus, Toujeo, Apidra, and Soliqua).

(f) The Sanofi-Express Scripts Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Sanofi medications including Ambien, Plavix, and Dupixent, as well as the at-issue Sanofi insulin and insulin-analog medications (Lantus, Toujeo, Apidra, and Soliqua).

486. Each Manufacturer-PBM Enterprise engaged in the shared purpose of exchanging false list prices and secret Manufacturer Payments for preferred formulary positions for the at-issue drugs in order to control the market for diabetes medications and profit off diabetics and payors, including the Plaintiff.

487. The members of each enterprise are bound by contractual relationships, financial ties, and the ongoing coordination of activities.

488. There is also a common communication network by which Eli Lilly and CVS Caremark, Eli Lilly and Express Scripts, Novo Nordisk and CVS Caremark, Novo Nordisk and Express Scripts, Sanofi and CVS Caremark, and Sanofi and Express Scripts share information and meet on a regular basis. These communications include, but are not limited to, communications relating to the use of false list prices for the at-issue diabetes medications and the regular flow of Manufacturer Payments from each Manufacturer Defendant to CVS Caremark and Express Scripts in exchange for formulary placement.

489. Each Manufacturer-PBM Enterprise functions as a continuing but separate unit separate and apart from the pattern of racketeering activity in which it engages. Each

Manufacturer-PBM Enterprise, for example, engages in the manufacture, distribution and sale of medications and other products other than the at-issue insulin and insulin- analog medications. Additionally, each Manufacturer engages in conduct other than mail and wire fraud in furtherance of the Insulin Pricing Scheme.

490. At all relevant times, each of the Manufacturer-PBM Enterprises was operated and conducted for unlawful purposes by each Manufacturer Defendant and Express Scripts and CVS Caremark, namely, carrying out the Insulin Pricing Scheme.

491. Each Manufacturer-PBM Enterprise derived secret profits from these activities that were greater than those any one of the Manufacturer Defendants or either Express Scripts or CVS Caremark could obtain absent their misrepresentations regarding their non-transparent pricing schemes.

492. To accomplish this common purpose, each Manufacturer Defendant periodically and systematically inflated the prices of the at-issue drugs and then secretly paid a significant, yet undisclosed, portion of this inflated price back to Express Scripts and CVS Caremark in the form of Manufacturer Payments.

493. Each Manufacturer-PBM Enterprise did so willfully and with knowledge that Plaintiff paid for the at-issue drugs at prices directly based on the false list prices.

494. Each Manufacturer-PBM Enterprise's inflation of the list prices and secret Manufacturer Payments was a quid pro quo exchange for preferred formulary placement.

495. Each Manufacturer-PBM Enterprise concealed from Plaintiff that these false prices and secret Manufacturer Payments resulted in each Manufacturer gaining formulary access without requiring significant price reductions and resulted in higher profits for Express Scripts and CVS

Caremark, whose earnings increase the more inflated the price is and the more payment it receives from each Manufacturer Defendant.

496. Each Manufacturer-PBM Enterprise also shares a common purpose of perpetuating the use of the false list prices for the at-issue drugs as the basis for the price that payors, including the Plaintiff, and diabetics pay for diabetes medications.

497. The Manufacturer Defendants would not be able to offer large pricing spreads to Express Scripts and CVS Caremark in exchange for favorable formulary positions without the use of the false list prices as the basis for the price paid by diabetics and payors, including the Plaintiff, for the at-issue drugs.

498. Express Scripts and CVS Caremark share this common purpose because nearly all profit and revenue generated from the at-issue drugs is tied to the false inflated prices generated by the Insulin Pricing Scheme. Without diabetics and payors, including the Plaintiff, paying for diabetes medications based on the inflated list prices, their profits from the Insulin Pricing Scheme would decrease.

499. As a result, CVS Caremark and Express Scripts have, with the knowing and willful participation and assistance of each Manufacturer Defendant, engaged in hidden profit-making schemes falling into four general categories: (1) garnering undisclosed Manufacturer Payments from each Manufacturer Defendant that Express Scripts and CVS Caremark retains to a large extent; (2) generating substantial profits from pharmacies because of the falsely inflated prices; (3) generating profits on the diabetes medications sold through Express Scripts and CVS Caremark's own mail-order and retail pharmacies; and (4) keeping secret discounts each Manufacturer Defendant provides in association with Express Scripts and CVS Caremark's mail-order and retail operations.

500. At all relevant times, Express Scripts and CVS Caremark and each Manufacturer Defendant has been aware of their respective Manufacturer-PBM Enterprise's conduct, has been a knowing and willing participant in and coordinator of that conduct and has reaped profits from that conduct.

501. Neither Express Scripts, CVS Caremark, nor any of the Manufacturer Defendants alone could have accomplished the purposes of the Manufacturer-PBM Enterprises without the other entities.

C. The Enterprises Misrepresent and Fail to Disclose Material Facts in Furtherance of the Insulin Pricing Scheme.

502. Each Manufacturer-PBM Enterprise knowingly made material misrepresentations to the public and the Plaintiff in furtherance of Insulin Pricing Scheme, including publishing artificially inflated prices for insulin on published indices and representing that:

a. the false list prices for the at-issue diabetes medications were reasonably related to the actual prices realized by Defendants and were a reasonable and fair basis on which to base the price Plaintiff paid for these drugs;

b. each Manufacturer priced its at-issue drugs according to each drug's value to the healthcare system and the need to fund innovation;

c. the Manufacturer Payments paid back to Express Scripts and CVS Caremark for each at-issue drug were for Plaintiff's benefit;

d. all "rebates" and discounts negotiated by CVS Caremark and Express Scripts with the Manufacturer Defendants were passed through to the Plaintiff;

e. the "rebates" negotiated by the members of each enterprise saved Plaintiff money;

f. each Manufacturer Defendant and Express Scripts and CVS Caremark were transparent with Plaintiff regarding the Manufacturer Payments and the PBMs did not retain any funds associated with prescription drug rebates or any the margin between guaranteed reimbursement rates and the actual amount paid to the pharmacies; and

g. Express Scripts and CVS Caremark constructed formularies in a manner that lowered the price of the at-issue drugs and promoted the health and safety of diabetics.

503. Each false list price published by the Manufacturer Defendants constituted a material misrepresentation to Plaintiff and the public, in that each purported to be a fair market price for the medication at issue, and each omitted to disclose the fraudulent spread between the list price and the net price of the medication or the basis therefor.

504. Examples of other specific affirmative representations by each RICO Defendant in furtherance of each enterprise's Insulin Pricing Scheme are set forth in this complaint.

505. At all times relevant to this Complaint, each Manufacturer-PBM Enterprise knew the above-described representations to be false.

506. At all times relevant to this Complaint, each Manufacturer-PBM Enterprise intentionally made these representations for the purpose of inducing Plaintiff into paying artificially inflated prices for diabetes medications.

507. Plaintiff relied on the material misrepresentations and omissions made by each Manufacturer-PBM Enterprise in paying prices for the at-issue diabetes medications based upon the false prices generated by Insulin Pricing Scheme.

508. Additionally, each PBM-Manufacturer Enterprise relied on the list prices negotiated and published by the other PBM-Manufacturer enterprises in setting their own list prices and determining the value of the kickbacks paid to the PBMs. Plaintiff was injured by the inflated prices that arose as a result.

509. Express Scripts and CVS Caremark convinced Plaintiff to pay prices for the at-issue drugs based upon the false list prices by utilizing the misrepresentations listed above to

convince Plaintiff that they had secured lower prices when, in fact, they did the opposite, all while concealing the Insulin Pricing Scheme.

510. Without these misrepresentations and each RICO Defendant's failure to disclose the Insulin Pricing Scheme, each Manufacturer-PBM Enterprise could not have achieved its common purpose, as Plaintiff would not have been willing to pay these false list prices.

D. Defendants' Use of the U.S. Mails and Interstate Wire Facilities

511. Each of the Manufacturer-PBM Enterprises engaged in and affected interstate commerce because each engaged in the following activities across state boundaries: the sale, purchase and/or administration of diabetes medications; the setting and publishing of the prices of these drugs; and/or the transmission of pricing information of diabetes medications; and/or the transmission and/or receipt of sales and marketing literature; and/or the transmission of diabetes medications through mail order and retail pharmacies; and/or the transmission and/or receipt of invoices, statements, and payments related to the use or administration of diabetes medications; and/or the negotiations and transmissions of contracts related to the pricing of and payment for diabetes medications.

512. Each Manufacturer-PBM Enterprise participated in the administration of diabetes medications to millions of individuals located throughout the United States, including in Hamblen County and elsewhere in Tennessee.

513. Each Manufacturer Defendant's and Express Scripts' and CVS Caremark's illegal conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information and products and funds through the U.S. mails and interstate wire facilities.

514. The nature and pervasiveness of the Insulin Pricing Scheme, which included each Manufacturer Defendant's and Express Scripts' and CVS Caremark's corporate headquarters operations, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities with each other and with pharmacies, physicians, payors, and diabetics in Hamblen County and throughout Tennessee.

515. Each Manufacturer-PBM Enterprise's use of the U.S. mails and interstate wire facilities to perpetrate the Insulin Pricing Scheme involved thousands of communications including:

a. Marketing materials about the published prices for diabetes medications, which each Manufacturer Defendant sent to Express Scripts and CVS Caremark located across the country, including in Hamblen County and throughout Tennessee;

b. Written and oral representations of the false list prices of diabetes medications that each Manufacturer Defendant and Express Scripts and CVS Caremark made at least annually and, in many cases, several times during a single year to the public;

c. Thousands of written and oral communications discussing, negotiating, and confirming the placement of each Manufacturer Defendant's diabetes medications on Express Scripts and CVS Caremark's formularies;

d. Written and oral representations made by each Manufacturer Defendant regarding information or incentives paid back to each Express Scripts and CVS Caremark for each diabetes medications sold and/or to conceal these Incentives or the Insulin Pricing Scheme;

e. Written communications made by each Manufacturer Defendant, including checks, relating to Manufacturer Payments paid to Express Scripts and CVS Caremark to persuade them to advocate the at-issue diabetes medications;

f. Written and oral communications with U.S. government agencies that misrepresented what the published prices were or that were intended to deter investigations into the true nature of the published prices or to forestall changes to reimbursement based on something other than published prices;

g. Written and oral communications with payors, including the Plaintiff, regarding the price of diabetes medications;

h. Written and oral communications to the Plaintiff, including marketing and solicitation material sent by Express Scripts and CVS Caremark regarding the

existence, amount, or purpose of payments made by each Manufacturer Defendant to Express Scripts and CVS Caremark for the diabetes medications described herein and the purpose of Express Scripts and CVS Caremark's formularies;

i. Transmission of published prices to third parties and payors, including the Plaintiff; and

j. Receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities—the wrongful proceeds of the Insulin Pricing Scheme.

516. Although Plaintiff pleads the dates of certain communications in allegations incorporated into this Count, it cannot allege the precise dates of others without access to books and records within each RICO Defendant's exclusive custody and control. Indeed, an essential part of the successful operation of the Insulin Pricing Scheme depended upon secrecy, and each Manufacturer Defendant and Express Scripts and CVS Caremark took deliberate steps to conceal its wrongdoing.

E. Conduct of the Manufacturer-PBM Enterprises' Affairs

517. Each Manufacturer Defendant and Express Scripts and CVS Caremark participates in the operation and management of Manufacturer-PBM Enterprises with which it is associated and, in violation of Section 1962(c) of RICO, and conducts or participates in the conduct of the affairs of those association-in-fact RICO enterprises, directly or indirectly. Such participation is carried out in the following ways:

a. Each Manufacturer Defendant directly controls the secret Manufacturer Payments it provides to Express Scripts and CVS Caremark for its diabetes medications.

b. Express Scripts and CVS Caremark directly manage and control their respective drug formularies and the placement of the at-issue diabetes medications on those formularies.

c. Express Scripts and CVS Caremark intentionally select higher-priced diabetes medications for formulary placement and exclude lower priced ones in order to generate larger profits and coordinate with the Manufacturer Defendants to increase the availability and use of higher-priced medications because they are more profitable for both groups of Defendants.

d. Each Manufacturer Defendant directly controls the publication of the false list prices generated by the Insulin Pricing Scheme.

e. Each Manufacturer Defendant directly controls the creation and distribution of marketing, sales and other materials used to inform Express Scripts and CVS Caremark of the profit potential from its diabetes medications.

f. Express Scripts and CVS Caremark directly control the creation and distribution of marketing, sales, and other materials used to inform payors and the public of the benefits and cost-saving potential of Express Scripts and CVS Caremark formularies and negotiations with the Manufacturers.

g. Express Scripts and CVS Caremark direct and control each enterprise's direct relationships with payors such as the Plaintiff by negotiating the terms of and executing the contracts that govern those relationships.

h. Express Scripts and CVS Caremark direct and control each enterprise's Insulin Pricing Scheme by hiding, obfuscating, and laundering Manufacturer Payments through their affiliated entities in order to retain a large and undisclosed proportion of the Manufacturer Payments to the detriment of payors, including Plaintiff.

i. Express Scripts and CVS Caremark distribute through the U.S. mail and interstate wire facilities promotional and other materials which claim that the Manufacturer Payments paid from each Manufacturer Defendant to Express Scripts and CVS Caremark save Plaintiff and other payors money on the at-issue drugs.

j. Each Manufacturer Defendant represented to the Plaintiff—by publishing and promoting false list prices without stating that these published prices differed substantially from the prices realized by each Manufacturer Defendant and Express Scripts and CVS Caremark—that the published prices of diabetes medications reflected or approximated the actual price realized by Defendants and resulted from transparent and competitive fair market forces.

F. Defendants' Pattern of Racketeering Activity

518. Each Manufacturer Defendant and Express Scripts and CVS Caremark has conducted and participated in the affairs of their respective Manufacturer-PBM Enterprises through a pattern of racketeering activity, including acts that are unlawful under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud.

519. Each Manufacturer Defendant's and Express Scripts' and CVS Caremark's pattern of racketeering involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of the Insulin Pricing Scheme. Each of these mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), in which each Manufacturer Defendant and Express Scripts and CVS Caremark intended to defraud Plaintiff.

520. By intentionally and falsely inflating the list prices, by misrepresenting the purpose behind both the Manufacturer Payments (made from each Manufacturer Defendant to Express Scripts and CVS Caremark) and Express Scripts' and CVS Caremark's formulary construction, and by subsequently failing to disclose such practices to Plaintiff, each Manufacturer Defendant and Express Scripts and CVS Caremark engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

521. Each Manufacturer Defendant's and Express Scripts' and CVS Caremark's racketeering activities amounted to a common course of conduct, with similar patterns and purposes, intended to deceive Plaintiff.

522. Each separate use of the U.S. mails and/or interstate wire facilities employed by each Manufacturer Defendant and Express Scripts and CVS Caremark was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiff.

523. Each Manufacturer Defendant and Express Scripts and CVS Caremark engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of

the respective Manufacturer-PBM Enterprises with which each of them is and was associated in fact.

G. The RICO Defendants' Motive

524. Each Manufacturer Defendant's and Express Scripts' and CVS Caremark's motives in creating and operating the Insulin Pricing Scheme and conducting the affairs of the Manufacturer-PBM Enterprises described herein was to control the market for diabetes medications and falsely obtain sales of, and profits from, diabetes medications.

525. The Insulin Pricing Scheme was designed to, and did, encourage others, including payors like Plaintiff, to advocate the use of each Manufacturer Defendant's respective products and to pay for those diabetes medications based on a falsely inflated price. Each Manufacturer Defendant used the Insulin Pricing Scheme to obtain formulary placement to sell more of its drugs without having to cut into its profits. Express Scripts and CVS Caremark used the Insulin Pricing Scheme to falsely inflate the price payors such as the Plaintiff paid for diabetes medications in order to profit off the Insulin Pricing Scheme, as discussed above.

H. The Manufacturer-PBM Enterprises' Insulin Pricing Scheme Injured Plaintiff.

526. Each Manufacturer-PBM Enterprise's violations of federal law and pattern of racketeering activity have directly and proximately caused the Plaintiff to be injured in its business or property.

527. The prices the Plaintiff pays for the at-issue drugs are directly tied to the false list prices generated by the Insulin Pricing Scheme.

528. No other intermediary in the supply chain has control over or is responsible for the list prices on which nearly all Plaintiff's payments are based other than the Manufacturer-PBM Defendant Enterprises.

529. Defendants collectively set the prices that the Plaintiff paid for the at-issue diabetes medications.

530. During the relevant period, Express Scripts and CVS Caremark provided PBM services to the Plaintiff and benefited therefrom.

531. During the relevant period, the Plaintiff paid Express Scripts and CVS Caremark for the at-issue drugs.

532. Each Manufacturer-PBM Enterprise controlled and participated in the Insulin Pricing Scheme that was directly responsible for the false list prices upon which the price Plaintiff paid was based.

533. Thus, Plaintiff was damaged by reason of the Insulin Pricing Scheme. But for the misrepresentations and false prices created by the Insulin Pricing Scheme that each Manufacturer-PBM Enterprise employed, Plaintiff would have paid less for diabetes Medications.

534. As a direct result of the Insulin Pricing Scheme the Plaintiff was further damaged by incurring increased healthcare costs and by losing tax revenue due to decreased workforce productivity.

535. The Plaintiff's damages are separate and distinct from any other victim that was harmed by the Manufacturer-PBM Defendant Enterprises' Insulin Pricing Scheme.

536. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(c) of RICO, Defendants are jointly and severally liable to the Plaintiff for three times the damages that were sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

537. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(a) of RICO, the Plaintiff seeks injunctive relief against each Manufacturer and Express

Scripts and CVS Caremark for their fraudulent reporting of their prices and their continuing acts to affirmatively misrepresent and/or conceal and suppress material facts concerning their false and inflated prices for diabetes medications, plus the costs of bringing this suit, including reasonable attorneys' fees.

538. Absent an injunction, the effects of this fraudulent, unfair, and unconscionable conduct will continue. Plaintiff continues to purchase the at-issue diabetes medications. Plaintiff will continue to pay based on the Defendants' false list prices. This continuing fraudulent, unfair, and unconscionable conduct is a serious matter that calls for injunctive relief as a remedy. Plaintiff seeks injunctive relief, including an injunction against each Manufacturer and Express Scripts and CVS Caremark, to prevent them from affirmatively misrepresenting and/or concealing and suppressing material facts concerning their conduct in furtherance of the Insulin Pricing Scheme.

Second Cause of Action (Count II)
Violations of RICO, 18 U.S.C. § 1962(d)
By Conspiring to Violate 18 U.S.C. § 1962(c)
(against all Defendants)

539. Plaintiff re-alleges and incorporates herein by reference the allegations set forth in the preceding paragraphs.

540. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

541. Defendants have violated § 1962(d) by agreeing and conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in the Insulin Pricing Scheme.

542. As set forth in detail above, Defendants each knowingly agreed to facilitate the Insulin Pricing Scheme and each has engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy. Specifically, Defendants agreed to and did

inflate the prices of the at-issue drugs in lockstep to achieve an unlawful purpose; Defendants agreed to and did make false or misleading statements or material omissions regarding the reasons for these price increases, the purpose of the Manufacturer Payments exchanged between Defendants and the PBMs' formulary construction; and PBMs agreed to and did, in concert, request and receive larger Manufacturer Payments and higher prices in exchange for formulary placement.

543. The nature of the above-described Defendant co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

544. Defendants have engaged and continue to engage in the commission of overt acts, including the following unlawful racketeering predicate acts:

a. Multiple instances of mail fraud in violations of 18 U.S.C. § 1341;

b. Multiple instances of wire fraud in violations of 18 U.S.C. § 1343; and

c. Multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

545. Defendants' conspiracy to violate the above federal laws and the effects thereof detailed above are continuing and will continue. Plaintiff has been injured in its property by reason of these violations: Plaintiff has paid more for the at-issue drugs than it would have but for Defendants' conspiracy to violate 18 U.S.C. § 1962(c).

546. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are jointly and severally liable to Plaintiff for three times the damages this District has sustained, plus the cost of this suit, including reasonable attorneys' fees.

Third Cause of Action (Count III)
Unlawful Restraint of Trade
Tenn. Code Ann. §§ 47-25-101, *et seq*.
(against all Defendants)

547. Plaintiff Hamblen County re-alleges and incorporates herein by reference each of the allegations from the preceding paragraphs.

548. As detailed in the foregoing paragraphs, Defendants entered into, established, and maintained a continuing contract, agreement, arrangement, or combination in unreasonable restraint of trade.

549. The purpose and effect of the arrangement was to effect the Insulin Pricing Scheme.

550. The contract, agreement, arrangement, or combination had a direct, substantial, and reasonably foreseeable effect upon commerce within the United States and within Tennessee by: (a) increasing prices paid by Plaintiff for the at-issue diabetes medications; (b) depriving Plaintiff of savings that they would otherwise have received in the absence of the conspiracy; and (c) depriving Plaintiff of free, open, and unrestricted competition in the purchase of the at-issue drugs sold by Defendants.

551. As a result of Defendants' unlawful conduct, Plaintiff has been injured by paying inflated prices for the at-issue diabetes medications.

552. By engaging in the conduct described above, Defendants formed a contract, agreement, arrangement, or combination in restraint of trade in violation of Tenn. Code Ann. §§ 47-25-101, *et seq*.

Fourth Cause of Action (Count IV)
Violation of Tennessee Consumer Protection Act
Tenn. Code Ann. §§ 47-18-101, *et seq*.
(against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark)

553. Plaintiff Hamblen County re-alleges and incorporates herein by reference each of the allegations from the preceding paragraphs.

554. The Tennessee Consumer Protection Act of 1977 makes unlawful "[u]nfair or deceptive acts or practices affecting the conduct of any trade or commerce[.]."[96]

555. Plaintiff is a "person" within the meaning of Tenn. Code Ann. § 47-18-103(18).

556. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark are each a "person" within the meaning of Tenn. Code Ann. § 47-18-103(18).

557. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark's conduct, collectively and as individuals, as described in this Complaint, constitutes deceptive acts in violation of the Tennessee Consumer Protection Act.

558. Because these Defendants' willful and knowing conduct caused injury to Plaintiff, Plaintiff seeks to recover actual damages; discretionary treble damages; punitive damages; reasonable attorneys' fees and costs; an order enjoining Defendants' unlawful conduct; and any other just and proper relief available under.

559. By engaging in the Insulin Pricing Scheme, as described herein, Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark have committed acts of unfair and deceptive trade practices in the conduct of trade or commerce within Tennessee and Hamblen County causing harm to Plaintiff as a reimbursor for, and purchaser and payor of, the at-issue drugs.

[96] Tenn. Code Ann. § 47-18-104(a).

560. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark have engaged in the following materially misleading conduct, which constitutes deceptive trade practice in violations of the Tennessee Consumer Protection Act:

- Making false and misleading misrepresentations of fact that the prices for the at-issue diabetes medications were legal, competitive, and fair market value prices. In particular:
    - A characteristic of every commodity in Tennessee's economy is its price, which is represented by every seller to every buyer that the product being sold is being sold at a legal, competitive, and fair market value.
    - At no point did these Defendants reveal that the prices associated with the lifesaving diabetic treatments at issue herein were not legal, competitive, or at fair market value.
    - At no point did these Defendants disclose that the prices associated with the at-issue drugs were generated by the Insulin Pricing Scheme.
    - At least once per year for each year during the relevant period, these Defendants reported and published false prices for each at-issue drug and in doing so represented that the reported prices were the actual, legal and fair prices for these drugs and resulted from competitive market forces.
    - In addition, by granting the at-issue drugs preferred formulary position—formulary positions that the PBMs represent are reserved for reasonably priced drugs and that are meant to promote the health of diabetics—the PBM Defendants knowingly and purposefully utilized the false prices that were generated by the Insulin Pricing Scheme.
    - By granting the at-issue diabetes medications preferred formulary positions, the PBM Defendants ensured that prices generated by the Insulin Pricing Scheme would harm Plaintiff.
    - The PBM Defendants also misrepresented their formularies promoted the cost-savings to Plaintiff.
    - Defendants' representations are false, and Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark knew they were false. Defendants knew that the prices they reported and utilized are artificially inflated for the purpose of maximizing profits through the Insulin Pricing Scheme.
    - These Defendants also knew that the PBMs' formulary construction fueled the precipitous price increases that damaged Plaintiff's financial well-being.

- Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark affirmatively withheld this truth from Plaintiff Hamblen County, even though these Defendants knew that the Plaintiff's intention was to pay the lowest possible price for diabetes medications and expectation was to pay a legal, competitive price that resulted from transparent market forces.

- Making false and misleading misrepresentations of fact related to the Manufacturer Payments and the negotiations that occurred between the PBM and Manufacturer Defendants.

- The PBM Defendants knowingly made false and misleading statements concerning the reasons for, existence of, and amount of price reductions by misrepresenting that the Manufacturer Payments lower the overall price of diabetes medications and promote the health of diabetics.

- These representations were false, and Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark knew they were false. The PBM Defendants knew that the Manufacturer Payments were not reducing the overall price of diabetes medications but rather are an integral part of the Insulin Pricing Scheme and are responsible for the inflated prices.

561. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark continue to make these misrepresentations and publish prices generated by the Insulin Pricing scheme, and Plaintiff continues to purchase diabetes medications at inflated prices.

562. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark acted knowingly and in a willful, wanton or reckless disregard for the safety of others in committing the violation of the Tennessee Consumer Protection Act described herein.

563. Each at-issue purchase Plaintiff made for diabetes medications at the prices generated by the Insulin Pricing Scheme constitutes a separate violation of the Tennessee Consumer Protection Act.

564. The acts and practices alleged herein are ongoing, repeated, and affect the public interest.

565. The acts and practices alleged herein substantially impact the community of diabetics, their families, healthcare providers, and the public, and have caused substantial actual harm, including to Plaintiff and its beneficiaries.

566. These Defendants' acts and practices in violation of the Tennessee Consumer Protection Act caused Plaintiff to suffer injuries alleged herein, including but not limited to paying excessive and inflated prices for diabetes medications as described herein.

567. As a direct and proximate result of these Defendants' conduct in committing the above and foregoing violations of the Tennessee Consumer Protection Act, these Defendants are directly and jointly and severally liable to Plaintiff for all restitution, damages, punitive damages, treble damages, penalties and disgorgement for which recovery is sought herein, including but not limited to the Plaintiff paying excessive and inflated prices for diabetes medications described herein every time it paid for an at-issue drug.

568. Additionally, Plaintiff did not receive the benefit of its bargain, or otherwise paid a price premium, for the at-issue diabetes medications because it paid an artificially inflated price due to these Defendants' illegal practices.

Fifth Cause of Action (Count V)
Breach of Contract
(against Defendants Express Scripts and CVS Caremark)

569. Plaintiff Hamblen County re-alleges and incorporates herein by reference each of the allegations from the preceding paragraphs.

570. In Tennessee, all contracts—including those between the PBM Defendants and Plaintiff—imply a covenant of good faith and fair dealing in the course of performance (the "Covenant").[97]

[97] *See, e.g.*, *Wallace v. Nat'l Bank of Commerce*, 938 S.W.2d 684, 686 (Tenn. 1996).

571. The Covenant protects "the parties' reasonable expectations as well as their right to receive the benefits of their agreement"[98] and is breached when "a party to the contract exercises discretion authorized in a contract in an unreasonable way."[99]

572. By engaging in the conduct alleged in this Complaint, specifically by arranging with Insulin Manufacturers to hide portions of their rebates by, *inter alia*, relabeling a portion of the rebates as "administrative fees" such that they do not have to be "passed through" to Plaintiff, the PBM Defendants deprived Plaintiff of its rights to receive the benefits of their agreement.

573. PBM Defendants made such arrangements willfully, with the dishonest purpose of enriching themselves at the expense of payors such as Plaintiff. Furthermore, they took efforts to conceal the terms of these arrangements so that payors such as Plaintiff could not discover that they were not receiving the fruits of their contract.

574. As a direct and proximate result of PBM Defendants' breach of the covenant of good faith and fair dealing, Plaintiff did not receive the benefit of its bargain and paid a price-premium for the at-issue diabetes medications because it paid an artificially inflated price due to these Defendants' illegal practices.

Sixth Cause of Action (Count VI)
Unjust Enrichment
(against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark)

575. Plaintiff Hamblen County re-alleges and incorporates herein by reference each of the allegations from the preceding paragraphs.

[98] *Dick Broad. Co. v. Oak Ridge FM, Inc.*, 395 S.W.3d 653, 666 (Tenn. 2013).

[99] *Universal Props. v. Regions Bank*, No. 3:11-cv-538, 2012 U.S. Dist. LEXIS 135256, at *23 (E.D. Tenn. Sep. 21, 2012)).

576. This cause of action is alleged in the alternative to any claim Plaintiff may have for legal relief.

577. Plaintiff conferred a benefit upon Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark. These Defendants deceived Plaintiff Hamblen County and have received a financial windfall from the Insulin Pricing Scheme at Plaintiff's expense.

578. These Defendants wrongfully secured and retained unjust benefits from Plaintiff in the form of amounts paid for diabetes medications and fees and payments collected based on the prices generated by the Insulin Pricing Scheme. They did not adequately compensate Plaintiff therefor.

579. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark were aware of the benefit, voluntarily accepted it, and retained and appreciated the benefit, to which it was not entitled, at Plaintiff's expense.

580. It is inequitable and unfair for these Defendants to retain these benefits.

581. The benefit these Defendants have wrongfully retained is in an amount not less than the difference between the reasonable or fair market value of the at-issue drugs for which Plaintiff paid and the actual value of the at-issue drugs these Defendants delivered.

582. Accordingly, Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark should not be permitted to retain the proceeds from the benefits conferred upon them by Plaintiff, which seeks disgorgement of these Defendants' unjustly acquired profits and other monetary benefits resulting from their unlawful conduct and seeks restitution and/or recission, in an equitable and efficient fashion to be determined by the Court.

583. As a direct and proximate cause of these Defendants' unjust enrichment at the expense of Plaintiff as referenced above, Plaintiff has suffered and continues to suffer ascertainable losses and damages as specified herein in an amount to be determined at trial.

MOTION FOR INJUNCTION

584. Plaintiff Hamblen County re-alleges and incorporates paragraphs 1–477.

585. By Defendants' violations of the Tennessee Consumer Protection Act, RICO, and common law, Plaintiff has suffered, and will continue to suffer, immediate and irreparable injury, loss, and damage, as discussed herein.

586. The ongoing and threatened injury to Plaintiff and its beneficiaries outweighs the harm that an injunction might cause Defendants.

587. As a direct and proximate result of the conduct of the Defendants in committing the above and foregoing acts, Plaintiff moves the Court for injunctive relief against the Defendants pursuant Tenn. Code Ann. § 47-18-109(b) and 18 U.S.C. § 1964(a), thereby enjoining Defendants from committing future violations of the Tennessee Consumer Protection Act and RICO.

588. Granting an injunction is consistent with the public interest because it will protect the health and economic interests of Plaintiff, as well as the integrity of the Tennessee marketplace.

PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiff Hamblen County prays for entry of judgment against the Defendants for all the relief requested herein and to which the Plaintiff may otherwise be entitled, specifically, but without limitation, to-wit:

A. That the Court determine that Defendants have violated the Tennessee Consumer Protection Act, have violated RICO, have breached their contract with Defendants, and have been unjustly enriched;

B. Judgment in favor of Plaintiff and against the Defendants for damages in excess of the minimum jurisdictional requirements of this Honorable Court, in a specific amount to be proven at trial;

C. That Plaintiff be granted the following specific relief:

1. In accordance with Tenn. Code Ann. § 47-18-109(b) and 18 U.S.C. § 1964(a), that Defendants, their affiliates, successors, transferees, assignees, and the officers, directors, partners, agents, and employees thereof, and all other persons acting or claiming to act on their behalf or in concert with them, be enjoined and restrained from in any manner continuing, maintaining or renewing the conduct, contract, conspiracy or combination alleged herein in violation of the and RICO, or from entering into any other contract, conspiracy or combination having a similar purpose or effect, and from adopting or following any practice, plan, program or device having a similar purpose or effect;

2. That Plaintiff:

i. be awarded restitution, damages, disgorgement, penalties and/or all other legal and equitable monetary remedies available under the state laws set forth in this Complaint and the general equitable powers of this Court in an amount according to proof;

ii. be awarded punitive damages because Defendants knowingly, willfully, wantonly and intentionally harmed the health, wellbeing and financial interests Plaintiff and its Beneficiaries;

iii. be awarded pre- and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of the initial complaint in this action;

iv. recover its costs of suit, including its reasonable attorney's fees, as provided by law and pursuant to the Tennessee Consumer Protection Act and 18 U.S.C. § 1964(c); and

v. be awarded such other, further and different relief as the case may require and the Court may deem just and proper under the circumstances.

JURY DEMAND

Plaintiff Hamblen County demands trial by jury on all issues so triable.

Dated: April 5, 2024

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

GREENE COUNTY, TENNESSEE,

Plaintiff,

v.

ELI LILLY AND COMPANY; NOVO NORDISK INC.; SANOFI-AVENTIS U.S. LLC; CVS HEALTH CORPORATION; CVS PHARMACY, INC.; CAREMARKPCS HEALTH, LLC; CAREMARK, LLC; CAREMARK RX, LLC; EVERNORTH HEALTH, INC. (F/K/A EXPRESS SCRIPTS HOLDING COMPANY); EXPRESS SCRIPTS, INC.; EXPRESS SCRIPTS ADMINISTRATORS, LLC; MEDCO HEALTH SOLUTIONS, INC.; ESI MAIL PHARMACY SERVICES, INC.; EXPRESS SCRIPTS PHARMACY, INC.; UNITEDHEALTH GROUP, INC.; OPTUM, INC.; OPTUMRX INC.; OPTUMRX HOLDINGS I LLC; OPTUMINSIGHT, INC.,

Defendants.

Civil Action No. _____

COMPLAINT

JURY TRIAL DEMANDED

Complaint and Demand for Jury Trial

TABLE OF CONTENTS

INTRODUCTION 1

PARTIES 10

A. Plaintiff 10

B. Manufacturer Defendants 11

C. PBM Defendants 15

JURISDICTION AND VENUE 38

ADDITIONAL FACTUAL ALLEGATIONS 39

A. Diabetes and Insulin Therapy 39

- The Diabetes Epidemic 39
- Insulin: A Century-Old Drug 40
- The Current Insulin Landscape 42
- Insulin Adjuncts: Type 2 Medications 42

B. The Dramatic Rise in the Price of Diabetes Medications in the U.S. 45

- The Defendant-Manufacturers Have Increased Prices in Lockstep 48

C. Pharmaceutical Payment and Supply Chain 52

D. The PBMs' Role in the Pharmaceutical Payment Chain 53

- The Rise of the PBMs in the Pharmaceutical Supply Chain 55
- The Insular Nature of the Pharmaceutical Industry 57

E. The Insulin Pricing Scheme 61

F. Defendants Play Down the Insulin Pricing Scheme and Its Harms 65

G. Defendant Profit from the Insulin Pricing Scheme 72

- The PBMs Pocket a Substantial Share of Manufacturer Payments 73
- The Insulin Pricing Scheme Allows the PBMs to Profit Off Pharmacies 80

- The Insulin Pricing Scheme Increases PBM Mail-Order Profits 84

H. Plaintiff Purchases the At-Issue Drugs Directly from Defendants 85

I. Defendants Deceived Plaintiff 87

J. The Insulin Pricing Scheme Has Damaged Plaintiff 100

K. Defendants' Recent Efforts in Response to Rising Insulin Prices 102

CLAIMS FOR RELIEF 105

FIRST CLAIM FOR RELIEF (Violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962(c)) (against Defendants Eli Lilly, Novo Nordisk, Sanofi, CVS Caremark, and Express Scripts) 105

A. Defendants Are Culpable "Persons" Under RICO. 105

B. The Manufacturer-PBM RICO Enterprises 106

C. The Enterprises Misrepresent and Fail to Disclose Material Facts in Furtherance of the Insulin Pricing Scheme. 110

D. Defendants' Use of the U.S. Mails and Interstate Wire Facilities 112

E. Conduct of the Manufacturer-PBM Enterprises' Affairs 114

F. Defendants' Pattern of Racketeering Activity 115

G. The RICO Defendants' Motive 117

H. The Manufacturer-PBM Enterprises' Insulin Pricing Scheme Injured Plaintiff.....117

SECOND CLAIM FOR RELIEF (Violations of RICO, 18 U.S.C. § 1962(d) By Conspiring to Violate 18 U.S.C. § 1962(c))(against all Defendants).....119

THIRD CLAIM FOR RELIEF (Unlawful Restraint of Trade, Tenn. Code Ann. §§ 47-25-101, *et seq*) (against all Defendants) 121

FOURTH CLAIM FOR RELIEF (Violation of Tennessee Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101, *et seq*) (against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx) 122

FIFTH CLAIM FOR RELIEF (Breach of Contract) (against Defendants Express Scripts, CVS Caremark, and OptumRx).....127

SIXTH CLAIM FOR RELIEF (Unjust Enrichment) (against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx)……...128

MOTION FOR INJUNCTION 130

PRAYER FOR RELIEF 130

JURY DEMAND 132

Plaintiff, Greene County, Tennessee ("Plaintiff," the "County" or "Greene County"), by and through undersigned counsel, brings this lawsuit against the above-named Defendants and alleges as follows:

INTRODUCTION

1. The cost of diabetes medications has risen more than tenfold over the past 20 years. Over the same period of time, the average cost of consumer goods and services has risen just 1.75-fold. The skyrocketing prices of diabetes medications are not tethered the rising cost of goods, production costs, investment in research and development, or competitive market forces. Instead, Defendants engineered these price increases via an opaque, conspiratorial kickback scheme (referred to herein as the "Insulin Pricing Scheme"), which has exponentially increased their profits at the expense of payors like Plaintiff and its plan members. The Insulin Pricing Scheme is a multibillion-dollar industry.

2. Diabetes is widespread. The total estimated cost of diabetes in the U.S. in 2017, according to the American Diabetes Association, was $327 billion. One in four healthcare dollars is spent caring for people with diabetes.

3. As of 2020, more than 13% of adults in Tennessee have been diagnosed with diabetes.[1] An additional 9.9% of the Tennessee adult population are prediabetic, with blood glucose levels higher than normal but not yet high enough to be diagnosed as diabetic.[2] In Greene, approximately 8.9%, of adult residents are living with diabetes.[3] In Tennessee alone, diabetes costs

[1] Tennessee Diabetes Action Legislative Report, Feb. 2021, https://www.capitol.tn.gov/Archives/senate/112GA/committees/health-welfare/2021/Diabetes%20Legislative%20Report_FinalDraft.%2001-29-2021%208%2045%20pm.pdf.

[2] *Id.*

[3] United States Diabetes Surveillance System, https://gis.cdc.gov/grasp/diabetes/diabetesatlas-analysis.html# (last visited January 26, 2024).

an estimated $5.2 billion per year in direct medical costs attributed to diabetes.[4] An additional $2.1 billion is spent on indirect costs from attributed to diabetes.[5]

4. Diabetics in Tennessee generally rely on daily insulin treatments, oral medications, or a combination of both to treat and control diabetes. Defendants Eli Lilly, Novo Nordisk, and Sanofi (collectively, the "Manufacturer Defendants" or the "Manufacturers") manufacture the vast majority of insulins and other diabetic medications available in the United States. In 2020, as in the years preceding, the Manufacturer Defendants controlled 92% by volume, and 96% by revenue, of the global market for diabetes drugs.

5. Defendants CVS Caremark, Express Scripts, and OptumRx (collectively, the "PBM Defendants" or the "PBMs") are pharmacy benefit managers that work with the Manufacturer Defendants to dictate the availability and price of the at-issue drugs for most of the U.S. market.[6] The PBM Defendants are, at once, (1) the three largest pharmacy benefit managers in the United States (controlling more than 80% of the PBM market); (2) the largest pharmacies in the United States (comprising three of the top five dispensing pharmacies in the U.S.); and (3) housed within the same corporate families as three of the largest insurance companies in the United States—Aetna (CVS Health), Cigna (Express Scripts), and UnitedHealthcare (OptumRx).

6. These corporate conglomerate Defendants sit at 4th (CVS Health), 5th (UnitedHealth Group), and 12th (Cigna) on the Fortune 500 list as of year-end 2022.

[4] Tennessee Diabetes Profile, https://www.cdc.gov/diabetes/programs/stateandlocal/state-diabetes-profiles/tennessee.html (last visited January 26, 2024).

[5] *Id.*

[6] In the context of this Complaint, the "at-issue drugs" or "at-issue medications" are: Apidra, Basaglar, Humalog, Humulin N, Humulin R, Humulin R 500, Humulin 70/30, Lantus, Levemir, Novolin N, Novolin R, Novolin 70/30, Novolog, Ozempic, Soliqua, Toujeo, Tresiba, Trulicity, and Victoza.

Figure 1: Manufacturers, PBMs & PBM-Affiliated Insurers

Manufacturers	PBMs	PBM-Affiliated Insurer
Eli Lilly		
Novo Nordisk		
Sanofi		
	CVS	Aetna
	Express Scripts	Cigna
	Optum	UnitedHealthcare

7. For transactions in which the PBM Defendants control the insurer, the PBM, and the pharmacy (e.g., Aetna–Caremark–CVS Pharmacy), these middlemen capture as much as half of the money spent on each insulin prescription (up from 25% in 2014), even though they contribute nothing to the development, manufacture, innovation, or production of the drugs.

8. As part of this work, the PBM Defendants establish national formulary offerings (i.e., approved drug lists), which, among other things, set the baseline for which diabetes medications are covered and which are not covered by nearly every payor in the United States, including in Tennessee and, more specifically, Greene County.

9. The Manufacturers and PBMs understand that the PBMs' national formularies drive drug utilization. The more accessible a drug is on the PBMs' national formularies, the more that drug will be purchased throughout the United States. Conversely, exclusion of a drug from one or more of the PBMs' formularies can render the drug virtually inaccessible for millions of covered persons.

10. Given the PBMs' market power and the crucial role their standard formularies play in the pharmaceutical pricing chain, both Defendant groups understand that the PBM Defendants wield enormous control over drug prices and purchasing behavior.

11. The unfair and deceptive conspiracy at the root of this complaint—the Insulin Pricing Scheme—was borne from this mutual understanding.

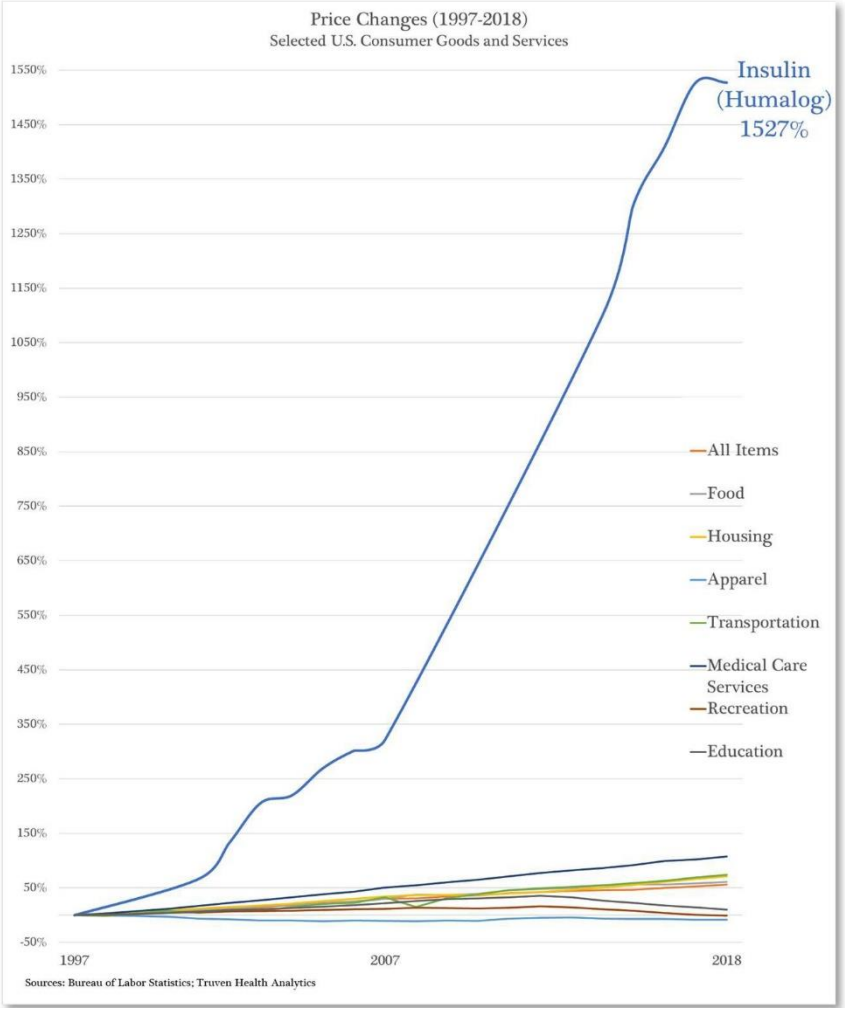
12. The Manufacturers set the initial list (wholesale) price for their respective insulin medications. Over the last 20 years, list prices have sharply increased in lockstep, even though the cost to produce these drugs decreased during that period.

13. Insulins, which today cost Manufacturers as little as $2 to produce, and which were originally priced at $20 the 1990s, now range in price from $300 to $700.

14. The Manufacturer Defendants have in tandem increased the prices of their insulins up to 1,000%, taking the same increase down to the decimal point within a few days of one another and, according to a U.S. Senate Finance Committee investigation, "sometimes mirroring" one another in "days or even hours."[7] Figure 2 shows the rate at which Defendant Eli Lilly raised the list price of its analog insulin, Humalog, compared to the rate of inflation for other consumer goods and services during the period from 1997- 2018.

[7] Charles E. Grassley & Ron Wyden, *Staff Report on Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug, Sen. Fin. Comm.*, at 6, 54, 55 (Jan. 2021), https://www.finance.senate.gov/imo/media/doc/GrassleyWyden%20Insulin%20Report%20 FINAL%201). Pdf (hereinafter "Grassley & Wyden" or "January 2021 Senate Insulin Report").

Figure 2: Price Increase of Insulin vs. Selected Consumer Goods, 1997-2018



15. Today's exorbitant prices do not accord with insulin's origins. The discoverers sold the original patent for $1 to ensure that the medication would remain affordable. But today, insulin is the poster child for skyrocketing pharmaceutical prices.

16. Nothing about these medications has changed over the past 100 years; today's $350 insulin is the same product Defendants once sold for $20.

How the Insulin Pricing Scheme Works

17. In the simplest terms, there are three important participants in the insulin medication chain.

a. **Greene County.** During the relevant period, Plaintiff Greene County operated a health plan for its employees and their dependents. The plan includes pharmacy benefits, meaning Plaintiff purchased the at-issue drugs for its beneficiaries. Operators of self-funded plans, like Plaintiff, may be referred to as payors or plan sponsors (or PBM "clients").

b. **PBMs.** Payors routinely engage pharmacy benefit managers to manage their prescription benefits, which includes negotiating prices with drug manufacturers and (ostensibly) helping payors manage drug spending. Each pharmacy benefit manager maintains a formulary—a list of covered medications. A pharmacy benefit manager's power to include or exclude a drug from its formulary theoretically should incentivize manufacturers to lower their list price. Pharmacy benefit managers also contract with pharmacies to reimburse them for medications purchased by the plan's beneficiaries. Pharmacy benefit managers are compensated by retaining a portion of what should—again in theory—be shared savings on the cost of medications.

c. **Manufacturers.** Manufacturers produce the at-issue insulin medications.[8] Each sets a list price for each of its products. The terms "list price" often is used interchangeably with the Wholesale Acquisition Cost (WAC) (defined by federal law as the undiscounted list price for a drug or biological to wholesalers or direct purchasers). The manufacturers self-report

[8] There are three types of insulin medications. First are *biologics*, which are manufactured insulins derived from living organisms. Second are *biosimilars*, which are "highly similar" copies of biologics. They are similar in concept to "generic" drugs; but in seeking approval they use biologics (rather than drugs) as comparators. Third, the confusingly-named *authorized generics* are not true generics—they are an approved brand-name drug marketed without the brand name on the label. FDA approved the original insulins as drug products rather than biologics, so although there was a regulatory pathway to introduce biosimilars generally (copies of biologics), companies could not introduce insulin biosimilars because their comparators were "drugs" rather than "biologics." In 2020, FDA moved insulin to the biologic regulatory pathway, thus opening the door to approval of biosimilars through an abbreviated approval process.

list prices to publishing compendiums such as First DataBank, Medi-Span, or Redbook, who then publish those prices.[9]

18. Given the PBMs' purchasing power and their control over formularies that govern the availability of drugs, their involvement should theoretically drive down list prices. Instead, to gain access to the PBMs' formularies, the Manufacturers artificially inflate their list prices and then pay a significant, but undisclosed, portion of the inflated price back to the PBMs (the "Manufacturer Payments").[10] The Manufacturer Payments bear a variety of dubious labels—rebates, discounts, credits, inflation/price protection fees, administrative fees, etc. By whatever name, the inflated list prices and resulting Manufacturer Payments are a quid pro quo for inclusion and favorable placement on the PBMs' formularies.[11]

19. Contracts between PBM Defendants and payors like Plaintiff tie the definition of "rebates" to patient drug utilization. But the contracts between PBMs and Manufacturers define "rebates" and other Manufacturer Payments differently—e.g., calling rebates for formulary placement "administrative fees." Defendants thus profit from the "rebates" and other Manufacturer Payments, and the payments are beyond a payor's contractual audit right to verify the accuracy of "rebate" payments they receive.

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[9] The related term Average Wholesale Price (AWP) is the published price for a drug sold by wholesalers to retailers.

[10] In this Complaint, "Manufacturer Payments" is defined as all payments or financial benefits of any kind conferred by the Manufacturer Defendants to PBM Defendants (or a subsidiary, affiliated entity, or group purchasing organization or rebate aggregator acting on a PBM's behalf), either directly via contract or indirectly via Manufacturer-controlled intermediaries. Manufacturer Payments includes rebates, administrative fees, inflation fees, pharmacy supplemental discounts, volume discounts, price or margin guarantees, and any other form of consideration exchanged.

[11] Favorable or preferred placement may, for example, involve placing a branded product in a lower cost-sharing tier or relaxing utilization controls (such as prior authorization requirements or quantity limits). Favorable placement of a relatively more expensive drug encourages use of that drug and leads to higher out-of-pocket costs for payors and copayors.

20. The PBMs' staggering revenues vastly exceed the fair market value of the services they provide and, specifically, the amount of Manufacturer Payments the PBMs receive in connection with the at-issue drugs vastly exceeds the fair market value of the services they provide with respect to those drugs.

21. The Manufacturers' list prices are not the result of free-market competition for payors' business. The Manufacturers' list prices are so untethered from the net prices that the Manufacturers ultimately realize that the Manufacturers know the list price constitutes a false price. It does not reflect the Manufacturers' actual costs to produce the at-issue drugs or the fair market value of the drugs.[12]

22. The PBMs grant formulary status based upon the highest inflated price—a price that the PBMs know is false—and based upon which diabetes medications will generate the largest profits for themselves.

23. The Insulin Pricing Scheme creates a "best of both worlds" scenario for Defendants. The Manufacturer Defendants buy formulary access and increase their revenues while the PBM Defendants receive significant secret Manufacturer Payments.

24. The PBM Defendants profit off the Insulin Pricing Scheme in numerous ways, including by: (1) retaining a significant, but undisclosed, share of the Manufacturer Payments, either directly or through rebate aggregators, (2) using the price produced by the Insulin Pricing Scheme to generate unwarranted profits from pharmacies, and (3) relying on those same artificial

[12] "Net price" refers to the price the manufacturer ultimately realizes, i.e., the list price less rebates, discounts, etc. (net sales divided by volume). At times, Defendants' representatives use "net price" to refer to the amount payors or plan members pay for medications. In this Complaint, "net price" refers to the former—the amount that the Defendant Manufacturers realize for the at-issue drugs, which is roughly the List Price less Manufacturer Payments.

list prices to drive up the PBMs' margins and pharmacy related fees, including those relating to their mail-order pharmacies.

25. As detailed below, although the PBM Defendants represent both publicly and directly to their client payors that they use their market power to drive down prices for diabetes medications, these representations are false and deceptive. Instead, the PBMs intentionally incentivize the Manufacturers to inflate list prices, and the PBMs' "negotiations" intentionally drive up the price of the at-issue drugs and are directly responsible for the skyrocketing price of diabetes medications, which confers unearned benefits upon the PBMs and Manufacturers alike.

26. Because the purchase price of every at-issue diabetes medication flows from the false list price generated by Defendants' unfair and deceptive scheme, every payor in the United States that purchases these life-sustaining drugs, including Plaintiff, has been directly harmed by the Insulin Pricing Scheme.

27. Even if temporary reductions in Plaintiff's costs for the at-issue drugs occurred from time to time, those costs remained higher than the prices that would have resulted from a transparent exchange in an open and competitive market.

28. As a payor for and purchaser of the at-issue drugs, and, as a direct result of the Insulin Pricing Scheme, Greene County has spent exorbitant amounts of capital on the at-issue diabetes medications.

29. A substantial portion of this exorbitant amount is attributable to Defendants' artificially inflated prices that did not arise from transparent or competitive market forces; rather, these inflated costs can be attributed to undisclosed dealings between the Manufacturer Defendants and the PBM Defendants as further described herein.

30. This action alleges that Defendants violated the Racketeer Influenced and Corrupt Organizations Act, Tennessee Consumer Protection Act, and Tennessee common law by engaging in the Insulin Pricing Scheme. The Insulin Pricing Scheme directly and foreseeably caused and continues to cause harm to Plaintiff.

31. This action seeks injunctive relief, restitution, disgorgement, actual damages, treble damages, punitive damages, and attorneys' fees and costs to address and abate the harm caused by the Insulin Pricing Scheme.

32. The relevant period for damages alleged in this Complaint is from 2003 through the present.

PARTIES

A. Plaintiff

33. Plaintiff Greene County is a body corporate and politic under the laws of the State of Tennessee.

34. Plaintiff, as a government entity, provides vital services to its population of over 70,000 residents including public safety, emergency management, and health services.

35. Any increase in spending has a detrimental effect on Plaintiff's overall budget and, in turn, negatively impacts its ability to provide necessary services to the community.

36. The Insulin Pricing Scheme has had such an effect.

37. Additionally, as a government employer, Plaintiff provides health benefits to its employees, retirees, and their dependents ("Beneficiaries"). These benefits include paying for Beneficiaries' pharmaceutical drugs, including the at-issue diabetes medications. Plaintiff also purchases the at-issue diabetes medications for use in county-run facilities.

38. Plaintiff maintains a self-insured health plan for its Beneficiaries.

39. Exclusive of the costs associated with providing diabetes medications at county-run facilities, such as correctional facilities, Plaintiff spends thousands of dollars per year on the costs of providing diabetes medications for its health-plan members. Accordingly, during the relevant period, and to the detriment of its Beneficiaries and taxpayers, Plaintiff has paid millions of dollars more for insulin than it otherwise would have paid absent Defendants' conduct.

40. Plaintiff seeks to recover for the losses it has suffered due to Defendants' illegal Insulin Pricing Scheme.

B. Manufacturer Defendants

41. **Defendant Eli Lilly and Company ("Eli Lilly")** is an Indiana corporation with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

42. Eli Lilly is registered to do business in the State of Tennessee. Eli Lilly may be served through its registered agent: National Registered Agents, Inc., 300 Montvue Road, Knoxville, Tennessee 37919-5546.

43. In Tennessee and nationally, Eli Lilly manufactures, promotes, and distributes several at-issue diabetes medications: Humulin N, Humulin R, Humalog, Trulicity, and Basaglar.

44. Eli Lilly's global revenues in 2019 were $4.13 billion from Trulicity, $2.82 billion from Humalog, $1.29 billion from Humulin and $1.11 billion from Basaglar.

45. Eli Lilly's global revenues in 2018 were $3.2 billion from Trulicity, $2.99 billion from Humalog, $1.33 billion from Humulin and $801 million from Basaglar.

46. Eli Lilly transacts business in Tennessee and in Greene County, targeting these markets for its products, including the at-issue diabetes medications.

47. Eli Lilly employs sales representatives throughout Tennessee to promote and sell Humulin N, Humulin R, Humalog, Trulicity, and Basaglar.

48. Eli Lilly also directs advertising and informational materials to Tennessee and Greene County physicians and potential users of Eli Lilly's products.

49. At all times relevant hereto, in furtherance of the Insulin Pricing Scheme, Eli Lilly published its prices for the at-issue diabetes medications throughout Tennessee with the express knowledge that payment and reimbursement by Plaintiff would be based on those false list prices.

50. During the relevant time period, Plaintiff purchased Eli Lilly's at-issue drugs at a price based on false list prices generated by the Insulin Pricing Scheme through its employee health plans and for use in county-run facilities.

51. All of the Eli Lilly diabetes medications related to the at-issue transactions were paid for and/or reimbursed in Tennessee based on the specific false and inflated prices Eli Lilly caused to be published in Tennessee in furtherance of the Insulin Pricing Scheme.

52. **Defendant Sanofi-Aventis U.S. LLC ("Sanofi")** is a Delaware limited liability company with its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

53. Sanofi may be served through its registered agent: Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808.

54. Sanofi manufactures, promotes, and distributes pharmaceutical drug both in Tennessee and nationally, including several at-issue diabetes medications: Lantus, Toujeo, Soliqua, and Apidra.

55. Sanofi's global revenues in 2019 were $3.50 billion from Lantus and $1.03 billion from Toujeo, $400 million from Apidra and $144 million from Soliqua.

56. Sanofi's global revenues in 2018 were $3.9 billion from Lantus, $923 million from Toujeo, $389 million from Apidra and $86 million from Soliqua.

57. Sanofi does business in Tennessee and in Greene County, targeting these markets for its products, including the at-issue diabetes medications.

58. Sanofi employs sales representatives throughout Tennessee and in this District to promote and sell Lantus, Toujeo, Soliqua, and Apidra.

59. Sanofi also directs advertising and informational materials to Tennessee physicians and potential users of Sanofi's products for the specific purpose of selling the at-issue drugs in Tennessee and Greene County and profiting from the Insulin Pricing Scheme.

60. At all times relevant hereto, in furtherance of the Insulin Pricing Scheme, Sanofi published its prices of its at-issue diabetes medications throughout Tennessee for the purpose of payment and reimbursement by payors, including Plaintiff.

61. During the relevant time period, Plaintiff Greene County purchased Sanofi's at-issue drugs at prices based on false list prices generated by the Insulin Pricing Scheme through its employee health plans and for use in county-run facilities.

62. All of the Sanofi diabetes medications related to the at-issue transactions were paid for and/or reimbursed in Tennessee and Greene County based on the specific false and inflated prices Sanofi caused to be published in Tennessee in furtherance of the Insulin Pricing Scheme.

63. **Defendant Novo Nordisk Inc. ("Novo Nordisk")** is a Delaware corporation with its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

64. Novo Nordisk is registered to do business in the State of Tennessee. Novo Nordisk may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

65. Novo Nordisk manufactures, promotes, and distributes pharmaceutical drugs both in Tennessee and nationally, including at-issue diabetic medications: Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic.

66. Nordisk's global revenues in 2019 were $2.89 billion from Novolog, $973 million from Levemir, $968 million from Tresiba, $2.29 billion from Victoza and $1.17 billion from Ozempic.[13]

67. Novo Nordisk's global revenues in 2018 were $4.19 billion from Novolog, $1.66 billion from Levemir, $1.19 billion from Tresiba, $3.61 billion from Victoza and $185 million from Ozempic.

68. Novo Nordisk transacts business in Tennessee and in Greene County, targeting these markets for its products, including the at-issue diabetes medications.

69. Novo Nordisk employs sales representatives throughout Tennessee and Greene County to promote and sell Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic.

70. Novo Nordisk also directs advertising and informational materials to Tennessee and Greene County physicians and potential users of Novo Nordisk's products.

71. At all times relevant hereto, in furtherance of the Insulin Pricing Scheme, Novo Nordisk published its prices of its at-issue diabetes medications throughout Tennessee for the purpose of payment and reimbursement by Plaintiff.

72. During the relevant time period, Plaintiff purchased Novo Nordisk's at-issue diabetes medications at prices based on false list prices generated by the Insulin Pricing Scheme through its employee health plans and for use in county-run facilities.

[13] Novo Nordisk, Annual Report (Form 20-F) (Dec. 31, 2019).

73. All Novo Nordisk diabetes medications related to the at-issue transactions were paid for and/or reimbursed in Tennessee based on the specific false and inflated prices Novo Nordisk caused to be published in Tennessee in furtherance of the Insulin Pricing Scheme.

74. Collectively, Defendants Eli Lilly, Novo Nordisk, and Sanofi are referred to as the "Manufacturer Defendants" or the "Manufacturers."

C. PBM Defendants

75. **Defendant CVS Health Corporation ("CVS Health")** is a Delaware corporation with its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895. CVS Health transacts business and has locations throughout the United States and Tennessee.

76. CVS Health may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

77. CVS Health—through its executives and employees, including its CEO, Chief Medical Officer, Executive Vice Presidents, Senior Executives in Trade Finance, Senior Vice Presidents, and Chief Communication Officers—is directly involved in creating and implementing the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs involved in the Insulin Pricing Scheme.

78. CVS Health's conduct had a direct effect in Tennessee and damaged Plaintiff Greene County as a payor and purchaser.

79. On a regular basis, CVS Health executives and employees communicate with and direct its subsidiaries related to the at-issue PBM services and formulary activities.

80. In each annual report for at least the last decade, CVS Health (or its predecessor) has repeatedly and explicitly stated that CVS Health:

- designs pharmacy benefit plans that minimize the costs to the client while prioritizing the welfare and safety of the clients' members;

- negotiates with pharmaceutical companies to obtain discounted acquisition costs for many of the products on CVS Health's drug lists, and these negotiated discounts enable CVS Health to offer reduced costs to clients; and

- utilizes an independent panel of doctors, pharmacists, and other medical experts, referred to as its Pharmacy and Therapeutics Committee, to select drugs that meet the highest standards of safety and efficacy for inclusion on its drug lists.

81. CVS Health publicly represents that it constructs programs that lower the cost of the at-issue diabetes medications. For example, in 2016, CVS Health announced a new program to "reduce overall spending in diabetes" that is available in all states, including Tennessee, stating:

> *CVS Health* introduced a new program available to help the company's pharmacy benefit management (PBM) clients to improve the health outcomes of their members, *lower pharmacy costs [for diabetes medications]* through aggressive trend management and decrease medical costs . . . [and that] participating clients could save between $3000 to $5000 per year for each member who successfully improves control of their diabetes" (emphasis supplied).[14]

82. In 2017, CVS Health stated that "*CVS Health* pharmacy benefit management (PBM) strategies reduced trend for commercial clients to 1.9 percent per member per year the lowest in five years. Despite manufacturer price increases of near 10 percent, *CVS Health* kept drug price growth at a minimal 0.2 percent."

83. In November 2018, CVS Health acquired Aetna for $69 billion and became the first combination of a major health insurer, PBM, and mail-order and retail pharmacy chain. As a result, CVS Health controls the health plan/insurer, the PBM, and the pharmacies utilized by approximately 40 million Aetna members in the United States, including in Tennessee. CVS Health controls the entire drug pricing chain for these 40 million Americans.

[14] CVS HEALTH, *CVS Health Introduces New "Transform Diabetes Care" Program to Improve Health Outcomes and Lower Overall Health Care Costs* (Dec. 13, 2016), https://cvshealth.com/newsroom/press-releases/cvs-health-introduces-newtransform-diabetes-care-program-improve-health.

84. CVS Health is the immediate or indirect parent of many pharmacy subsidiaries that own and operate hundreds of pharmacies throughout Tennessee that dispensed and received payment for the at-issue diabetes medications throughout the relevant time period.

85. **Defendant CVS Pharmacy, Inc. ("CVS Pharmacy")** is a Rhode Island corporation whose principal place of business is at the same location as CVS Health. CVS Pharmacy is a wholly owned subsidiary of CVS Health.

86. CVS Pharmacy is the immediate or indirect parent of many pharmacy subsidiaries that own and operate hundreds of pharmacies throughout Tennessee and is directly involved in these pharmacies dispensing and payment policies related to the at issue diabetes medications.

87. CVS Pharmacy is also the immediate and direct parent of Defendant Caremark Rx, LLC.

88. CVS Pharmacy is registered to do business in Tennessee and has been since at least 1997.

89. CVS Pharmacy is registered to do business in the State of Tennessee. CVS Pharmacy may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

90. During the relevant time period, CVS Pharmacy provided retail pharmacy services in Tennessee that gave rise to the Insulin Pricing Scheme, which damaged Plaintiff.

91. **Defendant Caremark Rx, LLC** is a Delaware limited liability company and an immediate or indirect parent of many subsidiaries, including pharmacy benefit management and mail-order subsidiaries that engaged in the activities in Tennessee that gave rise to this Complaint.

92. Caremark Rx, LLC is a wholly owned subsidiary of Defendant CVS Pharmacy and its principal place of business is at the same location as CVS Pharmacy and CVS Health.

93. Caremark Rx, LLC is registered to do business in Tennessee and has been since at least 2007. Caremark Rx, LLC may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

94. During the relevant time period, Caremark Rx, LLC provided PBM and mail order pharmacy services in Tennessee that gave rise to the Insulin Pricing Scheme and damaged payors in Tennessee, including Plaintiff.

95. **Defendant Caremark, LLC** is a California limited liability company whose principal place of business is at the same location as CVS Health. Caremark, LLC is a wholly owned subsidiary of Caremark Rx, LLC.

96. Caremark, LLC is registered to do business in Tennessee and has been since at least 2007. Caremark, LLC may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

97. During the relevant time period, Caremark, LLC provided PBM and mail order pharmacy services in Tennessee and Greene County that gave rise to the Insulin Pricing Scheme, which damaged Plaintiff.

98. **Defendant CaremarkPCS Health, LLC** is a Delaware limited liability company whose principal place of business is at the same location as CVS Health. CVS Health is the direct or indirect parent company of CaremarkPCS Health LLC.

99. CaremarkPCS Health, LLC, doing business as CVS Caremark, provides pharmacy benefit management services.

100. CaremarkPCS Health, LLC is registered to do business in Tennessee and has been since at least 2009. CaremarkPCS Health, LLC may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

101. During the relevant time period, CaremarkPCS Health, LLC provided PBM services in the State of Tennessee, which gave rise to the Insulin Pricing Scheme and damaged Plaintiff Greene.

102. Defendants CaremarkPCS Health, LLC and Caremark, LLC are agents and/or alter egos of Caremark Rx, LLC, CVS Pharmacy, and CVS Health.

103. As a result of numerous interlocking directorships and shared executives, Caremark Rx, LLC, CVS Pharmacy, and CVS Health are directly involved in the conduct of and control CaremarkPCS Health, LLC and Caremark, LLC's operations, management, and business decisions related to the at-issue formulary construction; Manufacturer Payments; and mail-order and retail pharmacy services—to the ultimate detriment of Plaintiff. For example:

a. During the relevant time period, these parent and subsidiaries have had common officers and directors, including:

- Thomas S. Moffatt, Vice President and Secretary of Caremark Rx, LLC, CaremarkPCS Health LLC, and Caremark, LLC, is also a Vice President, Assistant Secretary, and Senior Legal Counsel at CVS Health and the Vice President, Secretary and Senior Legal Counsel of CVS Pharmacy;

- Melanie K. Luker, Assistant Secretary of Caremark Rx, LLC, CaremarkPCS Health, LLC, and Caremark, LLC, is also a Manager of Corporate Services at CVS Health;

- Carol A. Denale, Senior Vice President and Treasurer of Caremark Rx, LLC, is also Senior Vice President, Treasurer and Chief Risk Officer at CVS Health Corporation;

- John M. Conroy has been Vice President of Finance at CVS Health since 2011, and was also President and Treasurer of Caremark, LLC and CaremarkPCS Health LLC in 2019; and

- Sheelagh Beaulieu has been the Senior Director of Income Tax at CVS Health while also acting as the Assistant Treasurer at CaremarkPCS Health LLC and Caremark LLC.

b. CVS Health owns all the stock of CVS Pharmacy, which, in turn, owns all the stock of Caremark Rx, LLC, which, in turn, owns all the stock of Caremark LLC. CVS Health also directly or indirectly owns all the stock of CaremarkPCS Health LLC.

c. CVS Health, as a corporate family, does not operate as separate entities. The public filings, documents, and statements of CVS Health present its subsidiaries, including CVS Pharmacy, CaremarkPCS Health, LLC, Caremark, LLC and Caremark Rx, LLC as divisions or departments of one unified "diversified health services company" that "works together across our disciplines" to "create unmatched human connections to transform the health care experience." The day-to-day operations of this corporate family reflect these public statements. These entities are a single business enterprise and should be treated as such as to all legal obligations discussed in this Complaint.[15]

d. All executives of CaremarkPCS Health, LLC, Caremark, LLC, Caremark Rx, LLC, and CVS Pharmacy ultimately report to the executives at CVS Health, including the President and CEO of CVS Health.

e. As stated above, CVS Health's CEO, Chief Medical Officer, Executive Vice Presidents, Senior Executives in Trade Finance, Senior Vice Presidents, and Chief Communication Officers are directly involved in the policies and business decisions of CaremarkPCS Health, LLC and Caremark, LLC that gave rise to Plaintiff Greene County's claims in this Complaint.

[15] CVS Caremark/CVS Health, Annual Report (Form 10-K) (Dec. 31, 2009-2019); CVS Health, *Our Purpose*, https://cvshealth.com/about-cvs-health/our-purpose (last visited Sept. 9, 2022); CVS Health, *Quality of Care*, https://cvshealth.com/health-withheart/improving-health-care/quality-of-care (last visited Sept. 9, 2022).

104. Collectively, Defendants CVS Health, CVS Pharmacy, Caremark Rx, LLC, Caremark, LLC and CaremarkPCS Health, LLC, including all predecessor and successor entities, are referred to as "CVS Caremark."

105. CVS Caremark is named as a Defendant in its capacities as a PBM and pharmacy.

106. In its capacity as a PBM, CVS Caremark coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the price of the at-issue diabetes medications, as well as for the placement of these Manufacturers' diabetes medications on CVS Caremark's formularies.

107. CVS Caremark has the largest PBM market share based on total prescription claims managed, representing approximately 40% of the national market. CVS Caremark's pharmacy services segment generated $141.5 billion in total revenues last year.

108. At all times relevant hereto, CVS Caremark offered pharmacy benefit services nationwide and to Tennessee payors, and derived substantial revenue therefrom, and, in doing so, made the at-issue misrepresentations (discussed below) and utilized the false prices generated by the Insulin Pricing Scheme to unlawfully profit off of payors like Plaintiff.

109. At all times relevant hereto, CVS Caremark offered pharmacy benefit management services nationwide and maintained standard formularies that are used nationwide, including in Tennessee. During the relevant time period, those formularies included diabetes medications, including all of those at issue in this Complaint.

110. CVS Caremark purchases drugs directly from manufacturers and through drug wholesalers for dispensing through its mail-order pharmacy.

111. During the relevant time period, CVS Caremark provided PBM services to Plaintiff and, in doing so, CVS Caremark set the price that Plaintiff paid for the at-issue drugs based on the

false list prices generated by the Insulin Pricing Scheme. Plaintiff paid CVS Caremark for the at-issue drugs.

112. In its capacity as a retail pharmacy, CVS Caremark further and knowingly profited from the false list prices produced by the Insulin Pricing Scheme by pocketing the spread between acquisition cost for the drugs at issue (an amount well below the list price generated by the Insulin Pricing Scheme), and the amounts it received from payors (which amounts were based on the false list prices and, in many cases, were set by CVS Caremark in its capacity as a PBM).

113. During the relevant time period, CVS Caremark provided mail-order and retail pharmacy services to Plaintiff and, in doing so, Plaintiff paid CVS Caremark for the at-issue drugs at prices based on the false list prices generated by the Insulin Pricing Scheme.

114. At all times relevant hereto, CVS Caremark dispensed the at-issue medications nationwide and directly to Plaintiff through its mail-order and retail pharmacies and derived substantial revenue from these activities in Tennessee.

115. At all times relevant hereto, CVS Caremark had express agreements with Defendants Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid by the Manufacturer Defendants to CVS Caremark, as well as agreements related to the Manufacturers' at-issue drugs sold through CVS Caremark's mail-order pharmacies.

116. **Defendant Evernorth Health, Inc. ("Evernorth")**, formerly known as Express Scripts Holding Company, is a Delaware corporation with its principal place of business at 1 Express Way, St. Louis, Missouri 63121.[16]

[16] Until 2021, Evernorth Health, Inc. conducted business under the name Express Scripts Holding Company. For the purposes of this Complaint "Evernorth" refers to Evernorth Health, Inc and Express Scripts Holding Company.

117. Evernorth may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

118. Evernorth, through its executives and employees, including its CEO and Vice Presidents, is directly involved in shaping the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs, related to the Insulin Pricing Scheme.

119. Evernorth's conduct had a direct effect in Tennessee and with respect to Plaintiff Greene County.

120. On a regular basis, Evernorth executives and employees communicate with and direct Evernorth's subsidiaries related to the at-issue PBM services and formulary activities.

121. Evernorth is the immediate or indirect parent of pharmacy and PBM subsidiaries that operate throughout Tennessee, which engaged in the activities that gave rise to this Complaint.

122. In December 2018, Evernorth merged with Cigna in a $67 billion deal to consolidate their businesses as a major health insurer, PBM, and mail-order pharmacy. As a result, the Evernorth corporate family controls the health plan/insurer, the PBM, and the mail-order pharmacies utilized by approximately 15 million Cigna members in the United States, including in Tennessee. Evernorth controls the entire drug pricing chain for these 15 million Americans.

123. In each annual report for at least the last decade, Evernorth has repeatedly and explicitly:

- Acknowledged that it is directly involved in the company's PBM services, stating "[Evernorth is] the largest stand-alone PBM company in the United States."

- Stated that Evernorth: "provid[es] products and solutions that focus on improving patient outcomes and assist in controlling costs; evaluat[es] drugs for efficacy, value and price to assist clients in selecting a cost-effective formulary; [and] offer[s] cost-effective home delivery pharmacy and specialty services that result in cost savings for plan sponsors and better care for members."

124. **Defendant Express Scripts, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. Express Scripts, Inc.'s principal place of business is the same location as Evernorth.

125. Express Scripts, Inc. is registered to do business in Tennessee and has been since at least 2017. Express Scripts, Inc. may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 39719-5546.

126. Express Scripts, Inc. is the immediate or indirect parent of pharmacy and PBM subsidiaries that operate throughout Tennessee that engaged in the conduct that gave rise to this Complaint.

127. During the relevant time period, Express Scripts Inc. was directly involved in the PBM and mail-order pharmacy services that gave rise to the Insulin Pricing Scheme and damaged Plaintiff.

128. Indeed, Express Scripts, Inc. provided pharmacy benefit services to Plaintiff, based on Plaintiff's reliance upon Express Scripts, Inc.'s response to Plaintiff's Request for Proposals.

129. **Defendant Express Scripts Administrators, LLC**, doing business as Express Scripts and formerly known as Medco Health, LLC, is a Delaware limited liability company and is a wholly owned subsidiary of Evernorth. Express Scripts Administrators, LLC's principal place of business is at the same location as Evernorth.

130. Express Scripts Administrators, LLC is registered to do business in Tennessee and may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

131. During the relevant time period, Express Scripts Administrators, LLC provided the PBM services in Tennessee discussed in this Complaint that gave rise to the Insulin Pricing Scheme that damaged Plaintiff.

132. **Defendant Medco Health Solutions, Inc. ("Medco")** is a Delaware Corporation with its principal place of business located at 100 Parsons Pond Road, Franklin Lakes, New Jersey.

133. Medco is registered to do business in Tennessee and may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

134. In 2012, Express Scripts acquired Medco for $29 billion.

135. Prior to the merger, Express Scripts and Medco were two of the largest PBMs in the United States and in Tennessee.

136. Prior to the merger, Medco provided the at-issue PBM and mail-order services, which gave rise to the Insulin Pricing Scheme and damaged Plaintiff, within Tennessee.

137. Following the merger, all of Medco's PBM and mail-order pharmacy functions were combined into Express Scripts. The combined company (Medco and Express Scripts) continued under the name Express Scripts with all of Medco's payor customers becoming Express Scripts' customers. The combined company covered over 155 million lives at the time of the merger.

138. At the time of the merger, on December 6, 2011, in his testimony before the Senate Judiciary Committee, David B. Snow, the then-CEO of Medco, publicly represented that "the merger of Medco and Express Scripts will result in immediate savings to our clients and, ultimately, to consumers. This is because our combined entity will achieve even greater [Manufacturer Payments] from drug manufacturers and other suppliers."

139. The then-CEO of Express Scripts, George Paz, during a Congressional subcommittee hearing in September 2011, echoed these sentiments: "A combined Express Scripts and Medco will be well-positioned to protect American families from the rising cost of prescription medicines."

140. **Defendant ESI Mail Pharmacy Service, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. ESI Mail Pharmacy Service, Inc.'s principal place of business is the same location as Evernorth.

141. ESI Mail Pharmacy Service, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

142. During the relevant time period, ESI Mail Pharmacy Services provided the mail-order pharmacy services in Tennessee discussed in this Complaint, which gave rise to the Insulin Pricing Scheme and damaged Plaintiff.

143. **Defendant Express Scripts Pharmacy, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. Express Scripts Pharmacy, Inc.'s principal place of business is at the same location as Evernorth.

144. Express Scripts Pharmacy, Inc. is registered to do business in Tennessee and has been since 2021. Express Scripts Pharmacy, Inc. may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

145. During the relevant time period, Express Scripts Pharmacy, Inc. provided the mail-order pharmacy services in Tennessee discussed in this Complaint, which gave rise to the Insulin Pricing Scheme and damaged Plaintiff.

146. As a result of numerous interlocking directorships and shared executives, Evernorth and Express Scripts, Inc. control Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., and Express Scripts Pharmacy, Inc's operations, management, and business decisions related to the at-issue formulary construction, negotiations, and mail-order pharmacy services to the ultimate detriment of Plaintiff. For example:

a. During the relevant time period, these parent and subsidiaries have had common officers and directors:

- Officers and/or directors shared between Express Scripts, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; David Queller, President; Jill Stadelman, Managing Counsel; and Scott Lambert, Treasury Manager Director;
- Executives shared between Express Scripts Administrators, LLC and Evernorth include Bradley Phillips, Chief Financial Officer; and Priscilla Duncan, Associate Senior Counsel;
- Officers and/or directors shared between ESI Mail Pharmacy Service, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; Priscilla Duncan, Associate Senior Counsel; and Joanne Hart, Treasury Director; and
- Officers and/or directors shared between Express Scripts Pharmacy, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; Jill Stadelman, Managing Counsel; Scott Lambert, Treasury Manager Director; and Joanne Hart, Treasury Director.

b. Evernorth directly or indirectly owns all the stock of Express Scripts Administrators, LLC, Medco Health Solutions, Inc., ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc. and Express Scripts, Inc.

c. The Evernorth corporate family does not operate as separate entities. The public filings, documents, and statements of Evernorth present its subsidiaries, including Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc. and Express Scripts, Inc., as divisions or departments of a single company that "unites businesses that have as many as 30+ years of experience . . . to

take health services further with integrated data and analytics that help us deliver better care to more people." The day-to-day operations of this corporate family reflect these public statements. All of these entities comprise a single business enterprise and should be treated as such as to all legal obligations detailed in this Complaint. All of the executives of Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc., and Express Scripts, Inc. ultimately report to the executives, including the CEO, of Evernorth.

d. As stated above, Evernorth's CEO and other executives and officers are directly involved in the policies and business decisions of Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., Express Scripts Pharmacy, Inc., and Express Scripts, Inc. that gave rise to Plaintiff's claims in this Complaint.

147. Collectively, Defendants Evernorth Health, Inc., Express Scripts, Inc., Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., and Express Scripts Pharmacy, Inc., including all predecessor and successor entities, are referred to as "Express Scripts."

148. Express Scripts is named as a Defendant in its capacities as a PBM and mail order pharmacy.

149. In its capacity as a PBM, Express Scripts coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the price of the at-issue diabetes medications, as well as for the placement of these Manufacturers' diabetes medications on Express Script's formularies.

150. Prior to merging with Cigna in 2019, Express Scripts was the largest independent PBM in the United States. During the relevant period of this Complaint, Express Scripts controlled

30% of the PBM market in the United States. Express Scripts has only grown larger since the Cigna merger.

151. In 2017, annual revenue for Express Scripts was over $100 billion.

152. As of December 31, 2018, more than 68,000 retail pharmacies, representing over 98% of all retail pharmacies in the nation, participated in one or more of Express Scripts' networks.

153. Express Scripts transacts business throughout the United States and Tennessee.

154. At all times relevant hereto, Express Scripts derived substantial revenue providing pharmacy benefits in Tennessee.

155. At all times relevant hereto, and contrary to their express representations, Express Scripts knowingly insisted that its payor clients use the false list prices produced by the Insulin Pricing Scheme as the basis for reimbursement of the at-issue drugs.

156. At all times relevant hereto, Express Scripts concealed its critical role in the generation of those false list prices.

157. At all times relevant hereto, Express Scripts maintained standard formularies that are used nationwide, including in Tennessee. During the relevant time period, those formularies included drugs produced by the Manufacturer Defendants, including the at-issue diabetes medications.

158. During the relevant time period, Express Scripts provided PBM services to Plaintiff and, in doing so, Express Scripts set the price that Plaintiff paid for the at-issue drugs, at prices based on the false list prices generated by the Insulin Pricing Scheme, and Plaintiff paid Express Scripts for the at-issue drugs.

159. In its capacity as a mail-order pharmacy, Express Scripts received payments from Tennessee payors for, and set the out-of-pocket price paid for, the at-issue drugs based on the falsely inflated prices generated by the Insulin Pricing Scheme and, as a result, damaged Plaintiff.

160. At all times relevant hereto, Express Scripts offered pharmacy benefit management services nationwide and maintained standard formularies that are used nationwide, including in Tennessee. During the relevant time period, those formularies included diabetes medications, including all of those at issue in this Complaint.

161. Express Scripts purchases drugs directly from manufacturers for dispensing through its mail-order pharmacy.

162. At all times relevant hereto, Express Scripts dispensed the at-issue medications nationwide and directly to Plaintiff through its mail-order pharmacies and derived substantial revenue from these activities in Tennessee.

163. During the relevant time period, in addition to its critical role in the Insulin Pricing Scheme, which detrimentally affected all payors and purchasers of the at-issue drugs, Express Scripts also provided PBM services directly to Plaintiff Greene County.

164. During the years when some of the largest at-issue price increases occurred, Express Scripts worked directly with OptumRx to negotiate Manufacturer Payments on behalf of OptumRx and its clients in exchange for preferred formulary placement.

165. For example, in a February 2014 email released by the U.S. Senate in conjunction with its January 2021 report titled “Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug” (“January 2021 Senate Insulin Report”), Eli Lilly describes a “Russian nested

doll situation" in which Express Scripts was negotiating rebates on behalf of OptumRx related to the at-issue drugs for Cigna (who later would become part of Express Scripts).[17]

166. At all times relevant hereto, Express Scripts had express agreements with Defendants Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid by the Manufacturer Defendants to Express Scripts, as well as agreements related to the Manufacturers' at-issue drugs sold through Express Scripts' mail-order pharmacies.

167. **Defendant UnitedHealth Group, Inc**. is a corporation organized under the laws of Delaware with its principal place of business at 9900 Bren Road East, Minnetonka, Minnesota, 55343.

168. UnitedHealth Group, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

169. UnitedHealth Group, Inc. is a diversified managed healthcare company. In 2015, UnitedHealth Group reported revenue in excess of $257 billion, and the company is currently ranked sixth on the Fortune 500 list. UnitedHealth Group, Inc. offers a spectrum of products and services including health insurance plans through its wholly owned subsidiaries and prescription drugs through its PBM, OptumRx.

170. Over one-third of the overall revenues of UnitedHealth Group come from OptumRx.

[17] CHARLES E. GRASSLEY & RON WYDEN, STAFF REPORT ON INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG, S. FIN. COMM., https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf; Letter from Joseph B. Kelley, Eli Lilly Vice President, Global Gov. Affairs, to Charles E. Grassley & Ron Wyden, S. Fin. Comm. (Mar. 8, 2019), https://www.finance.senate.gov/imo/media/doc/Eli%20Lilly_Redacted%20v1.pdf

171. UnitedHealth Group, through its executives and employees, is directly involved in the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs and related to the Insulin Pricing Scheme. For example, UnitedHealth Group executives structure, analyze, and direct the company's overarching policies, including with respect to PBM and mail-order services, as a means of maximizing profitability across the corporate family.

172. UnitedHealth Group's Sustainability Report states that "OptumRx works directly with pharmaceutical manufacturers to secure discounts that lower the overall cost of medications and create tailored formularies – or drug lists – to ensure people get the right medications. [*UnitedHealth Group*] then negotiate[s] with pharmacies to lower costs at the point of sale . . . [*UnitedHealth Group*] also operate[s] [mail-order pharmacies] . . .. [*UnitedHealth Group*] work[s] directly with drug wholesalers and distributors to ensure consistency of the brand and generic drug supply, and a reliance on that drug supply."

173. In addition to being a PBM and a mail-order pharmacy, UnitedHealth Group owns and controls a major health insurance company, UnitedHealthcare. As a result, UnitedHealth Group controls the health plan/insurer, the PBM, and the mail-order pharmacies utilized by approximately 26 million UnitedHealthcare members in the United States, including those in Tennessee. UnitedHealth Group controls the entire drug pricing chain for these 26 million Americans.

174. UnitedHealth Group's conduct had a direct effect in Tennessee and damaged Plaintiff.

175. UnitedHealth Group states in its Annual Reports that UnitedHealth Group "utilizes Optum's capabilities to help coordinate patient care, improve affordability of medical care, analyze

cost trends, manage pharmacy benefits, work with care providers more effectively and create a simpler consumer experience."

176. **Defendant Optum, Inc.** is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. Optum, Inc. is a health services company managing subsidiaries that administer pharmacy benefits, including Defendant OptumRx, Inc.

177. Optum, Inc. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

178. Optum, Inc. is directly involved, through its executives and employees, in the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs and related to the Insulin Pricing Scheme, which had a direct effect in Tennessee and damaged Plaintiff.

179. For example, according to Optum Inc.'s press releases, Optum, Inc. is "UnitedHealth Group's information and technology-enabled health services business platform serving the broad healthcare marketplace, including care providers, plan sponsors, payors, life sciences companies and consumers."[18] In this role Optum, Inc. is directly responsible for the "business units – OptumInsight, OptumHealth and OptumRx"[19] and the CEOs of all these companies report directly to Optum, Inc. regarding their policies, including those that inform the at-issue formulary construction and mail order activities.

180. **Defendant OptumRx, Inc.** is a California corporation with its principal place of business at 2300 Main Street, Irvine, California, 92614.

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[18] UNITEDHEALTH GROUP, https://www.unitedhealthgroup.com/ (last visited on Sept. 9, 2022); *UnitedHealth Group Announces "Optum" Master Brand for Its Health Services Businesses*, FIERCE HEALTHCARE (Apr. 11, 2011, 9:21 AM), https://www.fiercehealthcare.com/healthcare/unitedhealth-group-announces-optummaster-brand-for-its-health-services-businesses.

[19] *Id.*; UNITEDHEALTH GROUP, *UnitedHealth Group Announces "Optum" Master Brand for Its Health Services Businesses* (Apr. 11, 2011), https://www.unitedhealthgroup.com/newsroom/2011/0411optum.html.

181. OptumRx, Inc. operates as a subsidiary of OptumRx Holdings I, LLC, which, in turn, operates as a subsidiary of Defendant Optum, Inc.

182. OptumRx, Inc. is registered to do business in Tennessee and has been since at least 2008. OptumRx, Inc. may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

183. During the relevant time period, OptumRx, Inc. provided the PBM and mail order pharmacy services to Plaintiff and in Tennessee that gave rise to the Insulin Pricing Scheme, which damaged Plaintiff.

184. **Defendant OptumInsight, Inc**. is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota.

185. OptumInsight, Inc. is registered to do business in Tennessee and has been since at least 1997. OptumInsight, Inc. may be served through its registered agent: CT Corporation System, 300 Montvue Road, Knoxville, Tennessee 37919-5546.

186. OptumInsight, Inc. is an integral part of the Insulin Pricing Scheme and, during the relevant time period coordinated directly with the Manufacturer Defendants in furtherance of the conspiracy. OptumInsight analyzed data and other information from the Manufacturer Defendants to advise the other Defendants with regard to the profitability of the Insulin Pricing Scheme to the benefit of all Defendants.

187. As a result of numerous interlocking directorships and shared executives, UnitedHealth Group, OptumRx Holdings I, LLC, and Optum, Inc are directly involved in the conduct of and control OptumInsight and Optum Rx's operations, management, and business decisions related to the at-issue formulary construction, negotiations, and mail order pharmacy services to the ultimate detriment of Plaintiff. For example:

a. These parent and subsidiaries have common officers and directors, including:

- Sir Andrew Witty is president of UnitedHealth Group and CEO of Optum, Inc.;
- Dan Schumacher is president of Optum, Inc and is also named to the Office of the Chief Executive at UnitedHealth Group, Inc.;
- Terry Clark is a senior vice president and chief marketing officer at UnitedHealth Group and also oversees the branding, marketing and advertising for UnitedHealth Group and Optum, Inc.;
- Tom Roos serves as chief accounting officer for UnitedHealth Group and Optum, Inc.;
- Heather Lang is Deputy General Counsel, Subsidiary Governance at UnitedHealth Group, Inc. and also Assistant Secretary at OptumRx, Inc.;
- Peter Gill is Vice President at UnitedHealth Group, Inc. and also Treasurer at OptumRx, Inc.;
- John Santelli leads Optum Technology, the leading technology division of Optum, Inc serving the broad customer base of Optum and UnitedHealthcare and also serves as UnitedHealth Group's chief information officer; and
- Eric Murphy is the Chief Growth and Commercial Officer for Optum, Inc. and has also led OptumInsight, Inc.

b. UnitedHealth Group directly or indirectly owns all the stock of Optum, Inc., OptumRx, Inc., and OptumInsight, Inc.;

c. The UnitedHealth Group corporate family does not operate as separate entities. The public filings, documents, and statements of UnitedHealth Group present its subsidiaries, including Optum, Inc., OptumRx, Inc., and OptumInsight as divisions or departments of a single company that is "a diversified family of businesses" and that "leverages core competencies" to "help[] people live healthier lives and help[] make the health system work better for everyone." The day-to-day operations of this corporate family reflect these public statements. These entities are a single business

enterprise and should be treated as such as to all legal obligations detailed in this Complaint.[20]

d. All the executives of Optum, Inc., OptumRx, Inc., and OptumInsight ultimately report to the executives, including the CEO, of UnitedHealth Group.

e. As stated above, UnitedHealth Group's executives and officers are directly involved in the policies and business decisions of Optum, Inc., OptumRx, Inc., and OptumInsight that gave rise to Plaintiff's claims in this Complaint.

188. Collectively, Defendants UnitedHealth Group, Inc., OptumRx, Inc., OptumInsight, Inc. and Optum, Inc., including all predecessor and successor entities, are referred to as "OptumRx."

189. OptumRx is named as a Defendant in its capacities as a PBM and mail-order pharmacy.

190. OptumRx is a pharmacy benefit manager and, as such, coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the price of the at-issue diabetes medications, as well as for the placement of these Manufacturers' diabetes medications on OptumRx's drug formularies.

191. OptumRx provides pharmacy care services to more than 65 million people in the nation through a network of more than 67,000 retail pharmacies and multiple delivery facilities.[21]

192. In 2018, OptumRx managed more than $91 billion in pharmaceutical spending, representing 23% of the PBM market in the United States. OptumRx's 2018 revenue was $69 billion.

[20] UnitedHealth Group, Quarterly Report (Form 10-Q) (Mar. 31, 2017).
[21] UnitedHealth Group, Annual Report (Form 10-K) (Dec. 31, 2018).

193. In 2019, OptumRx managed more than $96 billion in pharmaceutical spending, with a revenue of $74 billion.[22]

194. At all times relevant hereto, OptumRx derived substantial revenue providing pharmacy benefits in Tennessee.

195. At all times relevant hereto, OptumRx offered pharmacy benefit management services nationwide and maintained standard formularies that are used nationwide, including in Tennessee. During the relevant time period, those formularies included diabetes medications, including all of those at issue in this Complaint.

196. At all times relevant hereto, and contrary to their express representations, OptumRx knowingly insisted that its payor clients use the false list prices produced by the Insulin Pricing Scheme as the basis for reimbursement of the at-issue drugs.

197. At all times relevant hereto, OptumRx concealed its critical role in the generation of those false list prices.

198. In its capacity as a mail-order pharmacy, OptumRx received payments from payors for, and set the out-of-pocket price paid for, the at-issue drugs based on the falsely inflated prices produced by the Insulin Pricing Scheme and, as a result, damaged Plaintiff.

199. At all times relevant hereto, OptumRx dispensed the at-issue medications nationwide and directly to Plaintiff and Plaintiff's Beneficiaries in Tennessee through its mail-order pharmacies and derived substantial revenue from these activities in Tennessee.

200. OptumRx purchases the Manufacturer Defendants' drugs, including the at issue diabetes medications, for dispensing through its mail-order pharmacies.

[22] UnitedHealth Group, Annual Report (Form 10-K) (Dec. 31, 2019).

201. At all times relevant hereto, OptumRx had express agreements with Defendants Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid by the Manufacturer Defendants to OptumRx, as well as agreements related to the Manufacturers' at-issue drugs sold through OptumRx's mail-order pharmacies.

202. Collectively, CVS Caremark, Optum Rx, and Express Scripts are referred to as the "PBM Defendants" or the "PBMs."

JURISDICTION AND VENUE

203. This action is directly filed in *In Re: Insulin Pricing Litigation*, MDL No. 3080, which was established on August 3, 2023, pursuant to the United States Judicial Panel on Multidistrict Litigation transfer order, and in accordance with this Court's August 2023 "Instructions for Opening a Case Relevant to MDL 3080". This Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1331 and pursuant to 18 U.S.C. § 1964(c) because this action alleges violations of the Racketeer influenced and Corrupt Organizations Act, 18 U.S.C. § 1962, which raises a federal question. This Court has supplemental jurisdiction over the state law claims in this action pursuant to 28 U.S.C. § 1367.

204. There is also federal subject matter jurisdiction over this action because complete diversity exists among the parties, 28 U.S.C. § 1332. The parties are citizens of different states, and the amount in controversy, exclusive of interests or costs, exceeds the sum or value of $75,000.

205. This Court also has personal jurisdiction over all Defendants under 18 U.S.C. § 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the Court in a single trial.

206. Venue is proper pursuant to 18 U.S.C. § 1965 because Defendants Sanofi, Novo Nordisk and Medco reside, are found, have an agent, or transact their affairs in this District, and the ends of justice require that any Defendant residing elsewhere be brought before this Court.

207. Venue is also proper in this District pursuant to 28 U.S.C. § 1391(b) and (c) because all Defendants transact business in, are found in, and/or have agents in this District, and because some of the actions giving rise to the Complaint took place within this District.

ADDITIONAL FACTUAL ALLEGATIONS

A. Diabetes and Insulin Therapy

The Diabetes Epidemic

208. Diabetes occurs when a person's blood glucose is too high. In people without diabetes, the pancreas secretes the hormone insulin, which controls the rate at which food is converted to blood glucose. When insulin is lacking or when cells stop responding to insulin, however, blood sugar stays in the bloodstream. Over time, this can cause serious health problems, including heart disease, blindness, and kidney disease.

209. There are two basic types of diabetes: Type 1 and Type 2. Roughly 90-95% of diabetics are Type 2, which develops when a person does not produce enough insulin or has become resistant to the insulin they produce. While Type 2 patients can initially be treated with tablets, in the long term most patients switch to insulin injections.

210. Diabetes has been on the rise for decades. In 1958, only 1.6 million Americans had diabetes. By the turn of the century, that number had grown to over ten million. Fourteen years later, the number had tripled. Today, more than 37 million Americans—approximately 11% of the country—live with the disease.

211. The prevalence of diabetes in Tennessee has increased as well. Over 760,000 Tennessee adults now live with diabetes and hundreds of thousands more have prediabetes.[23]

Insulin: A Century-Old Drug

212. Despite its potentially deadly impact, diabetes is highly treatable. Patients able to follow a prescribed treatment plan consistently may avoid the health complications associated with the disease. Unlike many high-burden diseases, treatment for diabetes has been available for almost a century.

213. In 1922, Frederick Banting and Charles Best, while working at the University of Toronto, pioneered a technique for removing insulin from an animal pancreas that could then be used to treat diabetes. After discovery, Banting and Best obtained a patent and then sold it to the University of Toronto for $1 (equivalent of $14 today), explaining "[w]hen the details of the method of preparation are published anyone would be free to prepare the extract, but no one could secure a profitable monopoly."[24]

214. After purchasing the patent, the University of Toronto contracted with Defendants Eli Lilly and Novo Nordisk to scale their production. Under this arrangement, Eli Lilly and Novo Nordisk were allowed to apply for patents on variations to the manufacturing process.

215. Although early iterations of insulin were immediately perceived as lifesaving, there have been numerous incremental improvements since its discovery.

216. The earliest insulin was derived from animals and, until the 1980s, was the only diabetes treatment.

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[23] https://www.cdc.gov/diabetes/programs/stateandlocal/state-diabetes-profiles/tennessee.html; Tennessee Diabetes Action Legislative Report, Feb. 2021, https://www.capitol.tn.gov/Archives/senate/112GA/committees/health-welfare/2021/Diabetes%20Legislative%20Report_FinalDraft.%2001-29-2021%208%2045%20pm.pdf.

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[24] Jessica DiGiacinto & Valencia Higuera, *Everything You Need to Know About Insulin*, HEALTHLINE (Oct. 5, 2021), http://www.healthline.com/health/type-2-diabetes/insulin; M. BLISS, THE DISCOVERY OF INSULIN (2013).

217. While effective, animal-derived insulin created the risk of allergic reaction. This risk was lessened in 1982 when synthetic insulin, known as human insulin, was developed by Defendant Eli Lilly. Eli Lilly marketed this insulin as Humulin. The development of human insulin benefited heavily from government and non-profit funding through the National Institute of Health and the American Cancer Society.

218. Over a decade later, Eli Lilly released the first analog insulin.

219. Analog insulin is laboratory-grown and genetically altered insulin. Analogs are slight variations on human insulin that make the injected treatment act more like the insulin naturally produced and regulated by the body.

220. Defendant Eli Lilly developed the first analog insulin, Humalog, in 1996.

221. Other rapid-acting analogs are Defendant Novo Nordisk's Novolog and Defendant Sanofi's Apidra, which have similar profiles. Diabetics use these rapid-acting insulins in combination with longer-acting insulins, such as Sanofi's Lantus and Novo Nordisk's Levemir.

222. The Manufacturer Defendants introduced these rapid-acting and long-acting analog insulins between 1996 and 2007.

223. In 2015, Sanofi introduced Toujeo, another long-acting insulin similar to Lantus; however, Toujeo is highly concentrated, making injection volume smaller than Lantus.

224. In 2016, Eli Lilly introduced Basaglar, which is a long-acting insulin biologically similar to Sanofi's Lantus.

225. Even though insulin was first extracted 100 years ago, and despite its profitability, only Defendants Eli Lilly, Novo Nordisk, and Sanofi manufacture insulin for the United States market. This did not occur by chance.

226. Many of the at-issue medications are now off-patent.

227. The Manufacturers maintain market domination through patent "evergreening." Drugs usually face generic competition when their 20-year patents expire. While original insulin formulas may technically be available for generic use, the Manufacturers "stack" patents around the original formulas, making new competition more costly and risky. For example, Sanofi has filed more than 70 patents on Lantus—more than 95% were filed after the drug was approved by the FDA—potentially providing more than three additional decades of patent "protection" for the drug. The market therefore remains highly concentrated.

The Current Insulin Landscape

228. While insulin today is generally safer and more convenient to use than when originally developed in 1922, there remain questions about whether the overall efficacy of insulin has significantly improved over the last twenty years.

229. For example, while long-acting analogs may have certain advantages over human insulins, such as affording more flexibility around mealtime planning, it has yet to be shown that analogs lead to better long-term outcomes. Recent work suggests that older human insulins may work just as well for patients with Type 2 diabetes.

230. Moreover, all insulins at issue have either been available in the same form since the late 1990s/early 2000s or are biologically equivalent to insulins available then.

231. As Dr. Kasia Lipska, a Yale researcher, explained in the Journal of the American Medical Association:

> We're not even talking about rising prices for better products here. I want to make it clear that we're talking about rising prices for the same product . . . there's nothing that's changed about Humalog. It's the same insulin that's just gone up in price and now costs ten times more.[25]

[25] Natalie Shure, *The Insulin Racket*, American Prospect (June 24, 2019), https://prospect.org/health/insulin-racket/ (last visited Jan. 14, 2023).

232. Production costs have also decreased in recent years. A September 2018 study calculated that, based on production costs, a reasonable price for a year's supply of human insulin is $48 to $71 per person and $78 to $133 for analog insulins. Another recent study found that the Manufacturers could profit at as little as $2 per vial.

233. United States diabetics spent an average of $5,705 each for insulin in 2016. According to a 2020 RAND report, the 2018 list price per vial across all forms of insulin was just $12 in Canada and less than $7 in Australia. In the U.S., it was $98.70.

234. While R&D costs often contribute significantly to a drug's price, the initial basic insulin research occurred 100 years ago and its costs have long-since been recouped. Other costs, such as developing the recombinant DNA-fermentation process and the creation of insulin analogs, were incurred decades ago.

Insulin Adjuncts: Type 2 Medications

235. The Manufacturer Defendants have released several non-insulin diabetes medications over the past decade. Novo Nordisk released Victoza in 2010, followed by Trulicity (Eli Lilly), Soliqua (Sanofi), and Ozempic (Novo Nordisk).[26] The following is a list of diabetes medications at issue in this lawsuit:

[26] Victoza, Trulicity, and Ozempic are glucagon-like peptide-1 receptor agonists ("GLP-1") and mimic the GLP-1 hormone produced in the body. Soliqua is a combination long-acting insulin and GLP-1 drug. Each of these drugs can be used in conjunction with insulins to control diabetes.

Table 1: Diabetes medications at issue in this case

Insulin Type	Action	Name	Company	FDA Approval	Current/Recent List Price
Human	*Rapid-Acting*	Humulin R	Eli Lilly	1982	$178 (vial)
		Humulin R 500	Eli Lilly	1982	$1784 (vial), $689 (pens)
		Novolin R	Novo Nordisk	1991	$165 (vial), $312 (pens)
	Intermediate	Humulin N	Eli Lilly	1982	$178 (vial), $566 (pens)
		Humulin 70/30	Eli Lilly	1989	$178 (vial), $566 (pens)
		Novolin N	Novo Nordisk	1991	$165 (vial), $312 (pens)
		Novolin 70/30	Novo Nordisk	1991	$165 (vial), $312 (pens)
Analog	*Rapid-Acting*	Humalog	Eli Lilly	1996	$342 (vial), $636 (pens)
		Novolog	Novo Nordisk	2000	$347 (vial), $671 (pens)
		Apidra	Sanofi	2004	$341 (vial), $658 (pens)
	Long-Acting	Lantus	Sanofi	2000	$340 (vial), $510 (pens)
		Levemir	Novo Nordisk	2005	$370 (vial), $555 (pens)
		Basaglar (Kwikpen)	Eli Lilly	2015	$392 (pens)
		Toujeo (Solostar)	Sanofi	2015	$466 (pens), $622 (max pens)
		Tresiba	Novo Nordisk	2015	$407 (vial) $610 (pens – 100u) $732 (pens – 200u)
Type 2 Medications		Trulicity	Eli Lilly	2014	$1013 (pens)
		Victoza	Novo Nordisk	2010	$813 (2 pens) $1220 (3 pens)
		Ozempic	Novo Nordisk	2017	$1022 (pens)
		Soliqua	Sanofi	2016	$928 (pens)

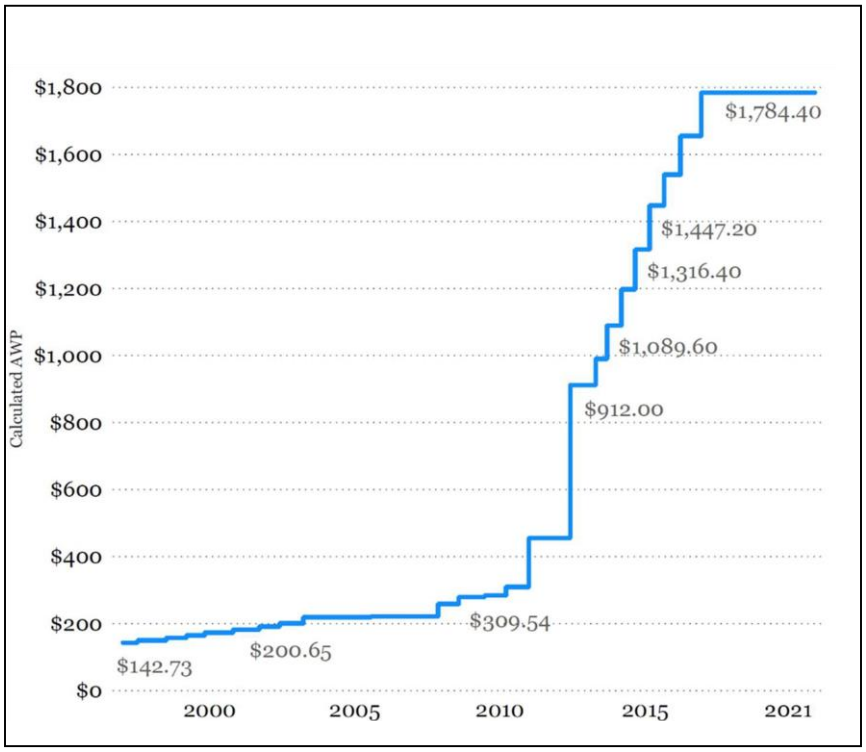
B. The Dramatic Rise in the Price of Diabetes Medications in the U.S.

236. Over the past 25 years, the list price of certain insulins has increased in some cases by more than 1000% (10x).

237. According to the U.S. Bureau of Labor Statistics, $165 worth of consumer goods and services in 1997 dollars would, in 2021, have cost $289 (1.75x).[27]

238. Since 1997, Eli Lilly has raised the list price of a vial of Humulin R (500U/mL) from $165 to $1784 in 2021 (10.8x).

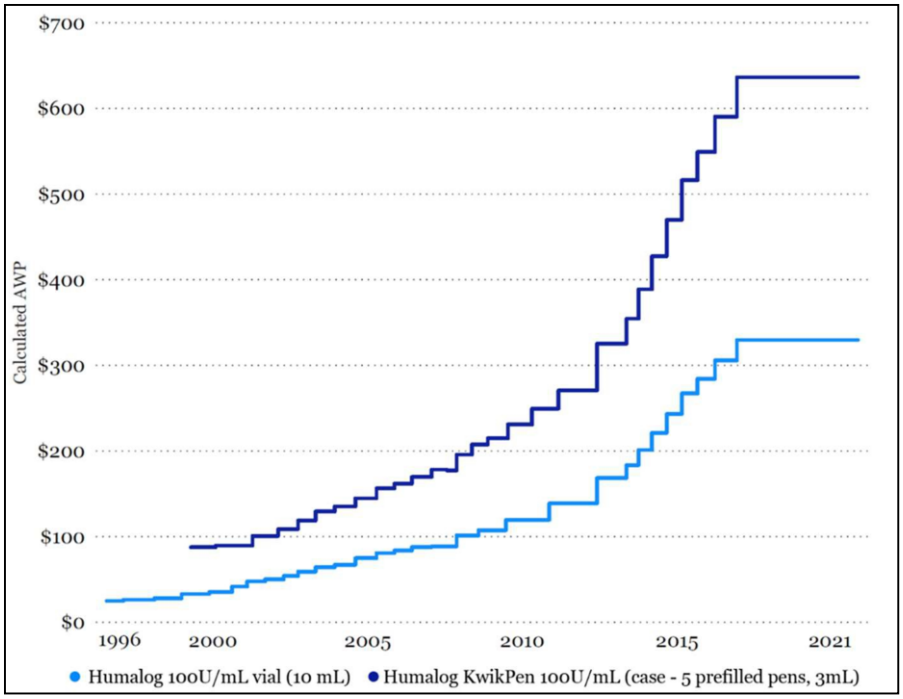
Figure 3: Rising list prices of Humulin R (500U/mL) from 1997-2021



239. Since 1996, Eli Lilly has raised the price for a package of Humalog pens from less than $100 to $663 (6.6x) and from less than $50 per vial to $342 (6.8x). (See Fig. 4.)

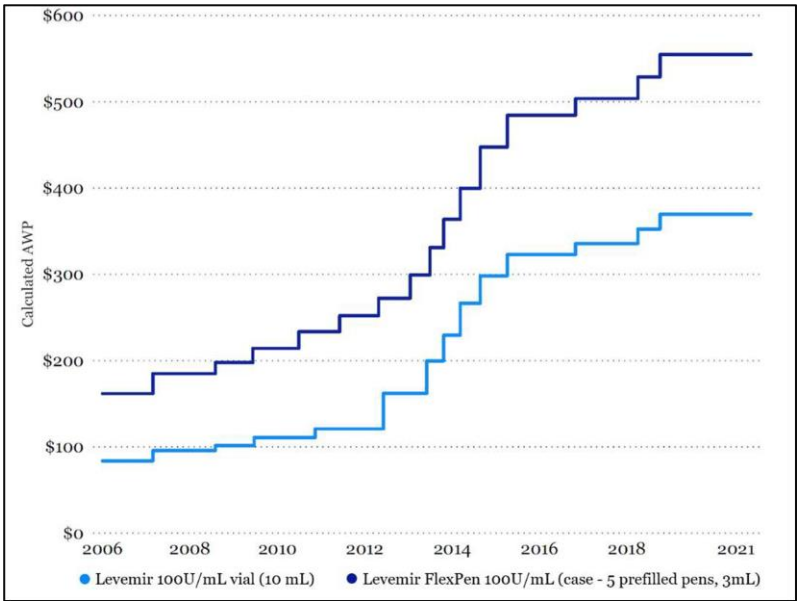
Figure 4: Rising list prices of Humalog vials and pens from 1996-2021

[27] https://www.bls.gov/data/inflation_calculator.htm (last visited Aug. 23, 2023). The Consumer Price Index (CPI) measures "the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services." (https://www.bls.gov/cpi/).



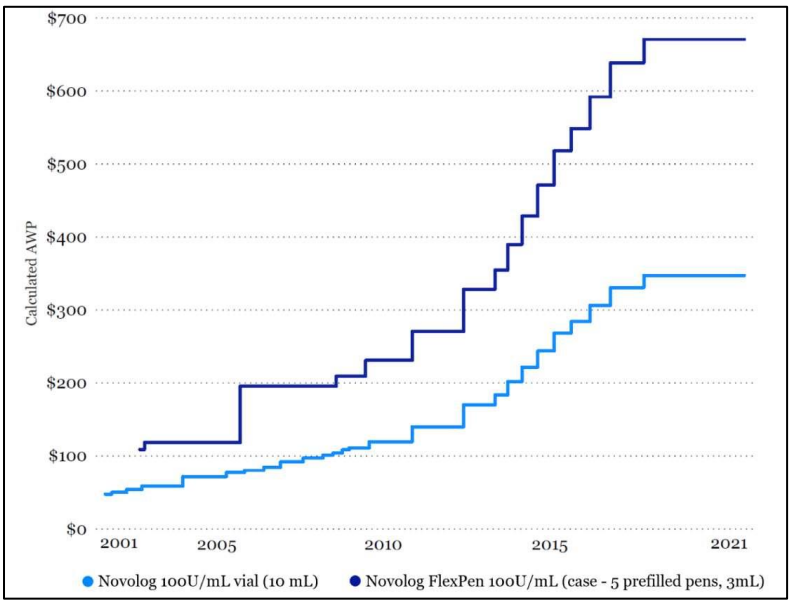
240. From 2006 to 2020, Novo Nordisk has raised Levemir's list price from $162 to $555 (3.4x) for pens and from under $100 to $370 per vial (3.7x).

Figure 5: Rising list prices of Levemir from 2006-2021



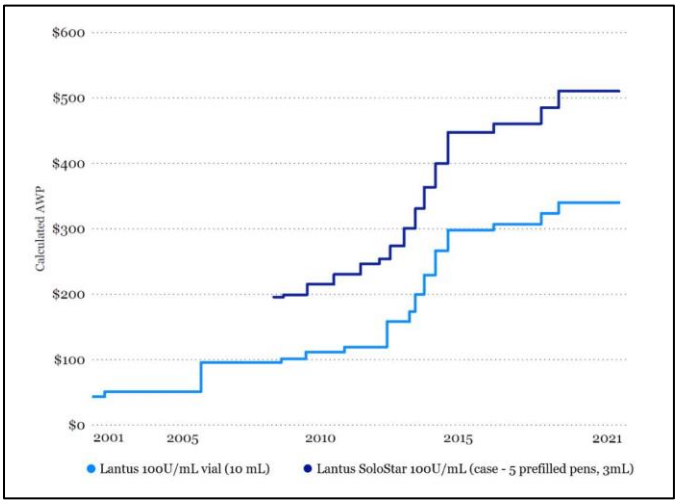
241. From 2002 to 2021, Novo Nordisk raised the list price of Novolog from $108 to $671 (6.2x) for a package of pens and from less than $50 to $347 (6.9x) for a vial.

Figure 6: Rising list prices of Novolog vials and pens from 2002-2021



242. Defendant Sanofi has kept pace. It manufactures a top-selling analog insulin—Lantus—which has been and remains a flagship brand for Sanofi. It has been widely prescribed nationally and within Tennessee, including to Plaintiff's Beneficiaries. Sanofi has raised the list prices for Lantus from less than $200 in 2006 to over $500 in 2020 (2.5x) for a package of pens and from less than $50 to $340 for a vial (6.8x). (See Fig. 7.)

Figure 7: Rising list prices of Lantus vials and pens from 2001-2021



243. The Manufacturer Defendants have similarly ballooned the prices for noninsulin diabetes medications.

244. Driven by these price hikes, payors' and diabetics' spending on these drugs has steadily increased with totals in the tens of billions of dollars. The Defendant-Manufacturers Have Increased Prices in Lockstep

245. The timing of the price increases reveals that the Manufacturer Defendants have not only dramatically increased prices for the at-issue diabetes treatments, but have done so in lockstep.

246. Between 2009 and 2015, for example, Sanofi and Novo Nordisk raised the list prices of their insulins in tandem 13 times, taking the same price increase down to the decimal point within a few days of each other (sometimes within a few hours).[28]

247. This conduct is known as "shadow pricing," which communicates between competitors their intention not to price compete against one another.

[28] Grassley & Wyden, *supra* note 2.

248. In 2016, Novo Nordisk and Sanofi's lockstep increases for the at-issue drugs represented the highest drug price increases in the pharmaceutical industry.

249. Eli Lilly and Novo Nordisk have engaged in the same lockstep behavior with respect to their rapid-acting analog insulins, Humalog and Novolog. Figure 8 demonstrates this collusive behavior with respect to Lantus and Levemir. Figure 9 demonstrates this behavior with respect to Novolog and Humalog.

Figure 8: Rising list prices of long-acting insulins

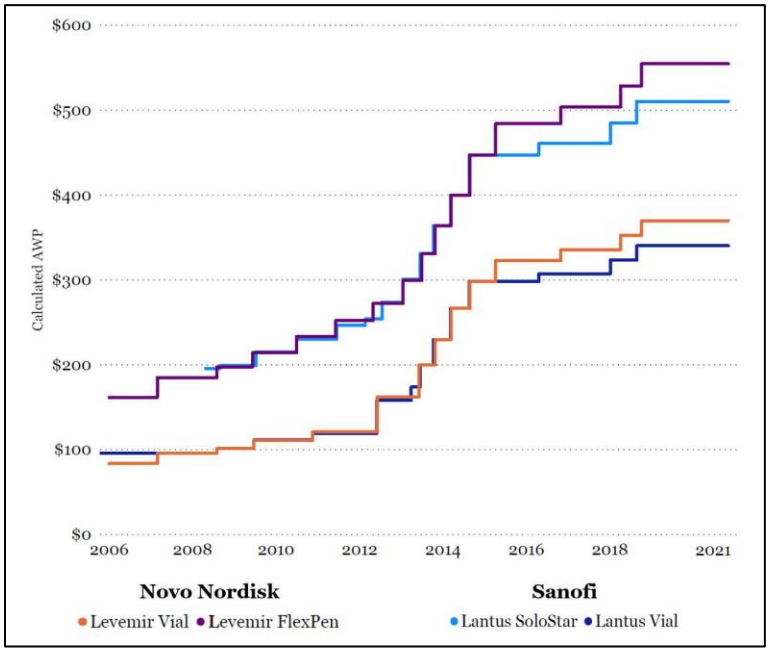
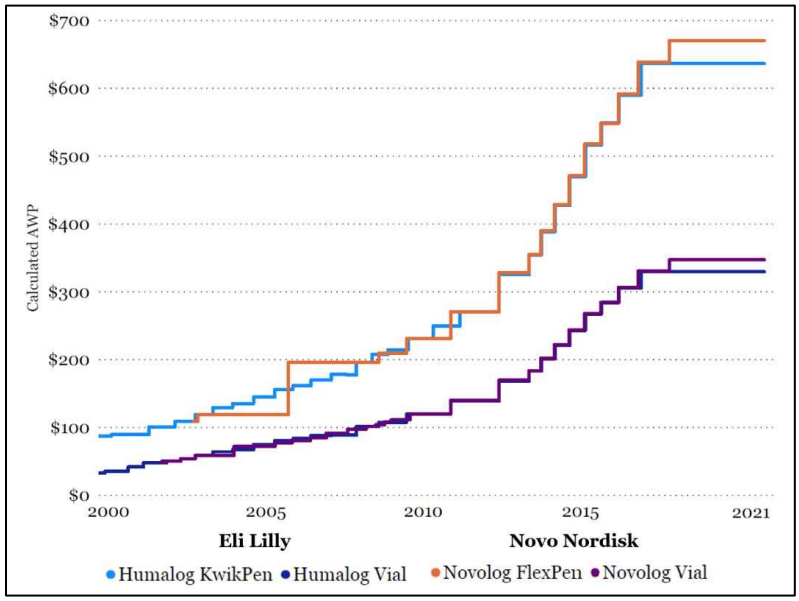
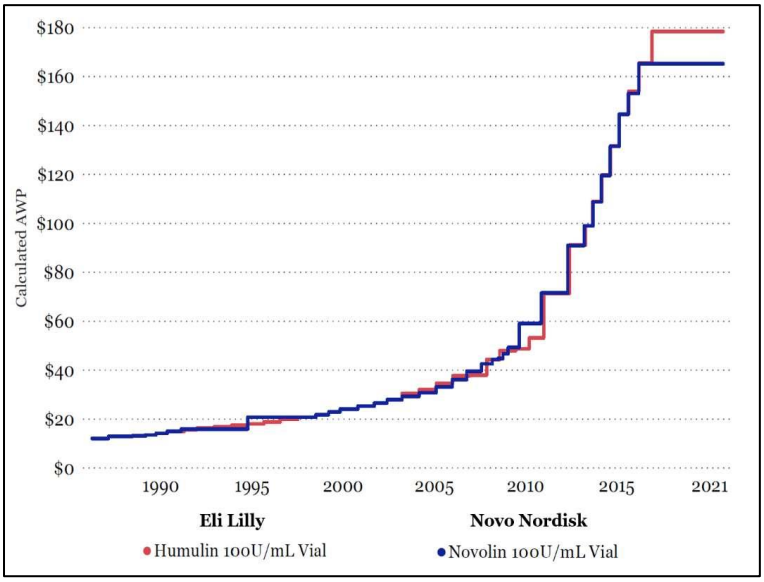


Figure 9: Rising list prices of rapid-acting insulins



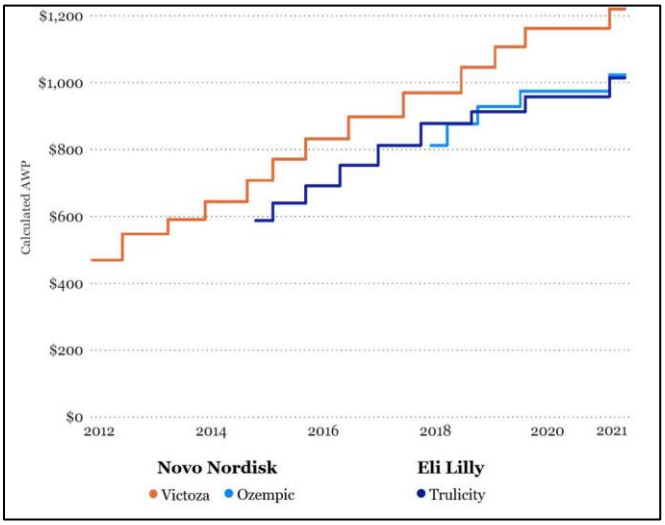
250. Figure 10 below demonstrates this behavior with respect to the human insulins—Eli Lilly's Humulin and Novo Nordisk's Novolin.

Figure 10: Rising list price increases for human insulins



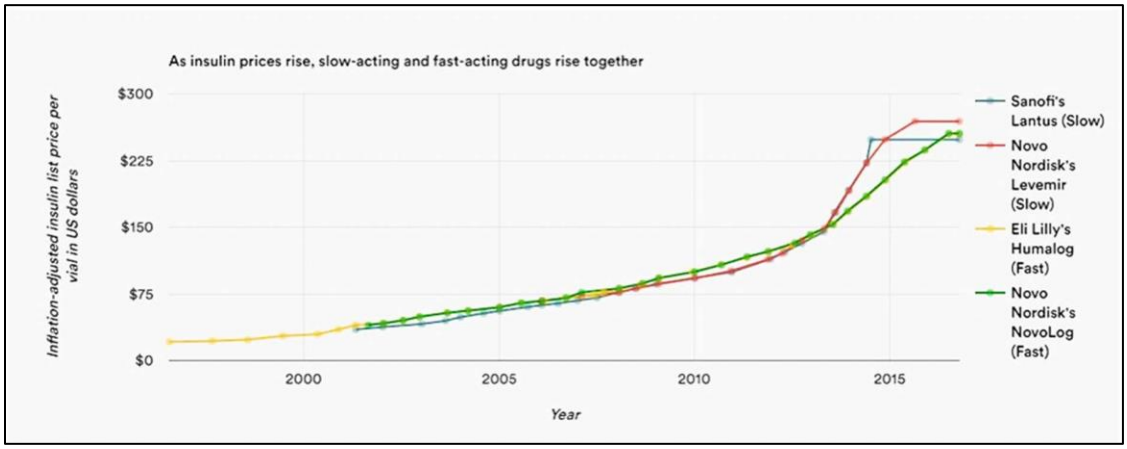
251. Figure 11 below demonstrates Novo Nordisk and Eli Lilly's lockstep price increases for their Type 2 drugs Trulicity, Victoza, and Ozempic.

Figure 11: Rising list prices of Type 2 drugs



252. Figure 12 below shows how, collectively, the Manufacturer Defendants have exponentially raised the prices of insulin products in near-perfect unison.

Figure 12: Lockstep insulin price increases



253. Because of the Manufacturer Defendants' collusive price increases, nearly a century after the discovery of insulin, diabetes medications have become unaffordable for many diabetics.

C. Pharmaceutical Payment and Supply Chain

254. The prescription drug industry is comprised of a deliberately opaque network of entities engaged in multiple distribution and payment structures. These entities include drug manufacturers, wholesalers, pharmacies, health plans/third-party payors, PBMs, and patients.

255. Given the complexities of the different parties involved in the pharmaceutical industry, there are many ways in which pharmaceutical drugs are distributed. Generally speaking, branded prescription drugs, such as the at-issue diabetes medications, are often distributed in one of three ways: (1) from manufacturer to wholesaler (distributor), wholesaler to pharmacy, and pharmacy to patient; (2) from manufacturer to mail-order pharmacy to patient; and (3) from manufacturer to mail-order pharmacy, mail-order pharmacy to self-insured payor, and then self-insured payor to patient.

256. The pharmaceutical industry, however, is unique in that the pricing chain is distinct from the distribution chain. The prices for the drugs distributed in the pharmaceutical chain are different for each participating entity, i.e., different actors pay different prices set by different entities for the same drugs. The unifying factor is that the price that each entity in the pharmaceutical chain pays for a drug is inexorably tied to the price set by the manufacturer. The pricing chain includes self-insured payors paying PBMs directly.

257. There is no transparency in this pricing system. Typically, only a brand drug's list price—also known as its Average Wholesale Price (AWP) or the mathematically related Wholesale Acquisition Cost (WAC)—is available.

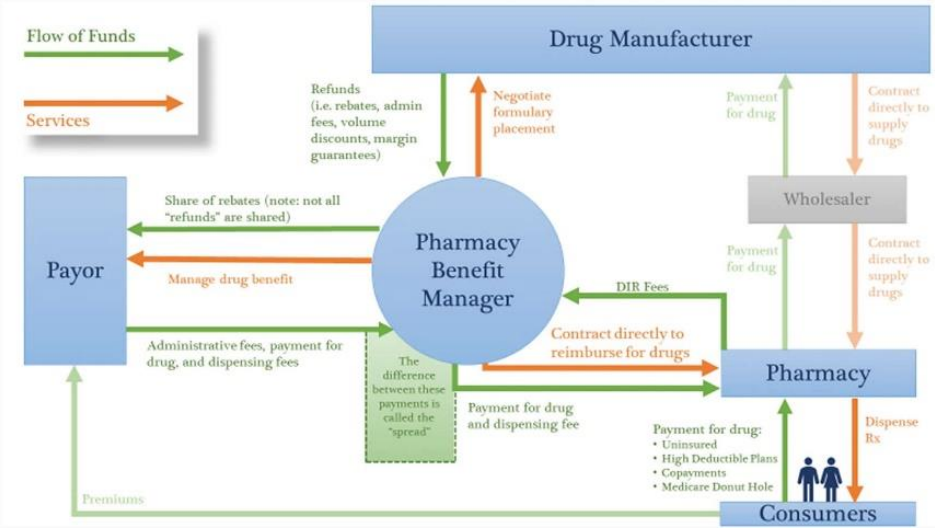
258. Drug manufacturers self-report AWP, or other prices upon which AWP is based, to publishing compendiums such as First DataBank, Redbook, and others who then publish those prices.

259. As a direct result of the PBMs' conduct, AWP persists as the most commonly and continuously used list price in reimbursement and payment calculations and negotiations for both payors and patients.

D. The PBMs' Role in the Pharmaceutical Payment Chain

260. The PBMs are at the center of this convoluted pharmaceutical payment chain, as illustrated in Figure 13 below.

Figure 13: Insulin distribution and payment chain



261. The PBM Defendants develop drug formularies, process claims, create a network of retail pharmacies, set the prices in coordination with the Manufacturers that the payor will pay for prescription drugs, and are paid by the payor to reimburse pharmacies for the drugs utilized by the payor's beneficiaries.

262. The PBMs also contract with a network of retail pharmacies. Pharmacies agree to dispense drugs to patients and pay fees back to the PBMs. The PBMs reimburse pharmacies for the drugs dispensed.

263. The PBM Defendants also own mail-order and specialty pharmacies, which purchase and take possession of prescription drugs, including those at-issue here, and directly supply those drugs to payors like Plaintiff Greene County, their Beneficiaries, and other patients, by mail.

264. Often, the PBM Defendants purchase drugs directly from the Manufacturers and distribute them directly to the patients. The prices that the PBM Defendants pay are significantly less than the purchase prices paid by payors.

265. Even where PBM Defendant mail-order pharmacies purchase drugs from wholesalers, their costs are set by direct contracts with the manufacturers.

266. In addition, and of particular significance here, the PBM Defendants contract with pharmaceutical manufacturers, including the Manufacturer Defendants. The PBMs extract from the Manufacturers rebates, fees, and other consideration that are paid back to the PBMs, including the Manufacturer Payments related to the at-issue drugs.

267. The Manufacturers also interact with the PBMs related to other services outside the scope of the Insulin Pricing Scheme, such as health and educational programs and patient and prescriber outreach with respect to drugs not at issue here.

268. These relationships allow PBMs to exert tremendous influence over what drugs are available throughout the United States, including in Greene County, on what terms, and at what prices.

269. Thus, PBMs are at the center of the flow of pharmaceutical money. Historically and today PBMs:

- negotiate the price that payors pay for prescription drugs (based on prices generated by the Insulin Pricing Scheme);

- separately negotiate a different (and often lower) price that pharmacies in their networks receive for the same drug;
- set the amount in fees that the pharmacy pays back to the PBM for each drug sold (based on prices generated by the Insulin Pricing Scheme);
- set the price paid for each drug sold through their mail-order pharmacies (based on prices generated by the Insulin Pricing Scheme); and
- negotiate the amount that the Manufacturers pay back to the PBM for each drug sold (based on prices generated by the Insulin Pricing Scheme).

270. Yet, for most of these transactions, only the PBMs are privy to the amount that any other entity in this supply chain is paying or receiving for the same drugs. The contracts between the PBMs and Manufacturers are undisclosed to Plaintiff. Payors, including Plaintiff, do not know and cannot learn the terms of those contracts.

271. This lack of transparency affords Defendants the opportunity to extract billions of dollars from this payment and supply chain without detection.

272. In every interaction that the PBMs have within the pharmaceutical pricing chain, they stand to profit from the prices generated by the Insulin Pricing Scheme.

The Rise of the PBMs in the Pharmaceutical Supply Chain

273. At first, in the 1960s, pharmacy benefit managers functioned largely as claims processors. Over time, however, they have taken on increasingly larger roles.

274. One of the roles the pharmacy benefit managers have taken on, as discussed above, was negotiating with drug manufacturers—ostensibly on behalf of payors. In so doing, the PBMs affirmatively represented that they were using their leverage to drive down drug prices.

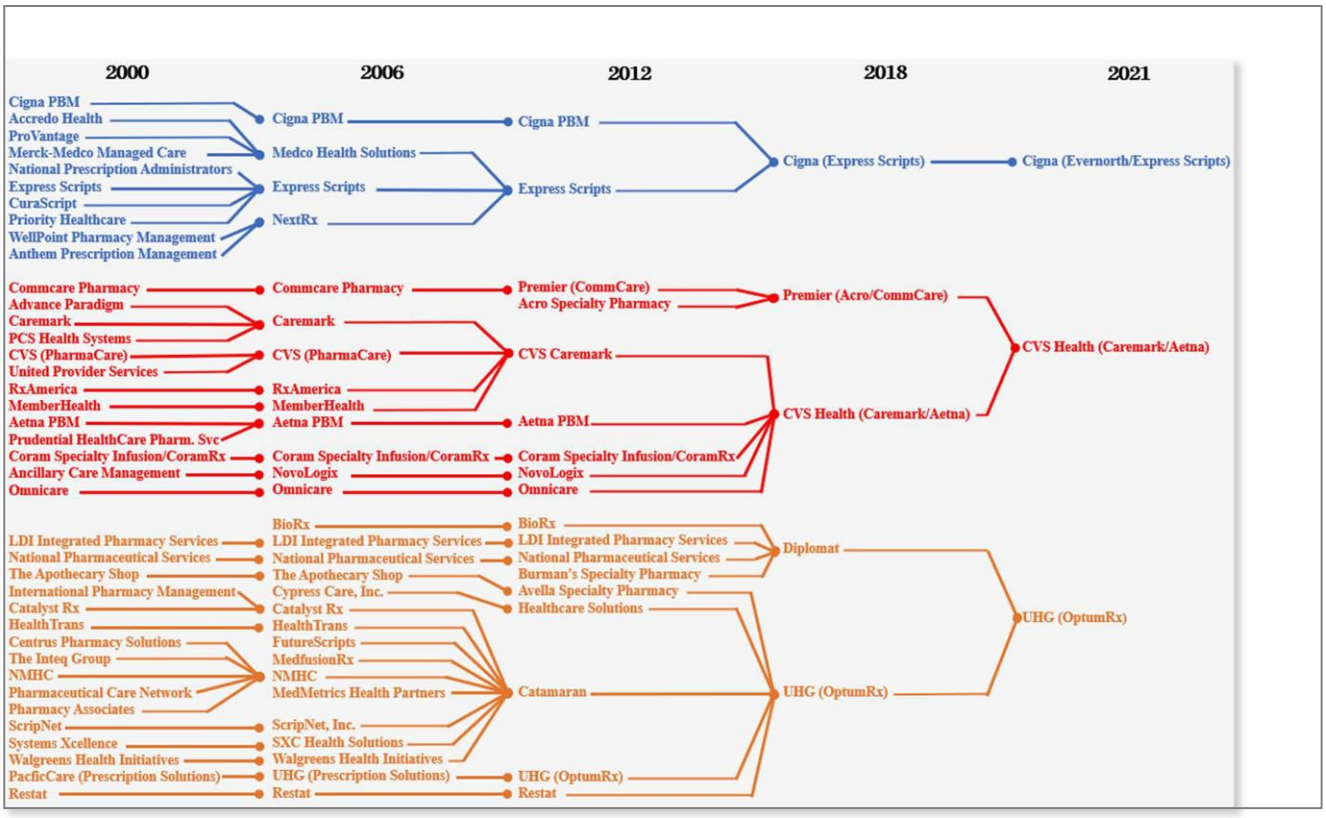
275. In the early 2000s, the PBMs started buying pharmacies, thus creating an additional incentive to collude with manufacturers to keep certain prices high.

276. These perverse incentives still exist today with respect to both retail and mail-order pharmacies housed within the PBMs' corporate families. Further recent consolidation in the industry has given the pharmacy benefit managers disproportionate market power.

277. Nearly forty pharmacy benefit manager entities have combined into what are now the three PBM Defendants. Moreover, each PBM Defendant now is owned by other significant players in the pharmaceutical chain, e.g., Express Scripts merged with Cigna; CVS bought Caremark, which now also owns Aetna; and UnitedHealth Group acquired OptumRx.

278. Figure 14 depicts this consolidation within the pharmacy benefit manager market.

Figure 14: PBM consolidation



279. After merging with or acquiring all of their competitors, and now backed by multibillion-dollar corporations, the PBM Defendants have taken over the market in the past

decade, controlling more than 80% of the market and managing pharmacy benefits for more than 270 million Americans.

280. Together, the PBM Defendants report more than $300 billion in annual revenue.

281. The PBMs use this market consolidation and the resulting purchasing power as leverage when negotiating with other entities in the pharmaceutical pricing chain.

The Insular Nature of the Pharmaceutical Industry

282. The insular nature of the pharmaceutical industry has provided Defendants with ample opportunity to contact and communicate with the other PBM and Manufacturer Defendants and to devise, coordinate, and carry out the Insulin Pricing Scheme.

283. The Manufacturer Defendants are all members of the industry-funded Pharmaceutical Research and Manufacturers of America ("PhRMA") and routinely communicate through PhRMA meetings and platforms in furtherance of the Insulin Pricing Scheme. According to PhRMA's 2019 IRS Form 990, it received $515,420,431 in "membership dues." All members are pharmaceutical companies.[29]

284. David Ricks (CEO of Eli Lilly), Paul Hudson (CEO of Sanofi), and Douglas Langa (President of Novo Nordisk and EVP of North American Operations), serve on the PhRMA board of directors and/or part of the PhRMA executive leadership team.

285. The PBM Defendants also routinely communicate through direct interaction with their competitors and the Manufacturers at trade associations and industry conferences.

[29] PhRMA 2019 Form 990, https://projects.propublica.org/nonprofits/organizations/530241211/202043189349300519/full; PhRMA, About PhRMA, https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/About-PhRMA2.pdf (last visited Aug.23,2023).

286. Each year during the relevant period, the main PBM trade association, the industry-funded Pharmaceutical Care Management Association ("PCMA"), held several yearly conferences, including its Annual Meeting and its Business Forum conferences.[30]

287. The PCMA is governed by PBM executives. The current (July 2023) board of the PCMA includes David Joyner (Executive Vice President and President of Pharmacy Services of PBM Defendant CVS Caremark); Adam Kautzner (President of PBM Defendant Express Scripts); and Heather Cianfrocco (CEO of PBM Defendant OptumRx).

288. In 2022, Former Express Scripts President Amy Bricker was the Chair of the PCMA board of directors and the only Express Scripts employee on the board. But when Ms. Bricker left Express Scripts in late 2022/early 2023, she was removed from the PCMA board. On February 3, 2023, PCMA issued a press release naming Mr. Kautzner to the board and appointing him Chairman of the Board of Directors. Mr. Kautzner was not on the board as of late 2022. Mr. Kauztner was added to the PCMA board and named Chair of the board to ensure that the PCMA board has directors from all three PBM Defendants and to facilitate the Insulin Pricing Scheme.

289. All PBM Defendants are members of the PCMA and, due to their leadership positions, have substantial control over that association.

290. Additionally, the Manufacturer Defendants are affiliate members of the PCMA.

291. Every year, high-level representatives and corporate officers from both the PBM and Manufacturer Defendants attend these conferences to meet in person and engage in discussions, including those in furtherance of the Insulin Pricing Scheme.

[30] The PCMA's industry funding in the form of "membership dues" is set out in its 2019 Form 990, https://projects.propublica.org/nonprofits/organizations/383676760/202042969349301134/full (last visited Aug, 23, 2023).

292. In fact, for at least the last eight years, all Manufacturer Defendants have been "Partners," "Platinum Sponsors," or "Presidential Sponsors" of these PBM conferences.

293. Notably, many of the forums at these conferences are specifically advertised as offering opportunities for private, non-public communications. For example, as Presidential Sponsors of these conferences, Manufacturer Defendants each hosted "private meeting rooms" that offer "excellent opportunities for . . . one-on-one interactions between PBM and pharma executives."[31]

294. Representatives from each Manufacturer Defendant have routinely met privately with representatives from each PBM Defendant during the Annual Meetings and Business Forum conferences that the PCMA holds (and the manufacturers sponsor) each year.

295. In addition, all PCMA members, affiliates and registered attendees of these conferences are invited to join PCMA-Connect, "invitation only LinkedIn group and online networking community."[32]

296. As PCMA members, the PBM and Manufacturer Defendants clearly utilized both PCMA-Connect, as well as the private meetings at the PCMA conferences, to exchange information and to reach agreements in furtherance of the Insulin Pricing Scheme.

297. Key at-issue lockstep price increases occurred shortly after the Defendants had convened at PCMA meetings. For example, on September 26 and 27, 2017, the PCMA held its annual meeting where each of the Manufacturer Defendants hosted private rooms and executives from each Defendant engaged in several meetings throughout the conference. Mere days after the

[31] PCMA, *The PCMA Annual Meeting 2021 Will Take Place at the Broadmoor in Colorado Springs, CO September 20 and 21*, https://www.pcmanet.org/pcmaevent/annual-meeting-2021/ (an event "tailored specifically for senior executives from PBMs and their affiliated business partners" with "private reception rooms" and "interactions between PBM members, drug manufacturers, and other industry partners") (last visited Aug 23, 2023).

[32] PCMA, *PCMA-Connect*, https://www.pcmanet.org/contact/pcma-connect/ (last visited Sept. 9, 2022).

conference, on October 1, 2017, Sanofi increased Lantus's list price by 3% and Toujeo's list by 5.4%. Novo Nordisk also recommended that their company make a 4% list price increase effective on January 1, 2018, to match the Sanofi increase.

298. Likewise, on May 30, 2014, Novo Nordisk raised the list price of Levemir a matter of hours after Sanofi made its list price increase on Lantus. These price hikes occurred just weeks after the 2014 PCMA spring conference in Washington, D.C., attended by representatives from all the PBM Defendants.

299. The PBMs control the PCMA and have exploited it to further their interests and to conceal the Insulin Pricing Scheme. The PCMA has brought numerous lawsuits and lobbying campaigns aimed at blocking drug-pricing transparency efforts, including recently suing the Department of Health and Human Services (HHS) to block the finalized HHS "rebate rule," which would eliminate anti-kickback safe harbors for Manufacturer Payments and instead offer them as direct-to-consumer discounts.

300. Notably, the PCMA's 2019 tax return reports more than a million dollars in revenue for "litigation support." Prior tax returns available at ProPublica reveal millions of dollars in revenue for "litigation support" (and tens of millions in revenue for "industry relations") year after year.[33]

301. Communications among the PBM Defendants are facilitated by the fluidity and frequency with which executives relocate from one PBM Defendant to another. For example:

- Mark Thierer worked as an executive at Caremark Rx (now CVS Caremark) prior to becoming the CEO of OptumRx in 2016 (he also served as Chairman of the Board for PCMA starting in 2012);

- Bill Wolfe was the President of the PBM Catalyst Rx (now OptumRx) prior to becoming the President of Aetna Rx in 2015 (he also served as a PCMA board member from 2015-2017 while with Aetna Rx);

[33] *See, e.g.*, PCMA 2019 Form 990, *supra* note 24, and prior years' returns on ProPublica.

- Derica Rice, former EVP for CVS Health and President of CVS Caremark, previously served as EVP and CFO for Eli Lilly;

- Duane Barnes was the Vice President of Medco (now Express Scripts) before becoming division President of Aetna Rx in 2006 (he also served as a PCMA board member);

- Everett Neville was the division President of Aetna Rx before becoming Senior Vice President of Express Scripts;

- Albert Thigpen was a Senior Vice President at CVS Caremark for 11 years before becoming a Senior Vice President at OptumRx in 2011;

- Harry Travis was the Chief Operating Officer at Medco (now Express Scripts) before becoming a Vice President at Aetna Rx in 2008; he served as SVP Member Services Operations for CVS Caremark from 2020-2022; and

- Bill Kiefer was a Vice President of Express Scripts for 14 years before becoming Senior Vice President of Strategy at OptumRx in 2013.

E. The Insulin Pricing Scheme

302. The market for the at-issue diabetes medications is unique in that it is highly concentrated with no true generics and few biosimilar options. The drugs and biosimilars have similar efficacy and risk profiles.

303. This affords the PBMs great leverage that, in theory, could be used to negotiate with the Manufacturer Defendants to drive down list prices for the at-issue drugs through open competition.

304. But the PBMs do not want the prices for diabetes medications to go down. A 2022 report by the Community Oncology Alliance put it this way:

> Among the different sources of revenue, the most prolific by far is in the form of rebates from pharmaceutical manufacturers that PBMs extract in exchange for placing the manufacturer's product drug on a plan sponsor's formulary or encouraging utilization of the manufacturer's drugs . . . . [T]he growing number and scale of rebates is the primary fuel of today's high drug prices. The truth is that PBMs have a vested interest to have drug prices remain high, and to extract rebates

> off of these higher prices. PBM formularies tend to favor drugs that offer higher rebates over similar drugs with lower net costs and lower rebates.[34]

305. The Manufacturer Defendants understand that PBM Defendants make more money as prices increase. This is confirmed by the January 2021 Senate Insulin Report after review of internal documents produced by the Manufacturers: [B]oth Eli Lilly and Novo Nordisk executives, when considering lower list prices, were sensitive to the fact that PBMs largely make their money on rebates and fees that are based on a percentage of a drug's list price.[35]

306. The documents eventually released by the Senate also show how the Manufacturers' pricing strategy focuses on *the PBMs' profitability*. In an internal August 6, 2015, email, Novo Nordisk executives debated delaying increasing the price of an at-issue drug in order to make the increase more profitable for *CVS Caremark*, stating:

> Should we take 8/18 [for a price increase], as agreed to by our [pricing committee], or do we recommend pushing back due to the recent CVS concerns on how we take price? . . . We know CVS has stated their disappointment with our price increase strategy (ie taking just after the 45th day) and how it essentially results in a lower price protection, admin fee and rebate payment for that quarter/time after our increase . . . it has been costing CVS a good amount of money. [36]

307. The Manufacturer Defendants also understand that because of the PBMs' market dominance, most payors, including Plaintiff Greene County and its Beneficiaries, accept the baseline national formularies offered by the PBMs with respect to the at-issue drugs.

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[34] Community Oncology Alliance & Frier Levitt, *Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers* (Feb. 2022), https://communityoncology.org/wpcontent/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf (last visited Jan. 14, 2023).

[35] Grassley & Wyden, *supra* note 2 at 89.

[36] Letter from Raphael A. Prober, Counsel for Novo Nordisk Inc., to Charles E. Grassley & Ron Wyden, S. Fin. Comm. (Mar. 8, 2019), https://www.finance.senate.gov/imo/media/doc/Novo_ Redacted.pdf (last visited Jan. 15, 2023).

308. The Insulin Pricing Scheme was borne from these understandings. Both sets of Defendants realized that if the Manufacturers artificially inflate their list prices while paying large, undisclosed Manufacturer Payments back to the PBMs, both the PBMs and Manufacturers would generate billions of unearned dollars. The plan worked.

309. Over the past several years the Manufacturers have raised prices in unison and have paid correspondingly larger Manufacturer Payments to the PBMs.

310. In exchange for the Manufacturers artificially inflating their prices and paying the PBMs substantial amounts in Manufacturer Payments, the PBM Defendants grant the Manufacturer Defendants' diabetes medications elevated prices and preferred status on their national formularies. During the relevant period, the rebate amounts (as a proportion of the list price) grew year-over-year while list prices themselves increased.

311. Beyond increased rebate demands, the PBMs also have sought and received larger and larger administrative fee payments and other Manufacturer Payments from the Manufacturers during the relevant period.

312. A recent study by the Pew Charitable Trust estimated that, between 2012 and 2016, the amount of administrative and other fees that the PBMs requested and received from the Manufacturers tripled, reaching more than $16 billion. The study observed that, although rebates were sent to payors during this period, PBMs retained the same volume of rebates in pure dollars, given the overall growth in rebate volume while administrative fees and spread pricing (charging a client payor more for a drug than the PBM pays the pharmacy) further offset reductions in retained rebate volumes.

313. Thus—and contrary to their public representations—the PBM Defendants' negotiations and agreements with the Manufacturer Defendants (and the formularies that result

from these agreements) have caused and continue to cause precipitous price increases for the at-issue drugs.

314. As a result of the Insulin Pricing Scheme, every payor, including Plaintiff, that pays for and/or reimburses for the at-issue drugs has been overcharged.

315. Moreover, the PBMs use this false price to misrepresent the amount of "savings" they generate for diabetics, payors, and the healthcare system. For example, in January 2016, Express Scripts' president Tim Wentworth stated at the 34th annual JP Morgan Healthcare Conference that Express Scripts "saved our clients more than $3 billion through the Express Scripts National Preferred Formulary."[37] Likewise, in April 2019, CVS Caremark President Derica Rice stated: "Over the last three years . . . CVS Caremark has helped our clients save more than $141 billion by blunting drug price inflation, prioritizing the use of effective, lower-cost drugs and reducing the member's out-of-pocket spend."[38]

316. In making these representations, the PBMs fail to disclose that the amount of "savings" generated is calculated based on the false list price, which is not paid by any entity in the pharmaceutical pricing chain and which all Defendants are directly responsible for artificially inflating.

317. The Insulin Pricing Scheme is a coordinated effort among the Manufacturer and PBM Defendants in which each agreed to, and did, participate, and which created enormous profits for all. For example:

a. The Manufacturers and the PBMs are in constant communication and regularly meet and exchange information to construct and refine the PBM formularies that

[37] Surabhi Dangi-Garimella, *PBMs Can Help Bend the Cost Curve: Express Scripts' Tim Wentworth*, AJMC (Jan. 12, 2016), https://www.ajmc.com/view/pbms-can-help-bendthe-cost-curve-express-scripts-tim-wentworth (last visited Jan. 15, 2023).

[38] CVS Health, *CVS Health PBM Solutions Blunted the Impact of Drug Price Inflation, Helped Reduce Member Cost, and Improved Medication Adherence in 2018* (Apr. 11, 2019), https://www.cvshealth.com/news-and-insights/press-releases/cvs-health-pbmsolutions-blunted-the-impact-of-drug-price (last visited Jan. 11, 2023).

form and fuel the scheme. As part of these communications, the Manufacturers are directly involved in determining not only where their own diabetes medications are placed on the PBMs' formularies and with what restrictions, but also in determining the same for competing products;

b. The Manufacturers and the PBMs share confidential and proprietary information with each other in furtherance of the Insulin Pricing Scheme, such as market data gleaned from the PBMs' drug utilization tracking efforts and mail-order pharmacy claims, internal medical efficacy studies, and financial data. Defendants then use this information in coordination to set the false prices for the at-issue medications and to construct their formularies in the manner that is most profitable for both sets of Defendants. The data that is used to further this coordinated scheme is compiled, analyzed, and shared either by departments directly housed within the PBM or by subsidiaries of the PBM, as is the case with OptumRx, which utilizes OptumInsight and Optum Analytics; and

c. The Manufacturers and the PBMs engage in coordinated outreach programs directly to patients, pharmacies, and prescribing physicians to convince them to switch to the diabetes medications that are more profitable for the PBMs and Manufacturers, even drafting and editing letters in tandem to send out to diabetes patients on behalf of the PBMs' clients. For example, the Grassley-Wyden Senate committee recently released an email where Eli Lilly discussed paying Defendant UnitedHealth Group and OptumRx additional rebates for every client that was converted to formularies that exclusively preferred Eli Lilly's at-issue drugs, including Humalog. The email continued: "United's leadership committee made one ask of Lilly – that we are highly engaged in the communication/pull through plan.[39] I of course indicated we fully expect to support this massive patient transition [to Eli Lilly's at-issue drugs favored by United] and provider education with the full breadth of Lilly resources. UHC also proactively thanked Lilly for our responsiveness, solution generation and DBU execution."

318. Rather than using their prodigious bargaining power to lower drug prices as they claim, Defendants instead used their dominant positions to conspire to generate billions of dollars in illicit profits at the expense of payors like Plaintiff.

F. Defendants Play Down the Insulin Pricing Scheme and Its Harms

319. On April 10, 2019, the United States House of Representatives Committee on Energy and Commerce held a hearing on industry practices titled, "Priced Out of a Lifesaving

[39] "Pull through" is an industry term that refers to an integrated process between PBMs and Manufacturers aimed at moving market share and increasing sales for a certain product following the PBM granting that product preferred placement on its formulary.

Drug: Getting Answers on the Rising Cost of Insulin."[40]

320. Representatives from all Defendants testified at the hearing, and each acknowledged before Congress that the price for insulin has increased exponentially in the past 15 years.

321. Further, each Defendant conceded that the price that diabetics pay out-of-pocket for insulin is too high. For example:

- Dr. Sumit Dutta, SVP and Chief Medical Officer of OptumRx since 2015, stated: "A lack of meaningful competition allows the [M]anufacturers to set high [list] prices and continually increase them which is odd for a drug that is nearly 100 years old and which has seen no significant innovation in decades. These price increases have a real impact on consumers in the form of higher out-of-pocket costs."

- Thomas Moriarty, Chief Policy and External Affairs Officer and General Counsel for CVS Health testified: "A real barrier in our country to achieving good health is cost, including the price of insulin products which are too expensive for too many Americans. Over the last several years, [list] prices for insulin have increased nearly 50 percent. And over the last ten years, [list] price of one product, Lantus, rose by 184 percent."

- Mike Mason, Senior Vice President of Eli Lilly when discussing how much diabetics pay out-of-pocket for insulin stated: "it's difficult for me to hear anyone in the diabetes community worry about the cost of insulin. Too many people today don't have affordable access to chronic medications . . ."

- Kathleen Tregoning, Executive Vice President External Affairs at Sanofi, testified: "Patients are rightfully angry about rising out-of-pocket costs and we all have a responsibility to address a system that is clearly failing too many people. . . we recognize the need to address the very real challenges of affordability . . . Since 2012, average out-of-pocket costs for Lantus have risen approximately 60 percent for patients . . ."

- Doug Langa, Executive Vice President of Novo Nordisk, stated: "On the issue of affordability . . . I will tell you that at Novo Nordisk we are accountable for the [list] prices of our medicines. We also know that [list] price matters to many, particularly those in high-deductible health plans and those that are uninsured."

[40] https:// www.congress.gov/event/116th-congress/house-event/109299?s=1&r=3 (last visited Jan. 9, 2023) (hereinafter *Priced Out of a Lifesaving Drug*).

322. None of the testifying Defendants claimed that the significant increase in the price of insulin was related to competitive factors such as increased production costs or improved clinical benefit.

323. Instead, Novo Nordisk's President Doug Langa's written testimony for the April 2019 hearing recognized "misaligned incentives" that have led to higher drug costs, including for insulin: "Chief among these misaligned incentives is the fact that the rebates pharmaceutical companies pay to PBMs are calculated as a percentage of WAC [list] price. That means a pharmaceutical company fighting to remain on formulary is constrained from lowering WAC price, or even keeping the price constant, if a competitor takes an increase. This is because PBMs will then earn less in rebates and potentially choose to place a competitor's higher-priced product on their formulary to the exclusion of others." Likewise, Mr. Langa's responses to questions for the record conceded that "[t]he disadvantage of a system in which administrative fees are paid as a percentage of the list price is that there is increased pressure to keep list prices high. . . ." The hearing transcript records Mr. Langa's further comments in this regard:

> So as you heard from Dr. Cefalu last week of the ADA [American Diabetes Association], there is this perverse incentive and misaligned incentives and this encouragement to keep list prices high. And *we've been participating in that system* because the higher the list price, the higher the rebate . . . There is a significant demand for rebates…. *We're spending almost $18 billion a year in rebates*, discount, and fees, and *we have people with insurance with diabetes that don't get the benefit of that*. (emphasis added)

324. Eli Lilly admitted that it raises list prices as a quid pro quo for formulary positions. At the April 2019 Congressional hearing, Mike Mason, Senior Vice President of Eli Lilly, testified:

> Seventy-five percent of our list price is paid for rebates and discounts . . . . $210 of a vial of Humalog is paid for discounts and rebates. . . . We have to provide rebates [to PBMs] in order to provide and compete for that [formulary position] so that people can use our insulin. In the very next question, Mr. Langa of Novo Nordisk was asked, "[H]ave you ever lowered a list price? His answer: "We have not."

325. Sanofi's Executive Vice President for External Affairs, Kathleen Tregoning, testified:

> The rebates is [sic] how the system has evolved. . . . I think the system became complex and rebates generated through negotiations with PBMs are being used to finance other parts of the healthcare system and not to lower prices to the patient.

Her written response to questions for the record acknowledged that "it is clear that payments based on a percentage of list price result in a higher margin [for PBMs] for the higher list price product than for the lower list price product."

326. The PBM Defendants also conceded at the April 2019 Congressional hearing that they grant preferred, or even exclusive, formulary position because of higher Manufacturer Payments paid by the Manufacturer Defendants.

327. In her responses to questions for the record, Amy Bricker, former SVP of Express Scripts and PCMA board member, confirmed that "manufacturers lowering their list prices" would give patients "greater access to medications;" yet when asked to explain why Express Scripts did not grant an insulin with a lower list price preferred formulary status, answered, "Manufacturers do give higher discounts [i.e., payments] for exclusive [formulary] position . . ." When asked why the PBM would not include both costly and lower-priced insulin medications on its formulary, Ms. Bricker stated plainly, "We'll receive less discount in the event we do that."[41]

328. As Dr. Dutta, SVP of OptumRx, perversely reasoned, the cheaper list-priced alternative Admelog is not given preference on the formulary because "it would cost the payer more money to do that . . . because the list price is not what the payer is paying. They are paying

[41] Buried in Express Scripts' 2017 10-K is the following: "We maintain contractual relationships with numerous pharmaceutical manufacturers, which provide us with, among other things administrative fees for managing rebate programs, including the development and maintenance of formularies that include particular manufacturer's products . . . ." That is, the Manufacturers pay the PBMs to effectively participate in the creation of formularies that payors are required to adopt as a condition for obtaining PBM services. Express Scripts Annual Report (Form 10-K) (FYE Dec. 31, 2017) at 24. It also notes that its business would be "adversely affected" if it were to "lose [its] relationship with one or more key pharmaceutical manufacturers." *Id.*

the net price."[42] In other words, under the pricing scheme, PBMs and manufacturers can make a drug with a lower list price effectively more expensive for payors and then ostensibly save payors from that artificially inflated price by giving preference to drugs that had higher list prices to begin with (yielding higher Manufacturer Payments to the PBMs).

329. While all Defendants acknowledged before Congress their participation in conduct integral to the Insulin Pricing Scheme, none revealed its inner workings or the connection between their coordination and the economic harm that payors, like Plaintiff, and Beneficiaries were unwittingly suffering. Instead, in an effort to obscure the true reason for precipitous price increases, each Defendant group pointed the finger at the other as the more responsible party.

330. The PBM Defendants testified to Congress that the Manufacturer Defendants are solely responsible for their list price increases and that the Manufacturer Payments that the PBMs receive are not correlated to rising insulin prices.

331. This testimony is false. The amounts Manufacturers pay back to the PBMs is *directly correlated* to an increase in list prices. On average, a $1 increase in Manufacturer Payments is associated with a $1.17 increase in list price. Reducing or eliminating Manufacturer Payments would lower prices and reduce out-of-pocket expenditures.

332. Further, in large part because of the increased list prices and related Manufacturer Payments, the PBMs' profit per prescription has grown substantially over the same time period that insulin prices have steadily increased. For example, since 2003, Defendant Express Scripts has seen its profit per prescription increase more than 500% per adjusted prescription.[43]

[42] *Id.* As noted in the hearing, even the "cheaper" alternative Admelog "costs over $200 a bottle."

[43] David Balto, *How PBMs Make the Drug Price Problem Worse*, Hill (Aug. 31, 2016, 5:51 PM), https://thehill.com/blogs/pundits-blog/healthcare/294025-how-pbms-make-thedrug-price-problem-worse (last visited Jan. 15, 2023).

333. Novo Nordisk's President, Doug Langa, submitted written testimony to Congress acknowledging "there is no doubt that the WAC [list price] is a significant component" of "what patients ultimately pay at the pharmacy counter." Yet, the Manufacturers urged upon Congress the fiction that the PBMs were solely to blame for insulin prices because of their demands for rebates in exchange for formulary placement. The Manufacturers claimed their hands were tied and sought to conceal their misconduct by suggesting that they have not profited off rising insulin prices.

334. Given the Manufacturers' claims that rebates were the sole reason for rising prices, each was asked directly during the Congressional hearing to guarantee it would decrease list prices if rebates were restricted or eliminated. The spokespersons for Eli Lilly, Novo Nordisk and Sanofi all said only that they would "consider it."

335. In addition, a 2020 study from the Institute of New Economic Thinking titled, "Profits, Innovation and Financialization in the Insulin Industry," demonstrates that during the time insulin price increases were at their steepest, distributions to the Manufacturers' shareholders in the form of cash dividends and share repurchases totaled $122 billion. In fact, during this period the Manufacturers spent a significantly lower proportion of profits on R&D compared to shareholder payouts. The paper also notes that "[t]he mean price paid by patients for insulin in the United States almost tripled between 2002 and 2013" and that "per-person spending on insulin by patients and insurance plans in the United States doubled between 2012 and 2016, despite only a marginal increase in insulin use."[44]

336. The 2022 Community Oncology Alliance report found:[45]

[44] Rosie Collington, *Profits, Innovation and Financialization in the Insulin Industry*, Inst. for New Econ. Thinking (Apr. 2020), https://www.ineteconomics.org/research/research-papers/ profits-innovation-and-financialization-in-the-insulin-industry (last visited Jan. 15, 2023).

[45] Community Oncology Alliance, *supra* note 29.

> [T]here are several important ways that PBM rebates increase the costs of drugs for both plan sponsors and patients. . . . PBMs employ exceedingly vague and ambiguous contractual terms to recast monies received from manufacturers outside the traditional definition of rebates, which in most cases must be shared with plan sponsors. Rebate administration fees, *bona fide* service fees, and specialty pharmacy discounts/fees are all forms of money received by PBMs and rebate aggregators which may not be shared with (or even disclosed to) the plan sponsor. These charges serve to increase the overall costs of drugs, while providing no benefit whatsoever to plan sponsors. . . . The total drug spend of a plan sponsor, regardless of whether it is a federal or state governmental program or a self-funded employer, will inevitably increase because PBMs are incentivized to favor expensive drugs that yield high rebates. . . .

337. In January 2021, the Senate Finance Committee (Grassley-Wyden) issued a report titled "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug,"[46] which detailed Congress's findings after reviewing more than 100,000 pages of internal company documents from Sanofi, Novo Nordisk, Eli Lilly, CVS Caremark, Express Scripts, OptumRx, and Cigna. The report concluded, among other things:

- The Manufacturer Defendants retain more revenue from insulin than in the 2000s—for example, Eli Lilly has reported a steady increase in Humalog revenue for more than a decade—from $1.5 billion in 2007 to $3 billion in 2018;
- The Manufacturer Defendants have aggressively raised the list price of their Insulin products absent significant advances in the efficacy of the drugs; and
- The Manufacturer Defendants only spend a fraction of their revenue related to the at-issue drugs on research and development—Eli Lilly spent $395 million on R&D costs for Humalog, Humulin, and Basaglar between 2014-2018, during which time the company generated $22.4 billion in revenue on these drugs.

[46] Grassley & Wyden, *supra* note 2 at 5, 7.

338. The truth is that, despite their finger pointing in front of Congress, the Manufacturers and PBMs are *both* responsible for their concerted efforts in creating the Insulin Pricing Scheme.

G. Defendants Profit from the Insulin Pricing Scheme

339. The Insulin Pricing Scheme affords the Manufacturer Defendants the ability to pay the PBM Defendants secret but significant Manufacturer Payments in exchange for formulary placement, which garners the Manufacturer Defendants greater revenues from sales without decreasing their profit margins. During the relevant period, the PBM Defendants granted national formulary position to each at-issue drug in exchange for large Manufacturer Payments and inflated prices.

340. The Manufacturer Defendants also use the inflated price to earn hundreds of millions of dollars in additional tax breaks by basing their deductions for donated insulins on the inflated list price.

341. Because of the increased list prices and related Manufacturer Payments, the PBMs' profit per prescription has grown exponentially during the relevant period as well. A recent study published in the Journal of the American Medical Association concluded that the amount of money that goes to the PBM Defendants for each insulin prescription increased more than 150% from 2014 to 2018. In fact, for transactions where the PBM Defendants control the PBM and the pharmacy (e.g., Caremark-CVS pharmacy) these Defendants were capturing an astonishing 40% of the money spent on each insulin prescription (up from only 25% just four years earlier), despite the fact that they do not contribute to the development, manufacture, innovation or production of the product.[47]

[47] Karen Van Nuys, et al., *Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans From 2014 to 2018*,

342. The PBM Defendants profit from the artificially inflated prices created by the Insulin Pricing Scheme in a number of ways, including by: (1) retaining a significant, yet undisclosed, percentage of the Manufacturers Payments, (2) using the inflated list price to generate profits from pharmacies, and (3) relying on the inflated list price to drive up the PBMs' margins through their own mail-order pharmacies.

The PBMs Pocket a Substantial Share of Manufacturer Payments

343. The first way in which the PBMs profit from the Insulin Pricing Scheme is by keeping a significant portion of the secret Manufacturer Payments.

344. The amount that the Manufacturers pay back to the PBMs has increased over time both in real dollars and as a proportion of the ever-increasing list prices.

345. Historically, contracts between PBMs and payors allowed the PBMs to keep most or all of the rebates they received, rather than forwarding them to the payor.

346. Over time, payors secured contract provisions guaranteeing payment to them of all or some portion of the rebates paid by the Manufacturers to the PBMs. Critically, however, "rebates" are only one aspect of the total Manufacturer Payments, particularly as "rebates" are narrowly defined and qualified by vague exceptions in the PBM contracts with payors.

347. Indeed, as described in the January 2021 Senate Insulin Report, the PBMs and Manufacturers coordinate to determine the contract options made available to payors: "Contracts between PBMs and manufacturers provide a menu of options from which their health plan clients can choose certain terms and conditions."[48] The contracts between the PBMs and Manufacturers also "stipulate terms the plans must follow regarding factors such as formulary placement and

JAMA Network (Nov. 5, 2021), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2785932 (last visited Aug. 23, 2023).

[48] Grassley & Wyden, *supra* note 2 at 40.

competition from other drugs in the therapeutic class."[49] Thus, the Manufacturers ultimately played a role in dictating the terms and conditions of the contracts that payors like Plaintiff entered into with PBMs. Of course, the payors were not involved in the coordination or the negotiation of the contracts between the PBMs and Manufacturers and the PBMs disclosed only the fact that such relationships may exist—the terms of the contracts, the consideration exchanged between the PBMs and Manufacturers, and the means of reaching these determinations all were and remain shrouded in secrecy.

348. The PBM and Manufacturer Defendants thus created a "hide-the-ball" system where payors like Plaintiff are not privy to rebate negotiations or contracts between the Manufacturers and the PBMs. The consideration exchanged between them (and not shared with payors) is labeled and relabeled. As more payors moved to contracts that required PBMs to remit some or all of the manufacturer "rebates" through to the payor, the PBMs rechristened Manufacturer Payments to shield them from scrutiny and from their payment obligations. Payments once called "rebates" now include administrative fees, volume discounts, service fees, inflation fees, or other industry monikers designed to obfuscate the substantial sums being secretly exchanged between the PBMs and the Manufacturers.

349. Just last year, the Senate Commerce, Science and Transportation Committee released testimony from David Balto—a former antitrust attorney with the DOJ and Policy Director for the FTC's Bureau of Competition—from a hearing on fairness and transparency in drug pricing:

> The PBM rebate system turns competition on its head with PBMs seeking higher, not lower prices to maximize rebates and profits. In the past decade, PBM profits have increased to $28 billion annually. . . . PBMs establish tremendous roadblocks to prevent payors from knowing the amount of rebates they secure. Even sophisticated buyers are unable to secure specific drug by drug rebate information.

[49] *Id.* at 44.

> PBMs prevent payors from being able to audit rebate information. As the Council of Economic Advisors observed, the PBM market lacks transparency as "[t]he size of manufacturer rebates and the percentage of the rebate passed on to health plans and patients are secret." Without adequate transparency, plan sponsors cannot determine if the PBMs are fully passing on any savings, or whether their formulary choices really benefit the plan and subscribers.

350. The renamed, undisclosed Manufacturer Payments are substantial. "Administrative fees" are one example. A heavily redacted complaint filed by Defendant Express Scripts in 2017 revealed that Express Scripts retains up to 13 times more in "administrative fees" than it remits to payors in rebates.[50]

351. These so-called administrative fees typically are based on a percentage of the drug price—as opposed to a flat fee—such that even if the actual "administrative" cost associated with processing two drugs is the same, the "administrative fee" would be correspondingly higher for the higher-priced drug, which creates (by design) a perverse incentive to give preference to more expensive drugs. Moreover, the PBM Defendants' contracts with payors, including those with Plaintiff, narrowly define "rebates" by tying them to patient drug utilization, so rebates for formulary placement are characterized as "administrative fees" that are not remitted to payors and are beyond a payor's contractual audit right to verify the accuracy of "rebate" payments under the contracts.

352. The opaque nature of these arrangements between the Manufacturers and PBM Defendants also makes it impossible for a given payor to discover, much less assess or confront, conflicts of interest that may affect it or its members. The January 2021 Senate Insulin Report observed with respect to these arrangements: "Relatively little is publicly known about these financial relationships and the impact they have on insulin costs borne by consumers."[51]

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[50] *Express Scripts, Inc. v. Kaleo, Inc.*, No. 4:17-cv-01520-RLW (E.D. Mo. 2017).
[51] Grassley & Wyden, *supra* note 2 at 4.

353. Unsurprisingly, the PBMs have gone to great lengths to obscure these renamed Manufacturer Payments in order keep them for themselves and to avoid scrutiny from payors and others.

354. For example, with regard to the Manufacturer Payments now known as "inflation fees," the PBMs often create a hidden gap between how much the Manufacturers pay them to increase their prices and the amount in "price protection guarantees" that the PBMs agree to pay back to their client payors.

355. In particular, the Manufacturer Defendants often pay the PBM Defendants "inflation fees" in order to increase the price of their diabetes medications. The thresholds for these payments are typically set at around 6% to 8%—if the Manufacturer Defendants raise their prices by more than the set percentage during a specified time period, they pay the PBM Defendants an additional "inflation fee" (based on a percentage of the list prices).

356. For many of their clients, the PBMs have separate "price protection guarantees" that state that if the overall drug prices for that payor increase by more than a set amount, then the PBMs will remit a portion of the amount to the client.

357. The PBMs set these "price protection guarantees" at a higher rate than the thresholds that trigger the Manufacturers' "inflation fees," usually around 10%-15%.

358. Thus, if the Manufacturers increase their list prices more than the 6% (or 8%) inflation fee rate but less than the 10%-15% client price protection guarantee rate, then the PBMs keep all of these "inflation fee" payments. This is a win-win for the Manufacturers and PBMs—they share and retain the entire benefit of these price increases while the PBM contracts with payors imply that payors are protected from price hikes by their price protection guarantees.

359. The PBMs also hide the renamed Manufacturer Payments with "rebate aggregators." Rebate aggregators, sometimes referred to as rebate group purchasing organizations ("GPOs"), are entities that negotiate for and collect payments from drug manufacturers, including the Manufacturer Defendants, on behalf of a large group of pharmacy benefit managers (including the PBM Defendants) and different entities that contract for pharmaceutical drugs.

360. These rebate aggregators are often affiliated with or owned by the PBM Defendants, such as Ascent Health Services (Express Scripts), Coalition for Advanced Pharmacy Services and Emisar Pharma Services (OptumRx), and Zinc (CVS Caremark).

361. The PBMs carefully guard the revenue streams from their rebate aggregator activities, hiding them in complex contractual relationships and not reporting them separately in their quarterly SEC filings.

362. Certain rebate-aggregator companies are located offshore, for example, in Switzerland (Express Scripts' Ascent Health) and Ireland (Emisar Pharma Services), making oversight even more difficult.

363. As summarized by the recent Community Oncology Alliance report:[52]

> PBMs have increasingly "delegated" the collection of manufacturer rebates to "rebate aggregators," which are often owned by or affiliated with the PBMs, without seeking authorization from plan sponsors and without telling plan sponsors. . . . Even some of the major PBMs (i.e., the "Big Three" PBMs) sometimes find themselves contracting with other PBMs' rebate aggregators for the collection of manufacturer rebates. . . . In both the private sector and with respect to government health care programs, the contracts regarding manufacturer rebates (i.e., contracts between PBMs and rebate aggregators, as well as contracts between PBMs/rebate aggregators and pharmaceutical manufacturers) are not readily available to plan sponsors.

364. For example, a 2017 audit conducted by a local governmental entity on Defendant OptumRx related to its PBM activities from 2013 to 2015 concluded that the auditor was unable

[52] Community Oncology Alliance, *supra* note 29.

to verify the percentage of rebates OptumRx remitted to its client payor because OptumRx would not allow the auditor access to its rebate contracts. The audit report explained:

> Optum[Rx] has stated that it engaged the services of an aggregator to manage its rebate activity. Optum[Rx] shared that under this model, they are paid by their aggregator a certain amount per prescription referred. Then, the aggregator, through another entity, seeks rebates from the drug manufacturers, based upon the referred [Payor Client] prescription utilization, and retains any rebate amounts that may be received. Optum[Rx] states that they have paid [Payor Client] all amounts it has received from its aggregator, and that they do not have access to the contracts between the aggregator (and its contractors) and the manufacturer. However, our understanding is that Optum[Rx] has an affiliate relationship with its aggregator.[53]

365. A footnote in the audit report clarifies that "Optum[Rx] contracted with Coalition for Advanced Pharmacy Services (CAPS), and CAPS in turn contracted with Express Scripts, Inc."

366. In other words, according to this report, OptumRx contracts with its own affiliate aggregator Coalition for Advanced Pharmacy Services, who then contracts with OptumRx's co-conspirator Express Scripts, who then contracts with the Manufacturers for rebates related to OptumRx's client's drug utilization. OptumRx then uses this complex relationship to obscure the amount of Manufacturer Payments that are being generated from its client's utilization.

367. A subsequent audit by the same local entity—covering the period September 2017 to September 2018, concluded:[54]

> Several material weaknesses in Broward's agreement with Optum were identified, many of which are commonplace across pharmacy benefit manager agreements in general. Due to contract weaknesses, comparison of Broward's PBM agreement, including rebate amounts received, to the Consultant's marketplace data is not feasible. Broward could save an estimated $1,480,000 per year in net prescription drug benefit expenses (based upon minimum rebate guarantees) by switching from

[53] Laura Rogers & Stacey Thomas, Broward County Florida, Audit of Pharmacy Benefit Management Services Agreement, No. 18-13 (Dec. 7, 2017), https://www.broward.org/Auditor/Reports/Documents/2017_1212%20Agenda%20Review%20of%20Pharmacy%20Benefit%20Management%20Services%20by%20StoneBridge/2017_1212%20Exh1_OptumRx.pdf (last visited Jan. 15, 2023).

[54] Broward County, Florida, *Analysis of Broward County's Prescription Drug Coverage*, https://www.broward.org/Auditor/Reports/Reports/082019_Exh1_BCRxDrug_19-15.pdf (last visited Aug. 23, 2023).

> its current flawed agreement with Optum, to an agreement with its Coalition, which offers clearly defined terms, increased rebate guarantees and cost saving requirements.

Among other "loopholes" discovered in the contract were a number of "flawed" (i.e., vague and manipulable) definitions—including the definition of Rebates, which "allows the exclusion of monies that should be included—and limitation with respect to "Pass Through Transparency Pricing."

368. The January 2021 Grassley-Wyden Senate Report summarizing findings of their two-year probe into the Insulin Pricing Scheme contained the following observation on these rebate aggregators[55]:

> [T]he recent partnership between Express Scripts and Prime Therapeutics may serve as a vehicle to avoid increasing legislative and regulatory scrutiny related to administrative fees by channeling such fees through a Swiss based group purchasing organization (GPO), Ascent Health. While there are several regulatory and legislative efforts underway to prohibit manufacturers from paying administrative fees to PBMs, there is no such effort to change the GPO safe harbor rules. New arrangements used by PBMs to collect fees should be an area of continued investigative interest for Congress.

369. Federal regulations governing Medicare attempt to capture all possible forms of Direct or Indirect Remuneration (DIR) to PBMs (and plan sponsors), defining DIR as "any form of price concession" received by a plan sponsor or PBM "from any source," including "discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, legal judgment amounts, settlement amounts from lawsuits or other legal action, and other price concessions or similar benefits. DIR also includes price concessions from and additional contingent payments to network pharmacies that cannot reasonably be determined at the point of sale."[56]

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[55] Grassley & Wyden, *supra* note 2 at 83.

[56] CMS, *Final Medicare Part D DIR Reporting Guidance for 2021* at 7, https://www.cms.gov/files/document/final2021dirreportingreqsmemo508v3.pdf (last visited Jan. 15, 2023).

370. The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) considers all of the following as DIR: rebates, grants, reduced price administrative services, PBM-retained rebates, PBM rebate guarantee amounts, all post-point of sale payments by pharmacies that are not included in the negotiating price including dispensing incentive payments, prompt pay discounts, and payment adjustments. On the other hand, "bona fide service fees from pharmaceutical manufacturers" and "remuneration for administrative services with no impact on the sponsor's or PBM's drug cost (e.g., PBM incentive payments)" are not considered DIR, but only to the extent they reflect fair market value for services rendered.[57]

371. Because the PBMs retain and conceal a majority of the secret Manufacturer Payments that they receive, they are able to reap significant profits on the Insulin Pricing Scheme.

372. Even where payor clients receive a portion of the Manufacturer Payments from their PBM, those payors still are significantly overcharged as a direct result of the Insulin Pricing Scheme given the extent to which Defendants have deceptively and egregiously inflated the prices of the at-issue drugs.

The Insulin Pricing Scheme Allows the PBMs to Profit Off Pharmacies

373. A second way the PBM Defendants profit off the Insulin Pricing Scheme is by using the Manufacturers' inflated price to derive profit from the pharmacies with whom they contract, including those in Greene County.

374. Each PBM Defendant decides which pharmacies are included in the PBM's network and how much it will reimburse these pharmacies for each drug dispensed.

375. The PBM Defendants, in coordination with the Manufacturers, directly reach out to patients, pharmacies, and prescribing physicians to convince them to switch to the diabetes

[57] *Id.* at 6-7.

medications that are more profitable for the PBMs and Manufacturers, even drafting and editing letters together to send to diabetes patients on behalf of the PBMs' clients [58]. The Defendants also petition these recipients to use the PBM Defendants' mail-order pharmacies and have succeeded in convincing patients, pharmacies, and prescribing physicians to do so.

376. The PBMs pocket the spread between the amount that the PBMs are paid by their clients for the at-issue drugs (which are based on the prices generated by the Insulin Pricing Scheme) and the amount the PBM reimburses the pharmacy (which often is less). In other words, the PBMs charge a client like Greene County more for a drug than the PBM pays the pharmacy and pockets the difference.

377. A bipartisan bill introduced in the Senate in 2022 (the Pharmacy Benefit Manager Transparency Act—S. 4293)—would have, criminalized spread pricing, which the bill defined as "[c]harg[ing] a health plan or payer a different amount for a prescription drug's ingredient cost or dispensing fee than the amount the pharmacy benefit manager reimburses a pharmacy for the prescription drug's ingredient cost or dispensing fee where the pharmacy benefit manager retains the amount of any such difference." The bill has not yet been enacted.[59]

378. Not coincidentally, the PBMs' industry-funded trade association PCMA spent $7.8 million on federal lobbying in 2021 and more $6 million through the third quarter of 2022.[60]

379. The PBMs often disclose the concept of spread pricing to payors, but only in vague terms that require no accountability and are not subject to the payors' audit rights because the revenue is not defined as a "rebate" in the PBM contracts with payors.

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[58] See supra 326(c).

[59] https://www.govtrack.us/congress/bills/117/s4293 (last visited Jan. 10, 2023).

[60] https://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2021&id=D000028342 (2021); https://www.opensecrets.org/federallobbying/clients/summary?cycle= 2022&id=D000028342 (2022) (last visited Jan. 10, 2023).

380. This spread pricing, like the secret Manufacturer Payment negotiation, happens behind closed doors. There is no transparency, no commitment from the PBM Defendants to account for the cost effectiveness of a drug, and no communication to either the payor or the pharmacy to let them know if they are getting a fair deal.

381. The higher the Manufacturers' list prices, the more money the PBMs make off this spread. At the same time, a Beneficiary's out-of-pocket co-pay or deductible cost often is more than if the client had simply paid cash outside of his or her plan. On top of this, the PBM contracts generally allow no rebates to payors where the Beneficiary is responsible for 100% of the drug cost, e.g., under his or her deductible.

382. The PBMs also use the Insulin Pricing Scheme to generate additional profits from pharmacies by charging the pharmacies post-purchase fees, including DIR (Direct or Indirect Remuneration) fees, based on the list prices—and again, the higher the list price for each diabetes medication sold, the more fees the PBMs generate—or by applying "retrospective" discounts. So, for example, a payor's (and member's co-pay or deductible) cost may be $100, but the price is discounted post-purchase (between the PBM and the (often self-owned) pharmacy) to $90 with the spread going to the PBM.

383. CMS addressed these and similar DIR issues in a proposed rule in 2017. While noting the growth of "pharmacy price concessions" that "are negotiated between pharmacies and their sponsors or PBMs," CMS nevertheless concluded:[61]

> When manufacturer rebates and pharmacy price concessions are not reflected in the price of a drug at the point of sale, beneficiaries might see lower premiums, but they do not benefit through a reduction in the amount they must pay in cost-sharing, and thus, end up paying a larger share of the actual cost of a drug. Moreover, given the increase in manufacturer rebates and pharmacy price concessions in recent

[61] Medicare Program; Contract Year 2019 Policy and Technical Changes, 82 Fed. Reg. 56336 (Nov. 29, 2017), https://www.govinfo.gov/content/pkg/FR-2017-11-28/pdf/2017-25068.pdf. Last visited Aug 23, 2023.

> years, the point-of-sale price of a drug that a Part D sponsor reports on a PDE record as the negotiated price is rendered less transparent . . . .

CMS expressed further concern that when rebates and other price concessions are not reflected in the negotiated point-of-sale drug price, it "can impede beneficiary access to necessary medications, which leads to poorer health outcomes and higher medical care costs for beneficiaries . . . ."

384. PBMs thus make money coming and going. In a pre-PBM world, a competitively priced drug might have a (hypothetical) net cost to a health plan $50 and that is what it paid. PBMs enter the picture and coordinate with Manufacturers to increase the list price to $150. The PBMs then "negotiate" the inflated price down to $100 and take a $50 rebate, some of which may be forwarded to the payor, whose net cost is less than the inflated list price, but whose real-world cost is considerably more than if the PBMs were not involved.

385. At the same time, the PBM receives "administrative fees" for including certain drugs on its formularies, which are not considered "rebates." The PBM also receives "service fees" or other payment for "administrative services" provided to the Manufacturers such as "formulary compliance initiatives," "education services," or "the sale of non-patient identifiable claim information." All of these revenues are outside the definition of "rebates."

386. The PBM then charges payors like the County for administrative fees for providing pharmacy benefit management services and charges for drug costs (i.e. ingredient costs) and per-prescription dispensing fees, as well as additional administrative fees for services not included in the PBM's general administrative obligations. The PBM also receives rebates and/or discounts (pre-purchase or post-purchase) from the pharmacies, which it often owns. These too are excluded from the definition of "rebates." These and other vaguely described revenue streams are sometimes disclosed but only in hazy, overly generalized terms. And they are beyond a payor's contractual

rights to audit for "transparency" purposes because they are not defined "rebates." Additionally, the PBM may take months to pay rebates to payors and the PBM retains all interest on, and the time-value of, the rebates pending payment.

387. Payors have no access to, and no knowledge of, the intricacies of the dealings between the PBM Defendants and the Manufacturers that are shrouded by such vague "disclosures" (which vary in detail, but not in substance, in all three of the PBM Defendants' adhesive contracts).

The Insulin Pricing Scheme Increases PBM Mail-Order Profit

388. Another way PBMs profit from the Insulin Pricing Scheme is through the PBM Defendants' own mail-order pharmacies. The higher the price that PBM Defendants are able to get customers, such as Plaintiff, to pay for diabetes medications, the higher the profits PBM Defendants realize through their mail-order pharmacies.

389. Because the PBMs base the price they charge for the at-issue diabetes medications on the Manufacturers' price, the more the Manufacturers inflate their prices, the more money the PBMs make. For example, the PBMs have colluded with the Manufacturers so that the PBMs often know when the Manufacturers are going to raise their prices. The PBMs use this opportunity to purchase a significant amount of the at- issue drugs prior to the price increase, at the lower rate. Then, after the Manufacturers raise their price, the PBMs charge their mail-order customers based on the higher, increased prices and pocket the difference. The PBMs make significant amounts of money through this arbitrage scheme.

390. The PBMs also charge the Manufacturer Defendants fees related to their mail-order pharmacies, such as pharmacy supplemental discount fees, that are directly tied to the

Manufacturers' price. Thus, once again, the higher the price, the more money the PBMs make on these fees.

391. In sum, every way in which the PBMs make money on diabetes medications is tied directly to creating higher prices and inducing larger secret Manufacturer Payments. The PBMs are not lowering the price of diabetes medications as they publicly represent; they are making billions of dollars by fueling these skyrocketing prices.

H. Plaintiff Purchases the At-Issue Drugs Directly from Defendants

392. As a government employer, Plaintiff serves its residents by providing public safety, emergency management, and health services, among other vital roles. As more federal and state responsibilities are mandated to local government, Plaintiff has a growing list of demands on a limited budget. Consequently, any significant increase in spending can have a severe detrimental effect on Plaintiff's overall budget and, in turn, negatively impact its ability to provide necessary services to the community.

393. One benefit Plaintiff provides the Beneficiaries of its healthcare plan is payment for a large portion of their pharmaceutical purchases. In this role, Plaintiff spent significant amounts on the at-issue diabetes medications during the relevant period.

394. Because Plaintiff maintains a self-funded plan for County employees, Plaintiff does not rely on a third-party insurer to pay for insured employees' medical care, pharmaceutical benefits, or prescription drugs. Rather, Plaintiff directly contracts with, and directly pays, PBMs (and their affiliated pharmacies) for pharmaceutical benefits and prescription drugs, including the at-issue medications.

395. Plaintiff also purchased, and still purchases, the at-issue drugs directly from these PBMs (and their affiliated pharmacies) for use in Plaintiff's county-run facilities.

396. In the context of Plaintiff's purchases of the at-issue drugs, Plaintiff and its Beneficiaries are the only victims of the Insulin Pricing Scheme. Plaintiff is the only named party that pays the full purchase price for the at-issue drugs, and the only named party that has not knowingly participated in the Insulin Pricing Scheme. Neither the PBM Defendants nor the Manufacturers Defendants suffer losses from the Insulin Pricing Scheme.

397. As part of purchasing the at-issue drugs from the PBMs, Plaintiff directly pays the PBMs artificially inflated costs resulting from the Insulin Pricing Scheme, including "administrative fees," "inflation fees," "discount fees," and more—all of which are associated with Plaintiff's purchase of the at-issue drugs from the PBM Defendants. Because the at-issue medications are potentially life-saving drugs, and because the Manufacturers control the market for these drugs, Plaintiff has no choice but to pay these exorbitant, artificially inflated prices directly to PBM Defendants.

398. Plaintiff also relies (and has relied) on PBM Defendants as administrative agents, for the alleged purposes of limiting its administrative burden and controlling pharmaceutical drugs costs.

399. In providing PBM services to Plaintiff, including developing and offering formularies for Plaintiff's prescription plan, constructing and managing Plaintiff's pharmacy network (which included the PBMs' retail and mail-order pharmacies), processing pharmacy claims, and providing mail-order pharmacy services, PBM Defendants set the amount Plaintiff paid in coordination with the Manufacturer Defendants and, utilizing the false prices, generated by the Insulin Pricing Scheme. Plaintiff paid PBM Defendants directly for the at-issue drugs.

I. Defendants Deceived Plaintiff

400. At no time has either Defendant group disclosed the Insulin Pricing Scheme or the reasons for the false list prices produced by it.

The Manufacturer Defendants Deceived Plaintiff

401. At all times during the relevant period, the Manufacturer Defendants knew that the list prices, net prices, and payors' net costs (purchase prices) generated by the Insulin Pricing Scheme were false, excessive, and untethered to any legal, competitive, or fair market price.

402. The Manufacturer Defendants knew that these prices did not bear any rational relationship to the actual costs incurred or prices realized by Defendants, did not result from transparent or competitive market forces, and were artificially and arbitrarily inflated for the sole purpose of generating profits for Defendants.

403. The insulin market, and Defendants' business arrangement relating thereto, exhibit the key features of oligopolies (see Fig. 14)—concentration of numerous competitors into a small group of firms that dominates the market, high barriers to entry, ability to set and control prices, firm interdependence, and maximal revenues.

404. The Manufacturer Defendants also knew that payors, including Plaintiff, relied on the false list prices generated by the Insulin Pricing Scheme to pay for the at-issue drugs.

405. The Manufacturer and PBM Defendants further knew that Plaintiff—like any reasonable consumer, and particularly one with fiduciary obligations to its Beneficiaries—wanted and expected to pay a price reflecting the lowest fair market value for the drugs (which was not necessarily the same as the lowest price in the market, given that all prices were inflated due to the Insulin Pricing Scheme).

406. Despite this knowledge, the Manufacturer Defendants published the prices generated by the Insulin Pricing Scheme throughout the United States and Tennessee through

publishing compendia, in various promotional and marketing materials distributed by entities downstream in the drug supply chain, and directly to pharmacies which then used these prices to set the amount that the pharmacies charged for the at-issue drugs.

407. The Manufacturer Defendants also publish these prices to the PBMs and pharmacies, which then use them to charge diabetics and payors like Plaintiff for the at-issue drugs.

408. By publishing their prices throughout Tennessee, the Manufacturer Defendants held these prices out as a reasonable price upon which to base the prices that payors actually pay for the at-issue drugs.

409. These representations are false. The Manufacturer Defendants knew that their artificially inflated list prices were not remotely related to their cost, their fair market value in a competitive market, or the net price received for the at-issue drugs.

410. During the relevant period, the Manufacturer Defendants published prices in Tennessee at hundreds of dollars per dose for the same at-issue drugs that would have been profitable to Manufacturers at prices less than $10 per dose.

411. The Manufacturer Defendants also have publicly represented that they price the at-issue drugs according to each drug's value to the health care system and the need to fund innovation. For example, briefing materials prepared for Dave Ricks, Eli Lilly's CEO, as a panelist at the 2017 Forbes Healthcare Summit included "Reactive Key Messages" on pricing that emphasized the significant research and development costs for insulin. During the relevant period, executives from Sanofi and Novo Nordisk also falsely represented that research and development costs were key factors driving the at-issue price increases.[62]

[62] Drug Pricing Investigation, H.R. Comm. On Oversight and Reform, 117th Cong. (2021), https://web.archive.org/web/20211215170722/https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf (last visited Jan. 10, 2023).

412. To the contrary, between 2005 and 2018, Eli Lilly spent $680 million on R&D costs related to Humalog while earning $31.35 billion in net sales during that same time period. In other words, Eli Lilly made more than 46 times its reported R&D costs on Humalog during this portion of the relevant period, i.e., R&D costs amounted to about 2% of net sales (whereas R&D costs for pharmaceuticals typically amount to around 20% of total revenues). Novo Nordisk has spent triple the amount it spends on R&D on stock buyouts and shareholder dividend payouts in recent years.[63]

413. The January 2021 Senate Insulin Report found that the PBMs consider insulins to be "interchangeable" from "a clinical perspective" and that Manufacturers focus their R&D efforts on new insulin-related device, equipment, and other mechanical parts which are separate from insulin's formulation."[64]

414. A House Oversight Committee staff report concluded that "drug companies' claims that reducing U.S. prescription drug prices will harm innovation is overblown" and that "[m]any drug companies spent a significant portion of their R&D budget on finding ways to suppress generic and biosimilar competition while continuing to raise prices, rather than on innovative research."[65]

415. In sum, the Manufacturer Defendants affirmatively withheld the truth from Plaintiff and specifically made these misrepresentations in furtherance of the Insulin Pricing Scheme and

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[63] *Id.*

[64] Grassley & Wyden, *supra* note 2 at 5, 17.

[65] U.S. House of Reps., *Drug Pricing Investigation: Industry Spending on Buybacks, Dividends and Executive Compensation* (July 2021), https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/COR%20Staff%20Report%20-%20Pharmaceutical%20Industry%20Buybacks%20Dividends%20Compared%20to%20Research.pdf (last visited Aug. 23, 2023).

to induce Plaintiff's reliance to purchase the at-issue drugs. The PBM Defendants Deceived Plaintiff

416. The PBM Defendants ensured that the Manufacturer Defendants' artificially inflated list prices harmed diabetics and payors by selecting the highest price at-issue drugs for preferred formulary placement and by requiring that their contracts with both pharmacies and with payors include such prices as the basis for payment.

417. The PBM Defendants perpetuate the use of the artificially inflated insulin prices because it allows them to obscure the actual price any entity in the drug pricing chain is paying for the at-issue drugs. This lack of transparency affords Defendants the opportunity to construct and perpetuate the Insulin Pricing Scheme and to profit therefrom at the expense of Tennessee payors, including Plaintiff.

418. At all times throughout the relevant period, the PBMs have purposefully, consistently, and routinely misrepresented that they negotiate with Manufacturer Defendants and construct formularies for the benefit of payors and patients by lowering the price of the at-issue drugs and by promoting the health of diabetics. Representative examples include: [66]

- Defendant CVS Caremark has for the past decade consistently stated in its annual reports that its design and administration of formularies are aimed at reducing the costs and improving the safety, effectiveness, and convenience of prescription drugs. CVS Caremark has further stated that it maintains an independent panel of doctors, pharmacists, and other medical experts to review and approve the selection of drugs based on safety and efficacy for inclusion on one of Caremark's template formularies and that CVS Caremark's formularies lower the cost of drugs.

- Likewise, Defendant Express Scripts has consistently represented that it works with clients, manufacturers, pharmacists, and physicians to increase efficiency in the drug distribution chain, to manage costs in the pharmacy benefit chain, and to improve members' health outcomes. Its annual reports consistently claim that in making formulary recommendations, Express Scripts' Pharmacy & Therapeutics Committee considers the drug's safety and efficacy, without any information on or

[66] CVS Health Annual Reports (Form 10-K) (FY 2010-2019); OptumRx Annual Reports (Form 10-K) (FY 2010-2019); Express Scripts Annual Reports (Form 10-K) (FY 2010-2019).

consideration of the cost of the drug, including any discount or rebate arrangement that Express Scripts negotiates with the Manufacturer, and that Express Scripts fully complies with the P&T Committee's clinical recommendations regarding drugs that must be included or excluded from the formulary based on their assessment of safety and efficacy.

- Similarly, Defendant OptumRx has consistently stated in its annual reports over the past decade that OptumRx's rebate contracting and formulary management assist customers in achieving a low-cost, high-quality pharmacy benefit. It has consistently claimed that it promotes lower costs by using formulary programs to produce better unit costs, encouraging patients to use drugs that offer improved value and that OptumRx's formularies are selected for health plans based on their safety, cost and effectiveness.

419. In addition to these general misrepresentations, the PBM Defendants have during the relevant period purposefully, consistently, and routinely made misrepresentations about the at-issue diabetes medications. Representative examples include:

- In a public statement issued in November 2010, CVS Caremark represented that it was focused on diabetes to "help us add value for our PBM clients and improve the health of plan members . . . a PBM client with 50,000 employees whose population has an average prevalence of diabetes could save approximately $3.3 million a year in medical expenditures."[67]

- In 2010, Andrew Sussman, Chief Medical Officer of CVS Caremark, stated on national television that "CVS is working to develop programs to hold down [diabetes] costs."[68]

- In a public statement issued in November 2012, CVS Caremark represented that formulary decisions related to insulin products "is one way the company helps manage costs for clients."[69]

- In 2016, Glen Stettin, Senior Vice President and Chief Innovation Officer at Express Scripts, said in an interview with a national publication that "[d]iabetes is wreaking havoc on patients, and it is also a runaway driver of costs for payors . . .

[67] Chain Drug Review, *CVS Expands Extracare for Diabetes Products* (May 11, 2010), https://www.chaindrugreview.com/cvs-expands-extracare-for-diabetes-products/ (last visited Jan. 15, 2023).

[68] CBS News, Diabetes Epidemic Growing (June 22, 2010, 11:29 AM), https://www.cbsnews.com/news/diabetes-epidemic-growing/ (last visited Aug. 23, 2023).

[69] Jon Kamp & Peter Loftus, *CVS' PBM Business Names Drugs It Plans to Block Next Year*, WSJ (Nov. 8, 2012), https://www.wsj.com/articles/SB10001424127887324439804578 107040729812454 (last visited Jan. 15, 2023).

[Express Scripts] helps our clients and diabetes patients prevail over cost and care challenges created by this terrible disease."[70] Mr. Stettin also claimed that Express Scripts "broaden[s] insulin options for patients and bend[s] down the cost curve of what is currently the costliest class of traditional prescription drugs."[71]

- In a 2018 Healthline interview, Mark Merritt, longtime President of the PBM trade association PCMA, stated: "[Through their formulary construction], PBMs are putting pressure on drug companies to reduce insulin prices."[72]

- CVS Caremark's Chief Policy and External Affairs Officer claimed in the April 2019 hearings that CVS Caremark "has taken a number of steps to address the impact of insulin price increases. We negotiate the best possible discounts off the manufacturers' price on behalf of employers, unions, government programs, and beneficiaries that we serve."[73]

- Dr. Sumit Dutta, SVP and Chief Medical Officer of OptumRx, testified before the U.S. Congress in the April 2019 hearing that for "insulin products . . . we negotiate with brand manufacturers to obtain significant discounts off list prices on behalf of our customers."[74]

- The PBM-funded trade association PCMA's website acknowledges, "the insulin market is consolidated, hindering competition and limiting alternatives, leading to higher list prices on new and existing brand insulins," but then misleadingly claims that "PBMs work hard to drive down costs using formulary management and rebates."[75]

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[70] https://www.bizjournals.com/stlouis/news/2016/08/31/express-scripts-launchesprogram-to-control.html (last visited Jan. 15, 2023).

[71] Angela Mueller, *Express Scripts Launches Program to Control Diabetes Costs*, St. Louis Bus. J. (Aug. 31, 2016), https://drugstorenews.com/pharmacy/express-scriptsimplements-latest-diabetes-care-value-program (last visited Jan. 15, 2023).

[72] Dave Muoio, *Insulin Prices: Are PBMs and Insurers Doing Their Part?*, Population Health Learning Network (Dec. 2016), https://www.hmpgloballearningnetwork.com/site/frmc/ article/insulin-prices-are-pbms-and-insurers-doing-their-part (last visited Jan. 15, 2023).

[73] *Priced Out of a Lifesaving Drug*, *supra* note 35.

[74] *Id*.

[75] PCMA, *PCMA on National Diabetes Month: PBMs Lowering Insulin Costs, Providing Support to Patients* (Nov. 16, 2020), https://www.pcmanet.org/pcma-on-nationaldiabetes-month-pbms-lowering-insulin-costs-providing-support-to-patients/ (last visited Aug. 23, 2023); Visante, *Insulins: Managing Costs with Increasing Manufacturer Prices* (2020), https://www. pcmanet.org/ wpcontent/uploads/2020/08/PCMA_Visante-Insulins-Prices-and-Costs-.pdf.

420. The PBM Defendants not only falsely represent that they negotiate with the Manufacturer Defendants to lower the price of the at-issue diabetes medications for *payors*, but also for diabetic *patients* as well. Representative examples include:

- Express Scripts' code of conduct, effective beginning in 2015, states: "At Express Scripts we're dedicated to keeping our promises to *patients and clients* . . . This commitment defines our culture, and all our collective efforts are focused on our mission to make the use of prescription drugs safer and more affordable."[76] (emphasis added)

- Amy Bricker, former President of Express Scripts and PCMA board member, testified before Congress in April 2019: "At Express Scripts we negotiate lower drug prices with drug companies on behalf of our clients, *generating savings that are returned to patients* in the form of lower premiums and reduced out-of-pocket costs."[77] (emphasis added)

- Ms. Bricker of Express Scripts also testified that "Express Scripts remains committed to . . . *patients* with diabetes and creating affordable access to their medications."[78] (emphasis added)

- OptumRx CEO John Prince testified to the Senate: "We *reduce the costs of prescription drugs* [and] we are leading the way to ensure that *those discounts directly benefit consumers*. . . . OptumRx's pharmacy care services business is *achieving better health outcomes for patients, lowering costs* for the system, and *improving the healthcare experience for consumers*. . . . OptumRx negotiates better prices with drug manufacturers *for our customers and for consumers*.[79] (emphasis added)

- In its 2017 Drug Report, CVS Caremark stated that the goal of its pharmacy benefit plans is to ensure "that the cost of a drug is aligned with the value it delivers in terms of *patient* outcomes . . . in 2018, we are doing even more to help keep drugs affordable with our new Savings *Patients* Money initiative." (emphasis added)[80]

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[76] Express Scripts, *Code of Conduct*, https://www.expressscripts.com/aboutus/codeconduct/ExpressScriptsCodeOfConduct.pdf (last visited Jan. 10, 2023).

[77] *Priced Out of a Lifesaving Drug*, *supra* note 35.

[78] *Id.*

[79] Grassley & Wyden, *supra* note 2—*Hearing Transcript* at 174, https://www.finance.senate.gov/imo/media/doc/435631.pdf (last visited Aug. 23, 2023).

[80] CVS Health, *2017 Drug Trend Report* (Apr. 5, 2018), https://payorsolutions.cvshealth.com/insights/2017-drug-trend-report (last visited Aug. 23, 2023).

- The PCMA website touts PBMs as "the only entity in the prescription drug supply and payment chain dedicated to reducing drug costs" and (contradicting the PBM representatives' Congressional testimony), that "when new manufacturers enter the market at a lower list price, PBMs use the competition to drive costs down."[81]

421. Not only have PBM Defendants intentionally misrepresented that they use their market power to save payors money, but they have specifically and falsely disavowed that their conduct drives prices higher. Representative examples include:

- On an Express Scripts' earnings call in February 2017, CEO Tim Wentworth stated: "Drugmakers set prices, and we exist to bring those prices down."[82]

- Larry Merlo, head of CVS Caremark sounded a similar refrain in February 2017: "Any suggestion that PBMs are causing prices to rise is simply erroneous."[83]

- In 2017, Express Scripts' Wentworth went on CBS News to argue that PBMs play no role in rising drug prices, stating that PBMs work to "negotiate with drug companies to get the prices down."[84]

- During the April 2019 Congressional hearings, when asked if PBM-negotiated rebates and discounts were causing the insulin price to increase, OptumRx's Chief Medical Officer Sumit Dutta answered: "we can't see a correlation when rebates raise list prices."[85]

- In 2019, when testifying under oath before Congress on the rising price of insulins, Amy Bricker—former President of Express Scripts and PCMA board member—testified: "I have no idea why the prices [for insulin] are so high none of it is the fault of rebates."[86]

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[81] PCMA, *PBMs Reduce Insulin Costs: PBMs are working to improve the lives of patients living with diabetes and their families*, https://www.pcmanet.org/insulin-managingcosts-with-increasing-manufacturer-prices/ (last visited Jan. 10, 2023).

[82] Samantha Liss, *Express Scripts CEO Addresses Drug Pricing 'Misinformation'*, St. Louis Post-Dispatch (Feb. 17, 2017), https://www.stltoday.com/business/local/expressscripts-ceo-addresses-drug-pricing-misinformation/article_8c65cf2a-96ef-5575-8b5c-95601ac51840.html (last visited Jan. 11, 2023).

[83] Lynn R. Webster, *Who Is To Blame For Skyrocketing Drug Prices?*, The Hill (July 27, 2017, 11:40 AM), https://thehill.com/blogs/pundits-blog/healthcare/344115-who-is-toblame-for-skyrocketing-drug-prices (last visited Jan. 11, 2023).

[84] CBS News, *Express Scripts CEO Tim Wentworth Defends Role of PBMs in Drug Prices* (Feb 7, 2017), https://www.cbsnews.com/news/express-scripts-tim-wentworth-pbmrising-drug-prices-mylan-epipen-heather-bresh/ (last visited Jan. 11, 2023).

[85] *Priced Out of a Lifesaving Drug*, *supra* note 35.

[86] *Id.*

422. All of Defendants' public statements regarding insulin pricing have been consistent with the misrepresentations above and those detailed below. None have contradicted those misrepresentations or revealed the Insulin Pricing Scheme.

423. The PBM Defendants understand that payors like Plaintiff rely on the PBMs to achieve the lowest prices for the at-issue drugs and to construct formularies designed to improve access to medications. Plaintiff did so rely.

424. Throughout the relevant period, the PBM Defendants also falsely claimed they are transparent about the Manufacturer Payments and that the amounts they remit (or not) to payors. In fact, the PBM Defendants' disclosures of their ties to the Manufacturer Defendants were vague, equivocal, and misleading. Their manner of defining "rebates" in payor contracts was illusory and subject to indeterminate conditions and exceptions. The PBM Defendants thereby facilitated and obtained secret Manufacturer Payments far above and beyond the amount of "rebates" remitted to payors.

425. The PBMs' internal processes and accounting were and are abstruse and opaque, allowing them to overtly mislead the public and payors like Plaintiff.

426. In 2011, for example, OptumRx's President stated: "We want our clients to fully understand our pricing structure . . . [e]very day we strive to show our commitment to our clients, and one element of that commitment is to be open and honest about our pricing structure."[87]

[87] UnitedHealth Group, *Prescription Solutions by OptumRx Receives 4th Consecutive TIPPS Certification for Pharmacy Benefits Transparency Standards* (Sept. 13, 2011), https://web.archive.org/web/20210805182422/https://www.unitedhealthgroup.com/newsroom/2011/0913tipps.html (last visited Jan. 11, 2023). *See also, e.g.*, published version of press release at https://www.businesswire.com/news/home/20110913006224/en/Prescription-Solutions-by-OptumRx-Receives-4th-Consecutive-TIPPSSM-Certification-for-Pharmacy-Benefits-Transparency-Standards (last visited Aug. 23, 2023).

427. In a 2017 CBS News interview, Express Scripts' CEO represented, among other things, that Express Scripts was "absolutely transparent" about the Manufacturer Payments they receive and that payors "know exactly how the dollars flow" with respect to these Manufacturer Payments.[88]

428. When testifying before the Senate Finance Committee, CVS Executive Vice President Derica Rice stated: "[A]s it pertains to transparency overall, we at CVS Caremark are very supportive. We provide full visibility to our clients of all our contracts and the discounts that we negotiate on their behalf. . . . And transparency—today we report and fully disclose not only to our clients, but to CMS [Medicare]."[89]

429. At the same hearing, Steve Miller of Cigna (Express Scripts) testified: "we are a really strong proponent for transparency for those who pay for health care. So the patient should know exactly what they are going to pay. Our plan sponsors should know exactly what is in their contract."[90]

430. John Prince of OptumRx chimed in: "Senator, if our discounts were publicly available, it would hurt our ability to negotiate effectively. Our discounts are transparent to our clients."[91]

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[88] CBS News, *supra* note 79.

[89] Grassley & Wyden, *supra* note 2—*Hearing Transcript* at 28, 32, https://www.finance.senate.gov/imo/media/doc/ 435631.pdf (last visited Jan. 11, 2023).

[90] *Id.* at 32.

[91] *Id.*

431. When testifying before Congress in April 2019, Amy Bricker, then a Senior Vice President of Defendant Express Scripts, claimed transparency with payors and echoed Mr. Prince's need for confidentiality around discounts:[92]

> Ms. Bricker. The rebate system is 100 percent transparent to the plan sponsors and the customers that we service. To the people that hire us, employers of America, the government, health plans, what we negotiate for them is transparent to them. . . The reason I'm able to get the discounts that I can from the manufacturer is because it's confidential [to the public].
>
> ***
>
> Mr. Sarbanes. Yeah, because it's a secret. What about if we made it completely transparent? Who would be for that?
>
> ***
>
> Ms. Bricker. Absolutely not . . . [i]t will hurt the consumer. . . . prices will be held high.

432. As recently as May 2022, JC Scott—President of the PBM trade group PCMA—testified as follows before the Senate Commerce Committee:

> PBMs are proud of the work they do to reduce prescription drug costs, expand affordable access to medications, and improve patient outcomes. PBMs negotiate with drug companies to lower prescription drug costs PBMs advocate for patients in the fight to keep prescription drugs accessible and affordable.

433. Mirroring the PCMA website (¶¶ 429, 430, *supra*), Mr. Scott also testified, "The PBM industry is the only stakeholder in the chain dedicated to seeking lower costs."

434. During the relevant period—as seen above—PBM Defendants represented to Plaintiff that they constructed formularies and negotiated with the Manufacturer Defendants for the benefit of payors and patients to maximize drug cost savings while promoting the health of diabetics.

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[92] *Priced Out of a Lifesaving Drug, supra* note 35.

435. Throughout the relevant period, the PBMs made the foregoing and similar misrepresentations consistently and directly to Tennessee payors, including Greene County, through bid proposals, member communications, invoices, formulary change notifications, and through extensive direct-to-consumer pull through efforts engaged in with the Manufacturers.

436. All of these representations are false. The Manufacturer and PBM Defendants in fact coordinated to publish the false prices and to construct the PBM formularies, causing the price of the at-issue drugs to skyrocket. For example:

a. In 2018, the US spent $28 billion (USD) on insulin compared with $484 million in Canada. The average American insulin user spent $3,490 on insulin in 2018 compared with $725 among Canadians.

b. Diabetics who receive their medications from federal programs that do not utilize PBMs also pay significantly less. For example, in December 2020, the United States House of Representatives Committee on Oversight and Reform issued a Drug Pricing Investigation Report finding that federal health care programs that negotiate directly with the Manufacturers (such as the Department of Veterans Affairs), and are thus outside the PBM Defendants' scheme, paid $16.7 billion less from 2011 through 2017 for the at-issue drugs than the Medicare Part D program, which relies on the PBM Defendants to set their at-issue drug prices (and are thus victims of the PBMs' concerted efforts to drive up the list prices).

437. Defendants knew their representations were false when they made them and coordinated to affirmatively withhold the truth from payors, including Plaintiff.

438. Defendants concealed the falsity of their representations by closely guarding their pricing negotiations, structures, agreements, sales figures, and the flow of money and other consideration between them.

439. The Defendants have never revealed the full amount of any drug-specific Manufacturer Payments exchanged between them.

440. The PBM Defendants do not disclose the terms of their agreements with the Manufacturers or the Manufacturer Payments they receive. Nor do they disclose the details related

to their agreements (formal or otherwise) with pharmacies. All of these revenue streams are beyond the scope of the payors' contractual audit rights.

441. Further, although PBMs negotiate drug-specific rebates with Manufacturers,[93] the PBM rebate payments to payor clients and summaries of such payments are in the aggregate, rather than on a drug-by-drug basis. It is impossible for payors like Plaintiff to tease out drug-specific rebates, much less the other undisclosed Manufacturer Payments. This allowed the PBM Defendants to hide the large Manufacturer Payments that they receive for the at-issue diabetes medications.

442. The PBM Defendants have gone so far as to sue governmental entities to block the release of details on their pricing agreements with the Manufacturers and pharmacies.

443. Even when audited by payors, the PBM Defendants routinely refuse to disclose their agreements with the Manufacturers and pharmacies, relying on overly broad confidential agreements, claims of trade secrets, and erecting other unnecessary roadblocks and restrictions.

444. Beneficiaries of the Plaintiff's health plans have no choice but to pay prices flowing from Defendants' inflated list prices because Beneficiaries need these medications to survive and the Manufacturer Defendants make virtually all diabetes medications available in the United States. The list prices generated by the Defendants' coordinated efforts directly impact out-of-pocket costs at the point of sale.

445. In sum, the entire insulin pricing structure created by the Defendants—from the false prices to the Manufacturers' misrepresentations related to the reason behind the price, to the inclusion of the false prices in payor contracts, to the non-transparent Manufacturer Payments, to

[93] Grassley & Wyden, *supra* note 2 at 40.

the misuse of formularies, to the PBMs' representations that they work to lower prices and promote the health of diabetics—is unconscionable, deceptive, and immensely lucrative.

446. Plaintiff did not know, because the Defendants affirmatively concealed, that (1) the Manufacturers and PBMs coordinated to create the PBM formularies in exchange for money and other consideration; (2) the list prices were falsely inflated; (3) the list prices were manipulated to satisfy PBM profit demands; (4) the list prices and net costs (purchase prices) paid by Plaintiff bore no relationship to the fair market value of the drugs themselves or the services rendered by the PBMs in coordinating their pricing; or (5) the entire insulin pricing structure Defendants created was false.

J. The Insulin Pricing Scheme Has Damaged Plaintiff

447. Plaintiff Greene County provides health and pharmacy benefits to its Beneficiaries, including employees, retirees, and their dependents, who have numbered in the thousands throughout the relevant period.

448. One benefit Plaintiff provides the Beneficiaries of its healthcare plan is paying for their pharmaceutical needs.

449. Plaintiff entered into an agreement with CVS Caremark, whereby CVS Caremark agreed to provide Plaintiff prescription drug benefits and other at-issue services.

450. Plaintiff and Medco entered into an agreement whereby Medco agreed to provide Plaintiff prescription drug benefits and other at-issue services.

451. Express Scripts acquired Medco in 2012.

452. Plaintiff and OptumRx entered into an agreement whereby OptumRx agreed to provide Plaintiff prescription drug benefits and other at-issue services.

453. Plaintiff has renewed and had an active agreement in place with either Express Scripts, Medco, CVS Caremark, or Optum Rx.

454. Plaintiff requested proposals from the PBM Defendants for the at issue services.

455. In response to Plaintiff's requests, all PBM Defendants submitted proposals.

456. Plaintiff was unaware of the Insulin Pricing Scheme. Plaintiff relied on Defendants' public statements and material omissions.

457. Plaintiff contracted with Defendant Express Scripts, Inc., CVS Caremark, and OptumRx for PBM services.

458. Defendants' Insulin Pricing Scheme has cost Plaintiff an exorbitant amount of money in overcharges.

459. Indeed, since 2003 Greene County has spent exorbitant amounts of money on the at-issue diabetes medications.

460. CVS Caremark's, Express Scripts', and OptumRx's respective relationships with Plaintiff were inherently unbalanced and their contracts adhesive. PBM Defendants had superior bargaining power and superior knowledge of their relationships with the Manufacturer Defendants, including those that ultimately dictate the drug costs Plaintiff incurred. Although PBM Defendants were supplying a vital service of a quasi-public nature, they exploited their superior positions to mislead Plaintiff and thwart its expectations, all at great expense to Greene County.

461. The Defendants' misrepresentations, omissions, and misconduct—including and as manifested in the Insulin Pricing Scheme—directly and proximately caused economic damage to Plaintiff as a payor/purchaser of Defendants' at-issue diabetes medications.

462. A substantial proportion of the money Plaintiff spent on diabetes medications is attributable to Defendants' inflated prices, which did not arise from competitive market forces but, instead, exist solely by virtue of the Insulin Pricing Scheme.

463. Because of Defendants' success in concealing the Insulin Pricing Scheme through act and omission, no payor, including Plaintiff, knew (or should have known) during the relevant period that the prices for the at-issue diabetes medications were (and are) artificially inflated due to the Insulin Pricing Scheme.

464. As a result, despite receiving some rebates and incurring drug costs based on discounts off list prices, Plaintiff has unknowingly overpaid for the Manufacturer Defendants' diabetes medications, which would have cost far less but for the Insulin Pricing Scheme.

465. In short, the Insulin Pricing Scheme has directly and proximately caused Plaintiff to substantially overpay for diabetes medications.

466. Because Defendants continue to generate exorbitant, unfair, and deceptive prices for the at-issue drugs through the Insulin Pricing Scheme, the harm to Plaintiff is ongoing.

K. Defendants' Recent Efforts in Response to Rising Insulin Prices

467. In reaction to mounting political and public outcry, Defendants have taken action both on Capitol Hill and in the public relations space.

468. First, in response to public criticism, Defendants have increased their spending to spread their influence in Washington D.C.

469. For example, in recent years Novo Nordisk's political action committee ("PAC") has doubled its spending on federal campaign donations and lobbying efforts. In 2017 alone, Novo Nordisk spent $3.2 million lobbying Congress and federal agencies, its biggest ever investment in

directly influencing U.S. policymakers. Eli Lilly and Sanofi also have contributed millions of dollars through their PACs in recent years.

470. Second, Defendants have recently begun publicizing programs ostensibly aimed at lowering the cost of insulins.

471. These affordability measures fail to address the structural issues that caused the price hikes. Rather, these are public-relations measures that do not solve the problem.

472. For example, in March 2019, Defendant Eli Lilly announced that it would produce an authorized generic version of Humalog, "Insulin Lispro," and promised that it would "work quickly with supply chain partners to make [the authorized generic] available in pharmacies as quickly as possible."

473. However, in the months after Eli Lilly's announcement, reports raised questions about the availability of "Insulin Lispro" in local pharmacies.

474. Following this the staff of the Offices of U.S. Senators Elizabeth Warren and Richard Blumenthal prepared a report examining the availability of this drug. The investigative report, *Inaccessible Insulin: The Broken Promise of Eli Lilly's Authorized Generic*, concluded that Eli Lilly's lower-priced, authorized generic insulin is widely unavailable in pharmacies across the country, and that the company has not taken meaningful steps to increase insulin accessibility and affordability.[94]

475. Eli Lilly did lower the price of Lispro by 40% effective January 1, 2022; but it is not included in any of the PBM Defendants' formularies as of January 2023.

[94] Sen. Elizabeth Warren & Sen. Richard Blumenthal, *Inaccessible Insulin: The Broken Promise of Eli Lilly's Authorized Generic*, (Dec. 2019), https://www.warren.senate.gov/imo/media/doc/Inaccessible%20Insulin%20report.pdf (last visited Aug. 23, 2023).

476. In 2019, Novo Nordisk partnered with Walmart to offer ReliOn brand insulins for a discounted price at Walmart. However, experts have warned that the Walmart/Novo Nordisk insulins are not substitutes for most diabetics' regular insulins and should only be used in an emergency or when traveling. In particular, for many diabetics, especially Type 1 diabetics, these insulins can be dangerous. In any event, ReliOn is not included in any of the PBM Defendants' formularies as of January 2023.

477. Thus, Defendants' "lower priced" insulin campaigns have not addressed the problem, and the PBMs continue to exclude drugs with lower list prices despite their assurances of cost-savings for payors and Beneficiaries. Plaintiff continues to suffer harm caused by the Insulin Pricing Scheme.

478. Likewise, FDA in 2020 approved the biosimilar Insulin Glargine-yfgn (branded as Semglee), which is manufactured and sold by newcomers to the market—Viatris and Biocon Biologics.[95] Insulin Glargine-yfgn (Semglee) is interchangeable with Defendant Sanofi's Lantus product and, according Viatris, its list price is three times cheaper than Lantus. It is not included in any of the PBM Defendants' formularies as of January 2023.

[95] As explained in n.3, insulin now is regulated as a biologic rather than a drug. Biosimilars are analogous to generic drugs—approved versions of original products that are virtually identical to, and interchangeable with, the original product.

CLAIMS FOR RELIEF

First Cause of Action (Count I)
Violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962(c)

(against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx)

479. Plaintiff Greene County re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

480. Plaintiff brings this count against all Defendants for violations of 18 U.S.C. § 1962(c).

481. Defendants Eli Lilly, Novo Nordisk, Sanofi, CVS Caremark, Express Scripts and OptumRx are (a) culpable "persons" who (b) willfully and knowingly (c) committed and conspired to commit two or more acts of mail and wire fraud (d) through a "pattern" of racketeering activity that (e) involves an "association in fact" enterprise, (f) the results of which had an effect on interstate commerce.

A. Defendants Are Culpable "Persons" Under RICO

482. Defendants Eli Lilly, Novo Nordisk, Sanofi, CVS Caremark, Express Scripts, and OptumRx, separately, are "persons" as that term is defined in 18 U.S.C. § 1961(3) because each is capable of holding a legal or beneficial interest in property.

483. Each one of Defendants Eli Lilly, Novo Nordisk, Sanofi, CVS Caremark, Express Scripts, and OptumRx are separate entities and "persons" that are distinct from the RICO enterprises alleged below.

B. The Manufacturer-PBM RICO Enterprises

484. For the purposes of this claim, the RICO enterprises are six separate associations-in-fact consisting of one of each of the PBM Defendants and one of each of the Manufacturer

Defendants, including those entities' directors, employees, and agents: the Eli Lilly-CVS Caremark Enterprise; the Eli Lilly-OptumRx Enterprise; the Eli Lilly-Express Scripts Enterprise; the Novo Nordisk-CVS Caremark Enterprise; the Novo Nordisk-OptumRx Enterprise; the Novo Nordisk-Express Scripts Enterprise; the Sanofi-CVS Caremark Enterprise; the Sanofi-OptumRx Enterprise; and the Sanofi-Express Scripts Enterprise.

485. These association-in-fact enterprises are collectively referred to herein as the "Manufacturer-PBM Enterprises."

486. Each Manufacturer-PBM Enterprise is a separate, ongoing, and continuing business organization consisting of corporations and individuals associated for the common purpose of manufacturing, selling, and facilitating the purchase of the Manufacturer Defendants' products, including the at-issue drugs. For example:

a. The Eli Lilly-OptumRx Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Eli Lilly medications including Prozac, Cymbalta, and Zyprexa, as well as the at-issue Eli Lilly insulin and insulin-analog medications (Trulicity, Humulin N, Humulin R, Humalog, and Basaglar), which are Eli Lilly's primary source of revenue.

b. The Eli Lilly-Express Scripts Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Eli Lilly medications including Prozac, Cymbalta, and Zyprexa, as well as the at-issue Eli Lilly insulin and insulin-analog medications (Trulicity, Humulin N, Humulin R, Humalog, and Basaglar), which are Eli Lilly's primary source of revenue.

c. The Eli Lilly-CVS Caremark Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Eli Lilly

medications including Prozac, Cymbalta, and Zyprexa, as well as the at-issue Eli Lilly insulin and insulin-analog medications (Trulicity, Humulin N, Humulin R, Humalog, and Basaglar), which are Eli Lilly's primary source of revenue.

d. The Novo Nordisk--OptumRx Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Novo Nordisk medications for the treatment of obesity, hemophilia, and hormone imbalance, as well as the at-issue Novo Nordisk insulin and insulin-analog medications (Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic), which account for more than three-quarters of Novo Nordisk's revenue.

e. The Novo Nordisk-Express Scripts Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Novo Nordisk medications for the treatment of obesity, hemophilia, and hormone imbalance, as well as the at-issue Novo Nordisk insulin and insulin-analog medications (Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic), which account for more than three-quarters of Novo Nordisk's revenue.

f. The Novo Nordisk-CVS Caremark Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Novo Nordisk medications for the treatment of obesity, hemophilia, and hormone imbalance, as well as the at-issue Novo Nordisk insulin and insulin-analog medications (Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic), which account for more than three-quarters of Novo Nordisk's revenue.

g. The Sanofi--OptumRx Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Sanofi medications

including Ambien, Plavix, and Dupixent, as well as the at-issue Sanofi insulin and insulin-analog medications (Lantus, Toujeo, Apidra, and Soliqua).

h. The Sanofi-Express Scripts Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Sanofi medications including Ambien, Plavix, and Dupixent, as well as the at-issue Sanofi insulin and insulin-analog medications (Lantus, Toujeo, Apidra, and Soliqua).

i. The Sanofi-CVS Caremark Enterprise associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Sanofi medications including Ambien, Plavix, and Dupixent, as well as the at-issue Sanofi insulin and insulin-analog medications (Lantus, Toujeo, Apidra, and Soliqua).

487. Each Manufacturer-PBM Enterprise engaged in the shared purpose of exchanging false list prices and secret Manufacturer Payments for preferred formulary positions for the at issue drugs in order to control the market for diabetes medications and profit off diabetics and payors, including Plaintiff.

488. The members of each enterprise are bound by contractual relationships, financial ties, and the ongoing coordination of activities.

489. There also is a common communication network by which Eli Lilly and OptumRx, Eli Lilly and Express Scripts, Eli Lilly and CVS Caremark, Novo Nordisk and OptumRx, Novo Nordisk and Express Scripts, Novo Nordisk and CVS Caremark, Sanofi and OptumRx, Sanofi and Express Scripts, and Sanofi and CVS Caremark share information and meet on a regular basis. These communications include, but are not limited to, communications relating to the use of false list prices for the at-issue diabetes medications and the regular flow of Manufacturer Payments from each Manufacturer Defendant to each PBM Defendant in exchange for formulary placement.

490. Each Manufacturer-PBM Enterprise functions as a continuing but separate unit separate and apart from the pattern of racketeering activity in which it engages. Each Manufacturer-PBM Enterprise, for example, engages in the manufacture, distribution and sale of medications and other products other than the at-issue insulin and insulin-analog medications. Additionally, each Manufacturer engages in conduct other than mail fraud and wire fraud in furtherance of the Insulin Pricing Scheme.

491. At all relevant times, each of the Manufacturer-PBM Enterprises was operated and conducted for unlawful purposes by each Manufacturer Defendant and PBM Defendant, namely, carrying out the Insulin Pricing Scheme.

492. Each Manufacturer-PBM Enterprise derived secret profits from these activities that were greater than those any one of the Manufacturer Defendants or PBM Defendants could obtain absent their misrepresentations regarding their pricing schemes.

493. To accomplish this common purpose, each Manufacturer Defendant periodically and systematically inflated the prices of the at-issue drugs and then secretly paid a significant, yet undisclosed, portion of this inflated price back to the PBM Defendants in the form of Manufacturer Payments.

494. Each Manufacturer-PBM Enterprise did so willfully and with knowledge that Plaintiff paid for the at-issue drugs at prices directly based on the false list prices.

495. Each Manufacturer-PBM Enterprise's inflation of the list prices and secret Manufacturer Payments was a quid pro quo exchange for preferred formulary placement.

496. Each Manufacturer-PBM Enterprise concealed from Plaintiff that these false prices and secret Manufacturer Payments resulted in each Manufacturer gaining formulary access without requiring significant price reductions and resulted in higher profits for each PBM Defendant,

whose earnings increase the more inflated the price is and the more payment it receives from each Manufacturer Defendant.

497. Each Manufacturer-PBM Enterprise also shares a common purpose of perpetuating the use of the false list prices for the at-issue drugs as the basis for the price that payors, including Plaintiff, and diabetics pay for diabetes medications.

498. The Manufacturer Defendants would not be able to offer large pricing spreads to the PBM Defendants in exchange for favorable formulary positions without the use of the false list prices as the basis for the price paid by diabetics and payors, including Plaintiff, for the at-issue drugs.

499. The PBM Defendants share this common purpose because nearly all the revenue and profit generated from the at-issue drugs is tied to the false inflated prices generated by the Insulin Pricing Scheme. Without diabetics and payors, including Plaintiff, paying for diabetes medications based on the inflated list prices, their profits from the Insulin Pricing Scheme would decrease.

500. As a result, the PBM Defendants have, with the knowing and willful participation and assistance of each Manufacturer Defendant, engaged in hidden profit-making schemes falling into four general categories: (a) garnering undisclosed Manufacturer Payments from each Manufacturer Defendant that the PBM Defendants retain to a large extent; (b) generating substantial profits from pharmacies because of the falsely inflated prices; (c) generating profits on the diabetes medications sold through the PBM Defendants' own mail-order and retail pharmacies; and (d) keeping secret discounts each Manufacturer Defendant provides in association with the PBM Defendants' mail-order and retail operations.

501. At all relevant times, each PBM Defendant and each Manufacturer Defendant have been aware of their respective Manufacturer-PBM Enterprise's conduct, have been knowing and willing participants in and coordinator of that conduct and have reaped profits from that conduct.

502. None of the PBM Defendants or the Manufacturer Defendants alone could have accomplished the purposes of the Manufacturer-PBM Enterprises without the other entities.

C. The Enterprises Misrepresent and Fail to Disclose Material Facts in Furtherance of the Insulin Pricing Scheme

503. Each Manufacturer-PBM Enterprise knowingly made material misrepresentations to the public and Plaintiff in furtherance of the Insulin Pricing Scheme, including publishing artificially inflated prices for insulin on published indices and representing that:

a. the false list prices for the at-issue diabetes medications were reasonably related to the actual prices realized by Defendants and were a reasonable and fair basis on which to base the price Plaintiff paid for these drugs;

b. each Manufacturer priced its at-issue drugs according to each drug's value to the healthcare system and the need to fund innovation;

c. the Manufacturer Payments paid back to each PBM Defendant for each at-issue drug were for Plaintiff' benefit;

d. all "rebates and discounts negotiated by the PBM Defendants with the Manufacturer Defendants were remitted to Plaintiff;

e. the "rebates" negotiated by the members of each enterprise saved Plaintiff money;

f. each Manufacturer Defendant and each PBM Defendant were transparent with Plaintiff regarding the Manufacturer Payments and the PBMs did not retain any funds associated prescription drug rebates or the margin between guaranteed reimbursement rates and the actual amount paid to the pharmacies; and

g. the PBM Defendants constructed formularies in a manner that lowered the price of the at-issue drugs and promoted the health and safety of diabetics.

504. Each false list price published by the Manufacturer Defendants constituted a material misrepresentation to Plaintiff and the public, in that each purported to be a fair market price for an at-issue drug, and each omitted to disclose the fraudulent spread between the list price and the net price of the medication or the basis therefor. Examples of other affirmative representations by each RICO Defendant in furtherance of each enterprise's Insulin Pricing scheme are alleged herein.

505. At all times relevant to this Complaint, each Manufacturer-PBM Enterprise knew the above-described representations to be false.

506. At all times relevant to this Complaint, each Manufacturer-PBM Enterprise intentionally made these representations for the purpose of inducing Plaintiff into paying artificially inflated prices for diabetes medications.

507. Plaintiff relied on the material misrepresentations and omissions made by each Manufacturer-PBM Enterprise in paying prices for the at-issue diabetes medications based upon the false prices generated by Insulin Pricing Scheme.

508. Additionally, each PBM-Manufacturer Enterprise relied on the list prices negotiated and published by the other PBM-Manufacturer enterprises in setting their own list prices and determining the value of the kickbacks paid to the PBMs. Plaintiff were injured by the inflated prices that arose as a result.

509. PBM Defendants convinced Plaintiff to pay prices for the at-issue drugs based on the false list price by utilizing the misrepresentations listed above to convince Plaintiff that they

had secured lower prices when, in fact, they did the opposite, all while concealing the Insulin Pricing Scheme.

510. Without these misrepresentations and each RICO Defendant's failure to disclose the Insulin Pricing Scheme, each Manufacturer-PBM Enterprise could not have achieved its common purpose, as Plaintiff would not have been willing to pay these false list prices.

D. Defendants' Use of the U.S. Mails and Interstate Wire Facilities

511. Each of the Manufacturer-PBM Enterprises engaged in and affected interstate commerce because each engaged in the following activities across state boundaries: the sale, purchase and/or administration of diabetes medications; the setting and publishing of the prices of these drugs; and/or the transmission of pricing information of diabetes medications; and/or the transmission and/or receipt of sales and marketing literature; and/or the transmission of diabetes medications through mail-order and retail pharmacies; and/or the transmission and/or receipt of invoices, statements, and payments related to the use or administration of diabetes medications; and/or the negotiations and transmissions of contracts related to the pricing of and payment for diabetes medications.

512. Each Manufacturer-PBM Enterprise participated in the administration of diabetes medications to millions of individuals located in all 50 states, including in this District.

513. Each Manufacturer Defendant's and each PBM Defendant's illegal conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information and products and funds through the U.S. mails and interstate wire facilities.

514. The nature and pervasiveness of the Insulin Pricing Scheme, which included each Manufacturer Defendant's and each PBM Defendant's corporate headquarters operations,

necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities with each other and with pharmacies, physicians, payors, and diabetics throughout the United States.

515. Each Manufacturer-PBM Enterprise's use of the U.S. mails and interstate wire facilities to perpetrate the Insulin Pricing Scheme involved thousands of communications including:

a. marketing materials about the published prices for diabetes medications, which each Manufacturer Defendant sent to each PBM Defendant across the country, in Greene County, and throughout Tennessee;

b. written and oral representations of the false list prices of diabetes medications that each Manufacturer Defendant and each PBM Defendant made at least annually and, in many cases, several times during a single year to the public;

c. thousands of written and oral communications discussing, negotiating, and confirming the placement of each Manufacturer Defendant's diabetes medications on each PBM Defendant's formularies;

d. written and oral representations made by each Manufacturer Defendant regarding information or incentives paid back to each PBM Defendant for each diabetes medications sold and/or to conceal these incentives or the Insulin Pricing Scheme;

e. written communications made by each Manufacturer Defendant, including checks, relating to Manufacturer Payments paid to each PBM Defendant to persuade them to advocate the at-issue diabetes medications;

f. written and oral communications with U.S. government agencies that misrepresented what the published prices were or that were intended to deter investigations into the

true nature of the published prices or to forestall changes to reimbursement based on something other than published prices;

g. written and oral communications with payors, including Plaintiff, regarding the price of diabetes medications;

h. written and oral communications to Plaintiff, including marketing and solicitation material sent by each PBM Defendant regarding the existence, amount, or purpose of payments made by each Manufacturer Defendant to each PBM Defendant for the diabetes medications described herein and the purpose of each PBM Defendants formularies;

i. transmission of published prices to third parties and payors, including Plaintiff; and

j. receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities-the wrongful proceeds of the Insulin Pricing Scheme.

516. Although Plaintiff plead the dates of certain communications in allegations incorporated into this Count, it cannot allege the precise dates of others without access to books and records within each RICO Defendant's exclusive custody and control. Indeed, an essential part of the successful operation of the Insulin Pricing Scheme depended upon secrecy, and each Manufacturer Defendant and PBM Defendant took deliberate steps to conceal its wrongdoing.

E. Conduct of the Manufacturer-PBM Enterprises' Affairs

517. Each Manufacturer Defendant and PBM Defendant participates in the operation and management of Manufacturer-PBM Enterprises with which it is associated and, in violation of Section 1962(c) of RICO, and conducts or participates in the conduct of the affairs of those association-in-fact RICO enterprises, directly or indirectly. Such participation is carried out in the following ways:

a. Each Manufacturer Defendant directly controls the secret Manufacturer Payments it provides to each PBM Defendant for its diabetes medications.

b. The PBM Defendants directly manage and control their respective drug formularies and the placement of the at-issue diabetes medications on those formularies.

c. The PBM Defendants intentionally select higher-priced diabetes medications for formulary placement and exclude lower priced ones in order to generate larger profits and they coordinate with the Manufacturer Defendants to increase the availability and use of higher-priced medications because they are more profitable for both groups of Defendants.

d. Each Manufacturer Defendant directly controls the publication of the false list prices generated by the Insulin Pricing Scheme.

e. Each Manufacturer Defendant directly controls the creation and distribution of marketing, sales and other materials used to inform each PBM Defendant of the profit potential from its diabetes medications.

f. Each PBM Defendant directly controls the creation and distribution of marketing, sales and other materials used to inform payors and the public of the benefits and cost-saving potential of each PBM Defendant's formularies and negotiations with the Manufacturers.

g. Each PBM Defendant directs and controls each enterprise's direct relationships with payors such as Plaintiff by negotiating the terms of and executing the contracts that govern those relationships.

h. Each PBM Defendant directs and controls each enterprise's Insulin Pricing Scheme by hiding, obfuscating, and laundering Manufacturer Payments through their affiliated

entities in order to retain a large and undisclosed proportion of the Manufacturer Payments to the detriment of payors, including Plaintiff.

i. Each PBM Defendant distributes through the U.S. mail and interstate wire facilities, promotional and other materials that claim the Manufacturer Payments paid from each Manufacturer Defendant to each PBM Defendant save Plaintiff and other payors money on the at-issue drugs.

j. Each Manufacturer Defendant represented to Plaintiff-by publishing and promoting false list prices without stating that these published prices differed substantially from the prices realized by each Manufacturer Defendant and each PBM Defendant-that the published prices of diabetes medications reflected or approximated the actual price realized by Defendants and resulted from transparent and competitive, fair market forces.

F. Defendants' Pattern of Racketeering Activity

518. Each Manufacturer Defendant and each PBM Defendant have conducted and participated in the affairs of their respective Manufacturer-PBM Enterprises through a pattern of racketeering activity, including acts that are unlawful under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud.

519. Each Manufacturer Defendant's and each PBM Defendant's pattern of racketeering involved thousands, if not hundreds of thousands of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of the Insulin Pricing Scheme. Each of these mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Collectively, these violations constitute a "pattern of racketeering activity," within the

meaning of 18 U.S.C. § 1961 (5), in which each Manufacturer Defendant and each PBM Defendant intended to defraud Plaintiff.

520. By intentionally and falsely inflating the list prices, by misrepresenting the purpose behind both the Manufacturer Payments made from each Manufacturer Defendant to each PBM Defendant and each PBM Defendant's formulary construction, and by subsequently failing to disclose such practices to Plaintiff, each Manufacturer Defendant and each PBM Defendant engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

521. Each Manufacturer Defendant's and each PBM Defendant's racketeering activities amounted to a common course of conduct, with similar patterns and purposes, intended to deceive Plaintiff.

522. Each separate use of the U.S. mails and/or interstate wire facilities employed by each Manufacturer Defendant and each PBM Defendant was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiff.

523. Each Manufacturer Defendant and each PBM Defendant engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the respective Manufacturer-PBM Enterprises with which each of them is and was associated in fact.

G. The RICO Defendants' Motive

524. Each Manufacturer Defendant's and each PBM Defendant's motive in creating and operating the Insulin Pricing Scheme and conducting the affairs of the Manufacturer-PBM Enterprises described herein was to control the market for diabetes medications and falsely obtain sales of and profits from diabetes medications.

525. The Insulin Pricing Scheme was designed to, and did, encourage others, including payors like Plaintiff, to advocate the use of each Manufacturer Defendant's products and to pay for those diabetes medications based on a falsely inflated price. Each Manufacturer Defendant used the Insulin Pricing Scheme to obtain formulary placement to sell more of its drugs without having to cut into its profits. Each PBM Defendant used the Insulin Pricing Scheme to falsely inflate the price payors like Plaintiff paid for diabetes medications in order to profit off the Insulin Pricing Scheme, as discussed above.

H. The Manufacturer-PBM Enterprises' Insulin Pricing Scheme Injured Plaintiff

526. Each Manufacturer-PBM Enterprise's violations of federal law and pattern of racketeering activity have directly and proximately caused Plaintiff to be injured in their business or property.

527. The prices Plaintiff pay for the at-issue drugs are tied directly to the false list prices generated by the Insulin Pricing Scheme.

528. No other intermediary in the supply chain has control over or is responsible for the list prices on which nearly all Plaintiff' payments are based other than the Manufacturer-PBM Defendant Enterprises.

529. Defendants collectively set the prices that Plaintiff paid for the at-issue diabetes medications.

530. During the relevant period, Express Scripts, CVS Caremark, and OptumRx provided PBM services to Plaintiff and benefited therefrom.

531. During the relevant period, Plaintiff paid Express Scripts, CVS Caremark, and OptumRx for the at issue drugs.

532. Each Manufacturer-PBM Enterprise controlled and participated in the Insulin Pricing Scheme that was directly responsible for the false list prices upon which the price Plaintiff paid was based.

533. Thus, Plaintiff was damaged by reason of the Insulin Pricing Scheme. But for the misrepresentations and false prices created by the Insulin Pricing Scheme that each Manufacturer-PBM Enterprise employed, Plaintiff would have paid less for diabetes medications.

534. While Defendants' scheme injured an enormous number of payors and plan members, Plaintiff's damages are separate and distinct from those of any other victim that was harmed by the Manufacturer-PBM Defendant Enterprises' Insulin Pricing Scheme.

535. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(c) of RICO, Defendants are jointly and severally liable to Plaintiff for three times the damages that were sustained, plus the costs of bringing this action, including reasonable attorneys' fees.

536. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(a) of RICO, Plaintiff seeks injunctive relief against each Manufacturer Defendant and each PBM Defendant for their fraudulent reporting of their prices and their continuing acts to affirmatively misrepresent and/ or conceal and suppress material facts concerning their false and inflated prices for diabetes medications, plus the costs of bringing this suit, including reasonable attorneys' fees.

537. Absent an injunction the effects of this fraudulent, unfair, and unconscionable conduct will continue. Plaintiff continues to purchase the at-issue diabetes medications. Plaintiff will continue to pay based on the Defendants' false list prices. This continuing fraudulent, unfair, and unconscionable conduct is a serious matter that calls for injunctive relief as a remedy. Plaintiff

seeks injunctive relief, including an injunction against each Manufacturer and each PBM Defendant, to prevent them from affirmatively misrepresenting and/or concealing and suppressing material facts concerning their conduct in furtherance of the Insulin Pricing Scheme.

Second Cause of Action (Count II)
Violations of RICO, 18 U.S.C. § 1962(d)
By Conspiring to Violate 18 U.S.C. § 1962(c)
(against all Defendants)

538. Plaintiff re-alleges and incorporates herein by reference the allegations set forth in the preceding paragraphs.

539. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

540. Defendants have violated § 1962(d) by agreeing and conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in the Insulin Pricing Scheme.

541. As set forth in detail above, Defendants each knowingly agreed to facilitate the Insulin Pricing Scheme and each has engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy. Specifically, Defendants agreed to and did inflate the prices of the at-issue drugs in lockstep to achieve an unlawful purpose; Defendants agreed to and did make false or misleading statements or material omissions regarding the reasons for these price increases, the purpose of the Manufacturer Payments exchanged between Defendants and the PBMs' formulary construction; and PBMs agreed to and did, in concert, request and receive larger Manufacturer Payments and higher prices in exchange for formulary placement.

542. The nature of the above-described Defendant co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that

they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

543. Defendants have engaged and continue to engage in the commission of overt acts, including the following unlawful racketeering predicate acts:

a. Multiple instances of mail fraud in violations of 18 U.S.C. § 1341;

b. Multiple instances of wire fraud in violations of 18 U.S.C. § 1343; and

c. Multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

544. Defendants' conspiracy to violate the above federal laws and the effects thereof detailed above are continuing and will continue. Plaintiff has been injured in its property by reason of these violations: Plaintiff has paid more for the at-issue drugs than it would have but for Defendants' conspiracy to violate 18 U.S.C. § 1962(c).

545. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are jointly and severally liable to Plaintiff for three times the damages this District has sustained, plus the cost of this suit, including reasonable attorneys' fees.

Third Cause of Action (Count III)
Unlawful Restraint of Trade
Tenn. Code Ann. §§ 47-25-101, *et seq*.
(against all Defendants)

546. Plaintiff Greene County re-alleges and incorporates herein by reference each of the allegations from the preceding paragraphs.

547. As detailed in the foregoing paragraphs, Defendants entered into, established, and maintained a continuing contract, agreement, arrangement, or combination in unreasonable restraint of trade.

548. The purpose and effect of the arrangement was to effect the Insulin Pricing Scheme.

549. The contract, agreement, arrangement, or combination had a direct, substantial, and reasonably foreseeable effect upon commerce within the United States and within Tennessee by: (a) increasing prices paid by Plaintiff for the at-issue diabetes medications; (b) depriving Plaintiff of savings that they would otherwise have received in the absence of the conspiracy; and (c) depriving Plaintiff of free, open, and unrestricted competition in the purchase of the at-issue drugs sold by Defendants.

550. As a result of Defendants' unlawful conduct, Plaintiff has been injured by paying inflated prices for the at-issue diabetes medications.

551. By engaging in the conduct described above, Defendants formed a contract, agreement, arrangement, or combination in restraint of trade in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*

Fourth Cause of Action (Count IV)
Violation of Tennessee Consumer Protection Act
Tenn. Code Ann. §§ 47-18-101, *et seq*.
(against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx)

552. Plaintiff Greene County re-alleges and incorporates herein by reference each of the allegations from the preceding paragraphs.

553. The Tennessee Consumer Protection Act of 1977 makes unlawful "[u]nfair or deceptive acts or practices affecting the conduct of any trade or commerce[.]."[96]

554. Plaintiff is a "person" within the meaning of Tenn. Code Ann. § 47-18-103(18).

555. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx are each a "person" within the meaning of Tenn. Code Ann. § 47-18-103(18).

[96] Tenn. Code Ann. § 47-18-104(a).

556. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark's conduct, collectively and as individuals, as described in this Complaint, constitutes deceptive acts in violation of the Tennessee Consumer Protection Act.

557. Because these Defendants' willful and knowing conduct caused injury to Plaintiff, Plaintiff seeks to recover actual damages; discretionary treble damages; punitive damages; reasonable attorneys' fees and costs; an order enjoining Defendants' unlawful conduct; and any other just and proper relief available under.

558. By engaging in the Insulin Pricing Scheme, as described herein, Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx have committed acts of unfair and deceptive trade practices in the conduct of trade or commerce within Tennessee and Greene County causing harm to Plaintiff as a reimbursor for, and purchaser and payor of, the at-issue drugs.

559. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx have engaged in the following materially misleading conduct, which constitutes deceptive trade practice in violations of the Tennessee Consumer Protection Act:

- Making false and misleading misrepresentations of fact that the prices for the at-issue diabetes medications were legal, competitive, and fair market value prices. In particular:
    - A characteristic of every commodity in Tennessee's economy is its price, which is represented by every seller to every buyer that the product being sold is being sold at a legal, competitive, and fair market value.
    - At no point did these Defendants reveal that the prices associated with the lifesaving diabetic treatments at issue herein were not legal, competitive, or at fair market value.
    - At no point did these Defendants disclose that the prices associated with the at-issue drugs were generated by the Insulin Pricing Scheme.

- At least once per year for each year during the relevant period, these Defendants reported and published false prices for each at-issue drug and in doing so represented that the reported prices were the actual, legal and fair prices for these drugs and resulted from competitive market forces.

- In addition, by granting the at-issue drugs preferred formulary position—formulary positions that the PBMs represent are reserved for reasonably priced drugs and that are meant to promote the health of diabetics—the PBM Defendants knowingly and purposefully utilized the false prices that were generated by the Insulin Pricing Scheme.

- By granting the at-issue diabetes medications preferred formulary positions, the PBM Defendants ensured that prices generated by the Insulin Pricing Scheme would harm Plaintiff.

- The PBM Defendants also misrepresented their formularies promoted the cost-savings to Plaintiff.

- Defendants' representations are false, and Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark knew they were false. Defendants knew that the prices they reported and utilized are artificially inflated for the purpose of maximizing profits through the Insulin Pricing Scheme.

- These Defendants also knew that the PBMs' formulary construction fueled the precipitous price increases that damaged Plaintiff's financial well-being.

- Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark affirmatively withheld this truth from Plaintiff Greene County, even though these Defendants knew that the Plaintiff's intention was to pay the lowest possible price for diabetes medications and expectation was to pay a legal, competitive price that resulted from transparent market forces.

- Making false and misleading misrepresentations of fact related to the Manufacturer Payments and the negotiations that occurred between the PBM and Manufacturer Defendants.

- The PBM Defendants knowingly made false and misleading statements concerning the reasons for, existence of, and amount of price reductions by misrepresenting that the Manufacturer Payments lower the overall price of diabetes medications and promote the health of diabetics.

- These representations were false, and Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, and CVS Caremark knew they were false. The PBM Defendants knew that the Manufacturer Payments were not reducing the overall price of diabetes medications but rather are an integral part of the Insulin Pricing Scheme and are responsible for the inflated prices.

560. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx continue to make these misrepresentations and publish prices generated by the Insulin Pricing scheme, and Plaintiff continues to purchase diabetes medications at inflated prices.

561. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx acted knowingly and in a willful, wanton or reckless disregard for the safety of others in committing the violation of the Tennessee Consumer Protection Act described herein.

562. Each at-issue purchase Plaintiff made for diabetes medications at the prices generated by the Insulin Pricing Scheme constitutes a separate violation of the Tennessee Consumer Protection Act.

563. The acts and practices alleged herein are ongoing, repeated, and affect the public interest.

564. The acts and practices alleged herein substantially impact the community of diabetics, their families, healthcare providers, and the public, and have caused substantial actual harm, including to Plaintiff and its beneficiaries.

565. These Defendants' acts and practices in violation of the Tennessee Consumer Protection Act caused Plaintiff to suffer injuries alleged herein, including but not limited to paying excessive and inflated prices for diabetes medications as described herein.

566. As a direct and proximate result of these Defendants' conduct in committing the above and foregoing violations of the Tennessee Consumer Protection Act, these Defendants are directly and jointly and severally liable to Plaintiff for all restitution, damages, punitive damages, treble damages, penalties and disgorgement for which recovery is sought herein, including but not limited to the Plaintiff paying excessive and inflated prices for diabetes medications described herein every time it paid for an at-issue drug.

567. Additionally, Plaintiff did not receive the benefit of its bargain, or otherwise paid a price premium, for the at-issue diabetes medications because it paid an artificially inflated price due to these Defendants' illegal practices.

Fifth Cause of Action (Count V)
Breach of Contract
(against Defendants Express Scripts, CVS Caremark, and OptumRx)

568. Plaintiff Greene County re-alleges and incorporates herein by reference each of the allegations from the preceding paragraphs.

569. In Tennessee, all contracts—including those between the PBM Defendants and Plaintiff—imply a covenant of good faith and fair dealing in the course of performance (the "Covenant").[97]

570. The Covenant protects "the parties' reasonable expectations as well as their right to receive the benefits of their agreement"[98] and is breached when "a party to the contract exercises discretion authorized in a contract in an unreasonable way."[99]

571. By engaging in the conduct alleged in this Complaint, specifically by arranging with Insulin Manufacturers to hide portions of their rebates by, *inter alia*, relabeling a portion of the rebates as "administrative fees" such that they do not have to be "passed through" to Plaintiff, the PBM Defendants deprived Plaintiff of its rights to receive the benefits of their agreement.

572. PBM Defendants made such arrangements willfully, with the dishonest purpose of enriching themselves at the expense of payors such as Plaintiff. Furthermore, they took efforts to

[97] *See, e.g.*, *Wallace v. Nat'l Bank of Commerce*, 938 S.W.2d 684, 686 (Tenn. 1996).

[98] *Dick Broad. Co. v. Oak Ridge FM, Inc.*, 395 S.W.3d 653, 666 (Tenn. 2013).

[99] *Universal Props. v. Regions Bank*, No. 3:11-cv-538, 2012 U.S. Dist. LEXIS 135256, at *23 (E.D. Tenn. Sep. 21, 2012)).

conceal the terms of these arrangements so that payors such as Plaintiff could not discover that they were not receiving the fruits of their contract.

573. As a direct and proximate result of PBM Defendants' breach of the covenant of good faith and fair dealing, Plaintiff did not receive the benefit of its bargain and paid a price-premium for the at-issue diabetes medications because it paid an artificially inflated price due to these Defendants' illegal practices.

Sixth Cause of Action (Count VI)
Unjust Enrichment
(against Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx)

574. Plaintiff Greene County re-alleges and incorporates herein by reference each of the allegations from the preceding paragraphs.

575. This cause of action is alleged in the alternative to any claim Plaintiff may have for legal relief.

576. Plaintiff conferred a benefit upon Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx. These Defendants deceived Plaintiff Greene County and have received a financial windfall from the Insulin Pricing Scheme at Plaintiff's expense.

577. These Defendants wrongfully secured and retained unjust benefits from Plaintiff in the form of amounts paid for diabetes medications and fees and payments collected based on the prices generated by the Insulin Pricing Scheme. They did not adequately compensate Plaintiff therefor.

578. Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx were aware of the benefit, voluntarily accepted it, and retained and appreciated the benefit, to which it was not entitled, at Plaintiff's expense.

579. It is inequitable and unfair for these Defendants to retain these benefits.

580. The benefit these Defendants have wrongfully retained is in an amount not less than the difference between the reasonable or fair market value of the at-issue drugs for which Plaintiff paid and the actual value of the at-issue drugs these Defendants delivered.

581. Accordingly, Defendants Eli Lilly, Novo Nordisk, Sanofi, Express Scripts, CVS Caremark, and OptumRx should not be permitted to retain the proceeds from the benefits conferred upon them by Plaintiff, which seeks disgorgement of these Defendants' unjustly acquired profits and other monetary benefits resulting from their unlawful conduct and seeks restitution and/or recission, in an equitable and efficient fashion to be determined by the Court.

582. As a direct and proximate cause of these Defendants' unjust enrichment at the expense of Plaintiff as referenced above, Plaintiff has suffered and continues to suffer ascertainable losses and damages as specified herein in an amount to be determined at trial.

MOTION FOR INJUNCTION

583. Plaintiff Greene County re-alleges and incorporates the preceding paragraphs.

584. By Defendants' violations of the Tennessee Consumer Protection Act, RICO, and common law, Plaintiff has suffered, and will continue to suffer, immediate and irreparable injury, loss, and damage, as discussed herein.

585. The ongoing and threatened injury to Plaintiff and its beneficiaries outweighs the harm that an injunction might cause Defendants.

586. As a direct and proximate result of the conduct of the Defendants in committing the above and foregoing acts, Plaintiff moves the Court for injunctive relief against the Defendants pursuant Tenn. Code Ann. § 47-18-109(b) and 18 U.S.C. § 1964(a), thereby enjoining Defendants from committing future violations of the Tennessee Consumer Protection Act and RICO.

587. Granting an injunction is consistent with the public interest because it will protect the health and economic interests of Plaintiff, as well as the integrity of the Tennessee marketplace.

PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiff Greene County prays for entry of judgment against the Defendants for all the relief requested herein and to which the Plaintiff may otherwise be entitled, specifically, but without limitation, to-wit:

A. That the Court determine that Defendants have violated the Tennessee Consumer Protection Act, have violated RICO, have breached their contract with Defendants, and have been unjustly enriched;

B. Judgment in favor of Plaintiff and against the Defendants for damages in excess of the minimum jurisdictional requirements of this Honorable Court, in a specific amount to be proven at trial;

C. That Plaintiff be granted the following specific relief:

1. In accordance with Tenn. Code Ann. § 47-18-109(b) and 18 U.S.C. § 1964(a), that Defendants, their affiliates, successors, transferees, assignees, and the officers, directors, partners, agents, and employees thereof, and all other persons acting or claiming to act on their behalf or in concert with them, be enjoined and restrained from in any manner continuing, maintaining or renewing the conduct, contract, conspiracy or combination alleged herein in violation of the and RICO, or from entering into any other contract, conspiracy or combination having a similar purpose or effect, and from adopting or following any practice, plan, program or device having a similar purpose or effect;

2. That Plaintiff:

i. be awarded restitution, damages, disgorgement, penalties and/or all other legal and equitable monetary remedies available under the state laws set forth in this Complaint and the general equitable powers of this Court in an amount according to proof;

ii. be awarded punitive damages because Defendants knowingly, willfully, wantonly and intentionally harmed the health, wellbeing and financial interests Plaintiff and its Beneficiaries;

iii. be awarded pre- and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of the initial complaint in this action;

iv. recover its costs of suit, including its reasonable attorney's fees, as provided by law and pursuant to the Tennessee Consumer Protection Act and 18 U.S.C. § 1964(c); and

v. be awarded such other, further and different relief as the case may require and the Court may deem just and proper under the circumstances.

JURY DEMAND

Plaintiff Greene County demands trial by jury on all issues so triable.

Dated: June 10, 2024

/s/ Michael J. Fuller, Jr.

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Counsel for Plaintiff

AUTHORITY TO REPRESENT

RE: City of Greeneville, Tennessee School Board, civil suit against those legally responsible for the wrongful distribution of prescription insulin, or the generics.

The City School Board for the City of Greeneville, Tennessee (hereinafter "CLIENT") hereby retains the law firm MCHUGH FULLER LAW GROUP, PLLC, pursuant to the Tennessee Rules of Professional Conduct, on a contingent fee basis, to pursue ***all*** civil remedies against those in the chain of distribution of Insulin and the price fixing of the product in Greeneville City, Tennessee, including, but not limited to, filing a claim for price fixing, RICO, and any other civil remedies allowed to abate the damages caused thereby. **Michael J. Fuller, Esq.** of the law firm FARRELL AND FULLER LAW GROUP, PLLC, shall serve as LEAD COUNSEL. CLIENT authorizes lead counsel to employ and/or associate additional counsel, with consent of CLIENT, to assist LEAD COUNSEL in the just prosecution of the case. CLIENT consents to the participation of the following firms:

FARRELL AND FULLER
270 MUNOZ RIVERA AVENUE, SUITE 201
SAN JUAN, PR 00918

JESSEE LAW OFFICE
CRYSTAL JESSEE
120 N. Main Ext.
Greeneville, Tennessee

In consideration, CLIENT agrees to pay thirty percent (30%) of the total recovery (gross) in favor of the CLIENT as an attorney fee whether the claim is resolved by compromise, settlement, or trial and verdict (and appeal). The gross recovery shall be calculated on the amount obtained before the deduction of costs and expenses. CLIENT grants Attorneys an interest in a fee based on the gross recovery. If a court awards attorneys' fees, Attorneys shall receive the "greater of" the gross recovery-based contingent fee or the attorneys' fees awarded. **There is no fee if there is no recovery.**

FARRELL AND FULLER LAW GROUP, PLLC and the other law firms, hereinafter referred to as the "Attorneys," agree to advance all necessary litigation expenses necessary to prosecute these claims. All such litigation expenses, including the reasonable internal costs of electronically stored information (ESI) and electronic discovery generally or the direct costs incurred from any outside

contractor for those services, will be deducted from any recovery after the contingent fee is calculated. **There is no reimbursement of litigation expenses if there is no recovery.**

The CLIENT acknowledges this fee is reasonable given the time and labor required, the novelty and difficulty of the questions involved, and the skill requisite to perform the legal service properly, the likelihood this employment will preclude other employment by the Attorneys, the fee customarily charged in the locality for similar legal services, the anticipated (contingent) litigation expenses and the anticipated results obtained, the experience, reputation, and ability of the lawyer or lawyers performing the services and the fact that the fee is contingent upon a successful recovery.

This litigation is intended to address a significant problem in the community. The litigation focuses on the manufacturers, distributors, retailers and pharmacy benefit managers and their role in the price fixing of insulin to drive up the cost for the counties that self-fund their health insurance. There is no easy solution. Many of the facts of the case are locked behind closed doors. The billion-dollar industry denies liability. The litigation will be very expensive and the litigation expenses will be advanced by the Attorneys with reimbursement contingent upon a successful recovery. The outcome is uncertain, as is all civil litigation, with compensation contingent upon a successful recovery. Consequently, there must be a clear understanding between the CLIENT and the Attorneys regarding the definition of a "successful recovery." Based upon the City's request, the City and Counsel will not purse pharmacies in the city that are locally owned and locally managed. Also, the City requests and we agree that any proposed settlement or resolution of the matter, other than by a fully adjudicated contested judgment which has become final, must be approved in writing by the client. The client agrees that they will not enroll in any other litigation concerning the price fixing of insulin, with any other firms, while this lawsuit is pending.

The Attorneys intend to present a damage model designed to abate the price fixing crisis. This damage model may take the form of money damages or equitable remedies (e.g., abatement fund). The purpose of the lawsuit is to seek reimbursement of the costs incurred in the past for the overpricing of insulin, that has led counties to pay substantially more for the product, and health insurance for their citizens. The CLIENT agrees to compensate the Attorneys, contingent upon prevailing, by paying 30% of any settlement/resolution/judgment, in favor of the CLIENT, whether it takes the form of monetary damages or equitable relief. For instance, if the remedy is in the form of monetary damages, CLIENT agrees to pay 30% of the gross amount to Attorneys as compensation and then reimburse the reasonable litigation expenses. If the remedy is in the form of equitable relief (e.g., abatement fund), CLIENT agrees that the first 30% of the relief shall be paid to Attorneys as compensation for their legal services and reasonable litigation expenses. To be clear, Attorneys shall not be paid nor receive reimbursement from public funds. However, any judgment arising from successful prosecution of the case, or any consideration arising from a settlement of the matter, whether monetary or equitable, shall not be considered public funds for purposes of calculating the contingent fee. Under no circumstances shall the CLIENT be obligated to pay any Attorneys fee or any litigation expenses except from moneys expended by defendant(s) pursuant to the resolution of the CLIENT's claims.

The division of fees, expenses and labor between the Attorneys will be decided by private agreement between the law firms and subject to approval by the CLIENT. Any division of fees will be governed by the Tennessee Rules of Professional Conduct including: (1) the division of fees is in proportion to the services performed by each lawyer or each lawyer assumes joint responsibility for

the representation; (2) the CLIENT agrees to the arrangement, and the agreement is confirmed in writing; and (3) the total fee is reasonable.

LEAD COUNSEL shall appoint a contact person to keep the CLIENT reasonably informed about the status of the matter in a manner deemed appropriate by the CLIENT. The CLIENT at all times shall retain the authority to decide the disposition of the case and personally oversee and maintain absolute control of the litigation. For your city, the contact person will be Crystal Jessee, from the Jessee Law Firm.

Upon conclusion of this matter, LEAD COUNSEL shall provide the CLIENT with a written statement stating the outcome of the matter and, if there is a recovery, showing the remittance to the client and the method of its determination. The closing statement shall specify the manner in which the compensation was determined under the agreement, any costs and expenses deducted by the lawyer from the judgment or settlement involved, and, if applicable, the actual division of the lawyers' fees with a lawyer not in the same firm, as required in Rule 1.5 (e) of the Tennessee Rules of Professional Conduct. The closing statement shall be signed by the CLIENT and each attorney among whom the fee is being divided.

Nothing in this Agreement and nothing in the Attorneys' statement to the CLIENT may be construed as a promise or guarantee about the outcome of this matter. The Attorneys make no such promises or guarantees. Attorneys' comments about the outcome of this matter are expressions of opinion only and the Attorneys make no guarantee as to the outcome of any litigation, settlement or trial proceedings.

SIGNED, this _____day of _____, 2024.

CITY of GREENEVILLE, TENNESSEE
School Board

Approve by: _____
Steve Starnes

Accepted By:_____
Michael J. Fuller, Esq.

Lead Counsel: FARRELL AND FULLER
270 MUNOZ RIVERA AVENUE, SUITE 201
SAN JUAN, PR 00918

Local Counsel:

CRYSTAL JESSEE
JESSEE LAW OFFICE
120 NORTH MAIN EXT.
GREENEVILLE, TN 37745

Comparison of Competing Firms to Represent GCS in Insulin Litigation

Primary Litigant	Location of Primary Litigant
Farrell & Fuller Law	San Juan, PR
Frantz Law Group	San Diego, CA
Primary Litigant	**Previous Relationshp with Primary Litigant**
Farrell & Fuller Law	None
Frantz Law Group	Yes, JUUL Lawsuit and Social Media Lawsuit
Primary Litigant	**Local Attorney/Point of Contact**
Farrell & Fuller Law	Crystal Jessee
Frantz Law Group	Chris McCarty

Primary Litigant	Previous Relationship with Local Attorney
Farrell & Fuller Law	None
Frantz Law Group	Yes, Board Attorney
Primary Litigant	**Fee Percentage**
Farrell & Fuller Law	30%
Frantz Law Group	30%
Primary Litigant	**Seeking Cap on the Price of Insulin After Suit**
Farrell & Fuller Law	No
Frantz Law Group	Yes, $35

Primary Litigant	Website
Farrell & Fuller Law	https://farrellfuller.com/
Frantz Law Group	https://www.frantzlawgroup.com/

Greeneville City Schools Door Maintenance Bid Document

ADVERTISEMENT FOR BIDS

Greeneville City Schools is seeking bids for preventative maintenance on interior doors and associated hardware.
Sealed bids will be received by Mr. Phillip Graham, Operations Supervisor, Greeneville City Schools Plant Operations Building, 312 Floral Street, Greeneville, Tennessee, 37743 until 2:00 p.m. on Tuesday, September 10th, 2024.
Prospective bidders may obtain bidding documents by emailing Mr. Phillip Graham at grahamp@gcschools.net or by calling 423-787-8003. Greeneville City Schools reserves the right to reject any or all bids and to determine which bid is in the best interest of the school system.
END OF ADVERTISEMENT FOR BIDS

BIDS

Bids shall be submitted on the original bid form and shall be signed by an authorized agent of the company submitting the bid.

The Bidder's name must be placed on the sealed envelope containing the executed Bid Form; otherwise, the Bid will not be considered. The envelope cover shall be plainly marked "Sealed Bid for GCS Commercial Door Repairs" and delivered to:

Mr. Phillip Graham
Operations Supervisor
Greeneville City Schools
312 Floral St Greeneville TN 37743

INFORMATION PROVIDED

Included in this document you will find:

1. Scope of Work and General Information.
2. Bid Form.
3. Information Sheet.

IMPORTANT DATES

Bid Opening on Tuesday, September 10, 2024, at 2:00 PM EST at 312 Floral St Greeneville TN 37743.

Bidder Initials CLS/AKS

SCOPE OF WORK

Greeneville City Schools will be accepting bids from qualified contractors with a minimum of 5 years of experience installing and repairing commercial doors and hardware including bathroom partitions; to provide management oversight and furnish all the necessary labor, tools, and equipment to service doors and hardware. Each bidding contractor shall include a list of commercial facilities where they have worked on commercial doors and hardware including the phone numbers of the contact of each location. The contractor shall be able to respond onsite to emergency calls within 1 hour.

INSTRUCTION TO BIDDERS

All bidders shall quote in conformance with exact conditions and specifications outlined in this document. Voluntary alternates will not be accepted.

INSURANCE

All bidding parties must include proof of workers compensation, one million dollar liability insurance policy listing Greeneville City Schools as additional insured, properly licensed and bonded in order to be considered.

EMPLOYEE SCREENING

Employee Screening: Comply with Owner's requirements regarding drug and background screening of Contractor personnel working on the Project site.

1. Maintain a list of approved screened personnel with the Owner's Representative.
2. Provide background checks on all personnel as administered through the Tennessee Bureau of Investigation's Tennessee Applicant Processing Services (TAPS).

BID FORM

Completely fill in all the attached bid forms when submitting bid. Bid may NOT be split between bidders. This entire Bid packet must be submitted with the bid. Each page shall be initialed by the bidder.

SUBCONTRACTING

All aspects of this work shall be performed by the bidding company. No part of this work shall be subcontracted to another entity.

Bidder Initials cls/aks

CLEAN UP

The contractor shall remove all scraps, packaging, and rubbish caused by their work and leave the work areas in a clean and neat condition.

WORK TIMES

Greeneville City Schools' foremost priority behind the safety of our students is education. Door work cannot disrupt normal class times. All work shall be completed during the hours specified for each location. Some locations will require work after 3:00 pm. If the contractor chooses to work on weekends this must be approved beforehand by Greeneville City Schools.

DOORS AND WINDOWS

Safety is paramount at Greeneville City Schools. At no time shall any exterior door or window be propped open.

DRESS AND DECORUM

Greeneville City Schools strives to provide a good environment for students and employees to learn and work in. Clothing with foul language, objectionable slogans, or advertisements for alcohol, tobacco, or other substances not appropriate for school age children will not be allowed. Per State law, tobacco products or e-cigarettes cannot be used while on school grounds unless they are being used in a vehicle.

DAMAGE TO THE BUILDING AND/OR CONTENTS

The successful bidder shall be responsible for any damage to the building and/or contents by their employees while on site.

Bidder Initials cls/aks

Greeneville City Schools Bid Form

Contractor or Company Name: CMLMC -

BID

Straight Hourly Rate per man $60.00 **per hour**

Hourly rate emergency calls per man $60.00 **per hour**

This hourly rate effective through June 2027.

Carolyn L. Sutton / Gabry K Sutton Owners 9/9/2024

Signature of Authorized Representative | Title | Date

Bidder Initials CLS/aks

INFORMATION SHEET

Cleaning Contractor:

Company Name	CMLMC
Street Address	2674 Carpenters Chapel Rd
City, State, Zip	Maryville, TN 37818
Contact Name	Asberry K. Sutton
Phone Number	770-548-6625
Email	cmlmc2018@gmail.com
Years in Business	5 1/2 yrs

Provide references for projects of similar size and scope:

Contact Name	Monty Humphreys — Humphrey's & Associates
Address	13 W Kent Street Suite 202 Chattanooga, TN 37405
Phone Number	(423) 825-4611
Contact Name	Rusty Parks — Parks & Sons Custom Woodworking
Address	Suite A 1727 Amherst Rd. Knoxville, TN 37909
Phone Number	(865) 765-2710
Contact Name	Raz Rasbury — R G & Associates
Address	1861 Polk St Chattanooga, TN
Phone Number	(423) 756-9365

Bidder Initials cls/aks

Bid Submission Check List

Please make sure you have completed the following:

- ✓ Included insurance certificate.
- ✓ Initialed each page of the bid packet including any addenda if applicable.
- ✓ Clearly marked the envelope "Sealed Bid for GCS Commercial Door Repairs".
- ✓ Sealed the envelope.

Bidder Initials cls / aks

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 09/09/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Kimberly Stevens	
Stevens Insurance Associates, LLC 7000 Lee Highway Suite 900 Chattanooga TN 37421-6735	PHONE (A/C, No, Ext): (423) 894-8821	FAX (A/C, No): (423) 894-3534
	E-MAIL ADDRESS: kstevens@truststevens.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A: Selective Insurance	
	INSURER B: Markel	
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

INSURED
CAROLYN SUTTON DBA CMLMC
2674 CARPENTERS CHAPEL RD
MOSHEIM TN 37818-2966

COVERAGES **CERTIFICATE NUMBER:** 24/25 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [ ] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			S 2648112	07/16/2024	07/16/2025	EACH OCCURRENCE	$ 1,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 500,000
							MED EXP (Any one person)	$ 15,000
							PERSONAL & ADV INJURY	$ 1,000,000
							GENERAL AGGREGATE	$ 3,000,000
							PRODUCTS - COMP/OP AGG	$ 3,000,000
								$
	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident)	$
							BODILY INJURY (Per person)	$
							BODILY INJURY (Per accident)	$
							PROPERTY DAMAGE (Per accident)	$
								$
	[ ] UMBRELLA LIAB [ ] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $						EACH OCCURRENCE	$
							AGGREGATE	$
								$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N [Y] If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		WC0223615-03	07/16/2024	07/16/2025	[X] PER STATUTE [ ] OTH-ER	
							E.L. EACH ACCIDENT	$ 100,000
							E.L. DISEASE - EA EMPLOYEE	$ 100,000
							E.L. DISEASE - POLICY LIMIT	$ 500,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Blanket additional insured with regard to general liability when required by contract. Blanket waiver of subrogation with regard to general liability when required by contract.

CERTIFICATE HOLDER

Greeneville City Schools
312 Floral St
Greeneville TN 37743

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Thomas N. Stevens Jr.

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The ACORD name and logo are registered marks of ACORD

Bid Submission Check List

Please make sure you have completed the following:

- ✓ Included insurance certificate.
- ✓ Initialed each page of the bid packet including any addenda if applicable.
- ✓ Clearly marked the envelope "Sealed Bid for GCS Commercial Door Repairs".
- ✓ Sealed the envelope.

Bidder Initials cls / aks

CMLMC
Asberry Sutton

"Sealed Bid for GCS Commercial Door Repairs"



Received	time	Date
Client	7 am	9/10/2024

Greeneville City Schools Door Maintenance Bid Document

ADVERTISEMENT FOR BIDS

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Prospective bidders may obtain bidding documents by emailing Mr. Phillip Graham at grahamp@gcschools.net or by calling 423-787-8003. Greeneville City Schools reserves the right to reject any or all bids and to determine which bid is in the best interest of the school system.
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Operations Supervisor
Greeneville City Schools
312 Floral St Greeneville TN 37743

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2. Bid Form.
3. Information Sheet.

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Bidder Initials _____

SCOPE OF WORK

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INSURANCE

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EMPLOYEE SCREENING

Employee Screening: Comply with Owner's requirements regarding drug and background screening of Contractor personnel working on the Project site.

1. Maintain a list of approved screened personnel with the Owner's Representative.
2. Provide background checks on all personnel as administered through the Tennessee Bureau of Investigation's Tennessee Applicant Processing Services (TAPS).

BID FORM

Completely fill in all the attached bid forms when submitting bid. Bid may NOT be split between bidders. This entire Bid packet must be submitted with the bid. Each page shall be initialed by the bidder.

SUBCONTRACTING

All aspects of this work shall be performed by the bidding company. No part of this work shall be subcontracted to another entity.

Bidder Initials 

CLEAN UP

The contractor shall remove all scraps, packaging, and rubbish caused by their work and leave the work areas in a clean and neat condition.

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DAMAGE TO THE BUILDING AND/OR CONTENTS

The successful bidder shall be responsible for any damage to the building and/or contents by their employees while on site.

Bidder Initials 

Greeneville City Schools Bid Form

Contractor or Company Name: GCE Construction

BID

Straight Hourly Rate per man $ 190.00 **per hour**

Hourly rate emergency calls per man $ 275.00 **per hour**

Signature of Authorized Representative | Owner/President (Title) | 9/4/2024 (Date)

Bidder Initials

INFORMATION SHEET

Cleaning Contractor:

Company Name: GCE Construction

Street Address: P.O, Box 177

City, State, Zip: LaFollette, TN 37766

Contact Name: Emily Gaylor

Phone Number: (423) 201-9836

Email: info@gceco.net

Years in Business: 26

Provide references for projects of similar size and scope:

Contact Name: Jake Rowe

Address: 1403 Tazewell Rd, Tazewell, TN 37879

Phone Number: (423) 851-1720

Contact Name: Riley DeBusk

Address: 1403 Tazewell Rd, Tazewell, TN 37879

Phone Number: (423) 300-1942

Contact Name: Bobby Crawford

Address: 101 S. Main St. Clinton, TN 37716

Phone Number: (865) 457-2519

Bidder Initials EJG

Bid Submission Check List

Please make sure you have completed the following:

- ✓ Included insurance certificate.
- ✓ Initialed each page of the bid packet including any addenda if applicable.
- ✓ Clearly marked the envelope "Sealed Bid for GCS Commercial Door Repairs".
- ✓ Sealed the envelope.

Bidder Initials EH

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 09/04/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	**CONTACT NAME:** Gena Anders
Assured Insurance Consultants LLC	**PHONE (A/C, No, Ext):** (423) 282-3111 **FAX (A/C, No):** (423) 282-3667
127 West Hwy 25-70, Ste A	**E-MAIL ADDRESS:** ganders@myassuredinsurance.com
Dandridge TN 37725	**INSURER(S) AFFORDING COVERAGE** / **NAIC #**
INSURED	**INSURER A :** Acuity 14184
Tim Gaylor Dba GCE Construction	**INSURER B :** Motorists Insurance Group 13331
PO BOX 177	**INSURER C :**
La Follette TN 37766	**INSURER D :**
	INSURER E :
	INSURER F :

COVERAGES **CERTIFICATE NUMBER:** CL2312605634 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [ ] POLICY [X] PRO-JECT [ ] LOC [ ] OTHER:			ZH4167	12/07/2023	12/07/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 250,000 $ 10,000 $ 1,000,000 $ 3,000,000 $ 3,000,000
	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $
A	[X] UMBRELLA LIAB [ ] OCCUR EXCESS LIAB [ ] CLAIMS-MADE DED RETENTION $			ZH4167	12/07/2023	12/07/2024	EACH OCCURRENCE AGGREGATE	$ 2,000,000 $ 2,000,000
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [N] (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		WCS3015273	12/07/2023	12/07/2024	[X] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ 1,000,000 $ 1,000,000 $ 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Greenville City Schools are listed as addtional insured.

CERTIFICATE HOLDER

Greenville City Schools
312 Floral St.
Greenville TN 37743

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Gena Anders

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GCE
CONSTRUCTION
EST. 1998

P.O. Box 177
Lafollette, TN 37766
P: 423-201-9836
www.gceco.net

Sealed Bid for GCS Commercial Door Repairs

FOR:
Mr. Phillip Graham
Operations Supervisor
Greeneville City Schools
312 Floral St, Greeneville, TN 37743

2:00 P.M. EST	**September 10, 2024**
TIME	DATE

BIDDER: GCE CONSTRUCTION

ADDRESS: P.O. BOX 177 LAFOLLETTE, TN 37766

LICENSE NUMBER: 76119

LICENSE CLASSIFICATION: BC

MONETARY LIMIT: $3,000,000.00

EXPIRATION: 3/31/2025

Rec'd by	Time	Date
RC	7:16am	9/9/24

Greeneville City Schools
BID TABULATION FORM

JOB NAME	Door Work, GCS Facilities
BID OPENING TIME	2 p.m. 9-10-2024
TABULATOR	Robin Crabtree

	Bidding Company	Sealed Envelope	License number	Addenda 1 Acknowledged	Addenda 2 Acknowledged	Base bid	Alternate Bid #2	Alternate Bid #3	Grand Total
	CMLMC	✓				$	$	$	$ 60 per hr
						$	$	$	$
	GCE Construction	✓				$	$	$	$ 190 per hr
						$	$	$	$
						$	$	$	$
						$	$	$	$
						$	$	$	$
						$	$	$	$
						$	$	$	$
						$	$	$	$
						$	$	$	$
						$	$	$	$
						$	$	$	$
						$	$	$	$
						$	$	$	$

COMMENTS

AWARD TO: CMLMC

LOWEST BIDDER? YES ***IF NO, JUSTIFICATION IS:

PREPARED BY: Robin Crabtree DATE: 9-10-2024

APPROVED BY: DATE:

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Solicitation Number: RFP #102623

CONTRACT

This Contract is between Sourcewell, 202 12th Street Northeast, P.O. Box 219, Staples, MN 56479 (Sourcewell) and IC Bus, LLC, 2701 Navistar Dr., Lisle, IL 60532 (Supplier).

Sourcewell is a State of Minnesota local government unit and service cooperative created under the laws of the State of Minnesota (Minnesota Statutes Section 123A.21) that offers cooperative procurement solutions to government entities. Participation is open to eligible federal, state/province, and municipal governmental entities, higher education, K-12 education, nonprofit, tribal government, and other public entities located in the United States and Canada. Sourcewell issued a public solicitation for School Buses with Related Accessories, Supplies, Parts, and Services from which Supplier was awarded a contract.

Supplier desires to contract with Sourcewell to provide equipment, products, or services to Sourcewell and the entities that access Sourcewell's cooperative purchasing contracts (Participating Entities).

1. TERM OF CONTRACT

A. EFFECTIVE DATE. This Contract is effective upon the date of the final signature below.

EXPIRATION DATE AND EXTENSION. This Contract expires December 22, 2027, unless it is cancelled sooner pursuant to Article 22. This Contract allows up to three additional one-year extensions upon the request of Sourcewell and written agreement by Supplier. Sourcewell retains the right to consider additional extensions beyond seven years as required under exceptional circumstances.

B. SURVIVAL OF TERMS. Notwithstanding any expiration or termination of this Contract, all payment obligations incurred prior to expiration or termination will survive, as will the following: Articles 11 through 14 survive the expiration or cancellation of this Contract. All other rights will cease upon expiration or termination of this Contract.

2. EQUIPMENT, PRODUCTS, OR SERVICES

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A. EQUIPMENT, PRODUCTS, OR SERVICES. Supplier will provide the Equipment, Products, or Services as stated in its Proposal submitted under the Solicitation Number listed above. Supplier's Equipment, Products, or Services Proposal (Proposal) is attached and incorporated into this Contract.

All Equipment and Products provided under this Contract must be new and the current model. Supplier may offer close-out or refurbished Equipment or Products if they are clearly indicated in Supplier's product and pricing list. Unless agreed to by the Participating Entities in advance, Equipment or Products must be delivered as operational to the Participating Entity's site.

This Contract offers an indefinite quantity of sales, and while substantial volume is anticipated, sales and sales volume are not guaranteed.

B. WARRANTY. Supplier warrants that all Equipment, Products, and Services furnished are free from liens and encumbrances, and are free from defects in design, materials, and workmanship. In addition, Supplier warrants the Equipment, Products, and Services are suitable for and will perform in accordance with the ordinary use for which they are intended. Supplier's dealers and distributors must agree to assist the Participating Entity in reaching a resolution in any dispute over warranty terms with the manufacturer. Any manufacturer's warranty that extends beyond the expiration of the Supplier's warranty will be passed on to the Participating Entity.

C. DEALERS, DISTRIBUTORS, AND/OR RESELLERS. Upon Contract execution and throughout the Contract term, Supplier must provide to Sourcewell a current means to validate or authenticate Supplier's authorized dealers, distributors, or resellers relative to the Equipment, Products, and Services offered under this Contract, which will be incorporated into this Contract by reference. It is the Supplier's responsibility to ensure Sourcewell receives the most current information.

3. PRICING

All Equipment, Products, or Services under this Contract will be priced at or below the price stated in Supplier's Proposal.

When providing pricing quotes to Participating Entities, all pricing quoted must reflect a Participating Entity's total cost of acquisition. This means that the quoted cost is for delivered Equipment, Products, and Services that are operational for their intended purpose, and includes all costs to the Participating Entity's requested delivery location.

Regardless of the payment method chosen by the Participating Entity, the total cost associated with any purchase option of the Equipment, Products, or Services must always be disclosed in the pricing quote to the applicable Participating Entity at the time of purchase.

DocuSign Envelope ID: 0ECD836D-7E4D-46E6-A1C9-4CF6B24936D4

A. SHIPPING AND SHIPPING COSTS. All delivered Equipment and Products must be properly packaged. Damaged Equipment and Products may be rejected. If the damage is not readily apparent at the time of delivery, Supplier must permit the Equipment and Products to be returned within a reasonable time at no cost to Sourcewell or its Participating Entities. Participating Entities reserve the right to inspect the Equipment and Products at a reasonable time after delivery where circumstances or conditions prevent effective inspection of the Equipment and Products at the time of delivery. In the event of the delivery of nonconforming Equipment and Products, the Participating Entity will notify the Supplier as soon as possible and the Supplier will replace nonconforming Equipment and Products with conforming Equipment and Products that are acceptable to the Participating Entity.

Supplier must arrange for and pay for the return shipment on Equipment and Products that arrive in a defective or inoperable condition.

Sourcewell may declare the Supplier in breach of this Contract if the Supplier intentionally delivers substandard or inferior Equipment or Products.

B. SALES TAX. Each Participating Entity is responsible for supplying the Supplier with valid tax-exemption certification(s). When ordering, a Participating Entity must indicate if it is a tax-exempt entity.

C. HOT LIST PRICING. At any time during this Contract, Supplier may offer a specific selection of Equipment, Products, or Services at discounts greater than those listed in the Contract. When Supplier determines it will offer Hot List Pricing, it must be submitted electronically to Sourcewell in a line-item format. Equipment, Products, or Services may be added or removed from the Hot List at any time through a Sourcewell Price and Product Change Form as defined in Article 4 below.

Hot List program and pricing may also be used to discount and liquidate close-out and discontinued Equipment and Products as long as those close-out and discontinued items are clearly identified as such. Current ordering process and administrative fees apply. Hot List Pricing must be published and made available to all Participating Entities.

4. PRODUCT AND PRICING CHANGE REQUESTS

Supplier may request Equipment, Product, or Service changes, additions, or deletions at any time. All requests must be made in writing by submitting a signed Sourcewell Price and Product Change Request Form to the assigned Sourcewell Supplier Development Administrator. This approved form is available from the assigned Sourcewell Supplier Development Administrator. At a minimum, the request must:

- Identify the applicable Sourcewell contract number;

DocuSign Envelope ID: 0ECD836D-7E4D-46E6-A1C9-4CF6B24936D4

- Clearly specify the requested change;
- Provide sufficient detail to justify the requested change;
- Individually list all Equipment, Products, or Services affected by the requested change, along with the requested change (e.g., addition, deletion, price change); and
- Include a complete restatement of pricing documentation in Microsoft Excel with the effective date of the modified pricing, or product addition or deletion. The new pricing restatement must include all Equipment, Products, and Services offered, even for those items where pricing remains unchanged.

A fully executed Sourcewell Price and Product Change Request Form will become an amendment to this Contract and will be incorporated by reference.

5. PARTICIPATION, CONTRACT ACCESS, AND PARTICIPATING ENTITY REQUIREMENTS

A. PARTICIPATION. Sourcewell's cooperative contracts are available and open to public and nonprofit entities across the United States and Canada; such as federal, state/province, municipal, K-12 and higher education, tribal government, and other public entities.

The benefits of this Contract should be available to all Participating Entities that can legally access the Equipment, Products, or Services under this Contract. A Participating Entity's authority to access this Contract is determined through its cooperative purchasing, interlocal, or joint powers laws. Any entity accessing benefits of this Contract will be considered a Service Member of Sourcewell during such time of access. Supplier understands that a Participating Entity's use of this Contract is at the Participating Entity's sole convenience and Participating Entities reserve the right to obtain like Equipment, Products, or Services from any other source.

Supplier is responsible for familiarizing its sales and service forces with Sourcewell contract use eligibility requirements and documentation and will encourage potential participating entities to join Sourcewell. Sourcewell reserves the right to add and remove Participating Entities to its roster during the term of this Contract.

B. PUBLIC FACILITIES. Supplier's employees may be required to perform work at government-owned facilities, including schools. Supplier's employees and agents must conduct themselves in a professional manner while on the premises, and in accordance with Participating Entity policies and procedures, and all applicable laws.

6. PARTICIPATING ENTITY USE AND PURCHASING

A. ORDERS AND PAYMENT. To access the contracted Equipment, Products, or Services under this Contract, a Participating Entity must clearly indicate to Supplier that it intends to access this Contract; however, order flow and procedure will be developed jointly between Sourcewell and Supplier. Typically, a Participating Entity will issue an order directly to Supplier or its authorized

DocuSign Envelope ID: 0ECD836D-7E4D-46E6-A1C9-4CF6B24936D4

subsidiary, distributor, dealer, or reseller. If a Participating Entity issues a purchase order, it may use its own forms, but the purchase order should clearly note the applicable Sourcewell contract number. All Participating Entity orders under this Contract must be issued prior to expiration or cancellation of this Contract; however, Supplier performance, Participating Entity payment obligations, and any applicable warranty periods or other Supplier or Participating Entity obligations may extend beyond the term of this Contract.

Supplier's acceptable forms of payment are included in its attached Proposal. Participating Entities will be solely responsible for payment and Sourcewell will have no liability for any unpaid invoice of any Participating Entity.

B. ADDITIONAL TERMS AND CONDITIONS/PARTICIPATING ADDENDUM. Additional terms and conditions to a purchase order, or other required transaction documentation, may be negotiated between a Participating Entity and Supplier, such as job or industry-specific requirements, legal requirements (e.g., affirmative action or immigration status requirements), or specific local policy requirements. Some Participating Entities may require the use of a Participating Addendum, the terms of which will be negotiated directly between the Participating Entity and the Supplier or its authorized dealers, distributors, or resellers, as applicable. Any negotiated additional terms and conditions must never be less favorable to the Participating Entity than what is contained in this Contract.

C. SPECIALIZED SERVICE REQUIREMENTS. In the event that the Participating Entity requires service or specialized performance requirements not addressed in this Contract (such as e-commerce specifications, specialized delivery requirements, or other specifications and requirements), the Participating Entity and the Supplier may enter into a separate, standalone agreement, apart from this Contract. Sourcewell, including its agents and employees, will not be made a party to a claim for breach of such agreement.

D. TERMINATION OF ORDERS. Participating Entities may terminate an order, in whole or in part, immediately upon notice to Supplier in the event of any of the following events:

1. The Participating Entity fails to receive funding or appropriation from its governing body at levels sufficient to pay for the equipment, products, or services to be purchased; or
2. Federal, state, or provincial laws or regulations prohibit the purchase or change the Participating Entity's requirements.

E. GOVERNING LAW AND VENUE. The governing law and venue for any action related to a Participating Entity's order will be determined by the Participating Entity making the purchase.

7. CUSTOMER SERVICE

DocuSign Envelope ID: 0ECD836D-7E4D-46E6-A1C9-4CF6B24936D4

A. PRIMARY ACCOUNT REPRESENTATIVE. Supplier will assign an Account Representative to Sourcewell for this Contract and must provide prompt notice to Sourcewell if that person is changed. The Account Representative will be responsible for:

- Maintenance and management of this Contract;
- Timely response to all Sourcewell and Participating Entity inquiries; and
- Business reviews to Sourcewell and Participating Entities, if applicable.

B. BUSINESS REVIEWS. Supplier must perform a minimum of one business review with Sourcewell per contract year. The business review will cover sales to Participating Entities, pricing and contract terms, administrative fees, sales data reports, performance issues, supply issues, customer issues, and any other necessary information.

8. REPORT ON CONTRACT SALES ACTIVITY AND ADMINISTRATIVE FEE PAYMENT

A. CONTRACT SALES ACTIVITY REPORT. Each calendar quarter, Supplier must provide a contract sales activity report (Report) to the Sourcewell Supplier Development Administrator assigned to this Contract. Reports are due no later than 45 days after the end of each calendar quarter. A Report must be provided regardless of the number or amount of sales during that quarter (i.e., if there are no sales, Supplier must submit a report indicating no sales were made).

The Report must contain the following fields:

- Participating Entity Name (e.g., City of Staples Highway Department);
- Participating Entity Physical Street Address;
- Participating Entity City;
- Participating Entity State/Province;
- Participating Entity Zip/Postal Code;
- Participating Entity Contact Name;
- Participating Entity Contact Email Address;
- Participating Entity Contact Telephone Number;
- Sourcewell Assigned Entity/Participating Entity Number;
- Item Purchased Description;
- Item Purchased Price;
- Sourcewell Administrative Fee Applied; and
- Date Purchase was invoiced/sale was recognized as revenue by Supplier.

B. ADMINISTRATIVE FEE. In consideration for the support and services provided by Sourcewell, the Supplier will pay an administrative fee to Sourcewell on all Equipment, Products, and Services provided to Participating Entities. The Administrative Fee must be included in, and not added to, the pricing. Supplier may not charge Participating Entities more than the contracted

DocuSign Envelope ID: 0ECD836D-7E4D-46E6-A1C9-4CF6B24936D4

price to offset the Administrative Fee.

The Supplier will submit payment to Sourcewell for the percentage of administrative fee stated in the Proposal multiplied by the total sales of all Equipment, Products, and Services purchased by Participating Entities under this Contract during each calendar quarter. Payments should note the Supplier's name and Sourcewell-assigned contract number in the memo; and must be mailed to the address above "Attn: Accounts Receivable" or remitted electronically to Sourcewell's banking institution per Sourcewell's Finance department instructions. Payments must be received no later than 45 calendar days after the end of each calendar quarter.

Supplier agrees to cooperate with Sourcewell in auditing transactions under this Contract to ensure that the administrative fee is paid on all items purchased under this Contract.

In the event the Supplier is delinquent in any undisputed administrative fees, Sourcewell reserves the right to cancel this Contract and reject any proposal submitted by the Supplier in any subsequent solicitation. In the event this Contract is cancelled by either party prior to the Contract's expiration date, the administrative fee payment will be due no more than 30 days from the cancellation date.

9. AUTHORIZED REPRESENTATIVE

Sourcewell's Authorized Representative is its Chief Procurement Officer.

Supplier's Authorized Representative is the person named in the Supplier's Proposal. If Supplier's Authorized Representative changes at any time during this Contract, Supplier must promptly notify Sourcewell in writing.

10. AUDIT, ASSIGNMENT, AMENDMENTS, WAIVER, AND CONTRACT COMPLETE

A. AUDIT. Pursuant to Minnesota Statutes Section 16C.05, subdivision 5, the books, records, documents, and accounting procedures and practices relevant to this Contract are subject to examination by Sourcewell or the Minnesota State Auditor for a minimum of six years from the end of this Contract. This clause extends to Participating Entities as it relates to business conducted by that Participating Entity under this Contract.

B. ASSIGNMENT. Neither party may assign or otherwise transfer its rights or obligations under this Contract without the prior written consent of the other party and a fully executed assignment agreement. Such consent will not be unreasonably withheld. Any prohibited assignment will be invalid.

C. AMENDMENTS. Any amendment to this Contract must be in writing and will not be effective until it has been duly executed by the parties.

DocuSign Envelope ID: 0ECD836D-7E4D-46E6-A1C9-4CF6B24936D4

D. WAIVER. Failure by either party to take action or assert any right under this Contract will not be deemed a waiver of such right in the event of the continuation or repetition of the circumstances giving rise to such right. Any such waiver must be in writing and signed by the parties.

E. CONTRACT COMPLETE. This Contract represents the complete agreement between the parties. No other understanding regarding this Contract, whether written or oral, may be used to bind either party. For any conflict between the attached Proposal and the terms set out in Articles 1-22 of this Contract, the terms of Articles 1-22 will govern.

F. RELATIONSHIP OF THE PARTIES. The relationship of the parties is one of independent contractors, each free to exercise judgment and discretion with regard to the conduct of their respective businesses. This Contract does not create a partnership, joint venture, or any other relationship such as master-servant, or principal-agent.

11. INDEMNITY AND HOLD HARMLESS

Supplier must indemnify, defend, save, and hold Sourcewell and its Participating Entities, including their agents and employees, harmless from any claims or causes of action, including attorneys' fees incurred by Sourcewell or its Participating Entities, arising out of any act or omission in the performance of this Contract by the Supplier or its agents or employees; this indemnification includes injury or death to person(s) or property alleged to have been caused by some defect in the Equipment, Products, or Services under this Contract to the extent the Equipment, Product, or Service has been used according to its specifications. Sourcewell's responsibility will be governed by the State of Minnesota's Tort Liability Act (Minnesota Statutes Chapter 466) and other applicable law.

12. GOVERNMENT DATA PRACTICES

Supplier and Sourcewell must comply with the Minnesota Government Data Practices Act, Minnesota Statutes Chapter 13, as it applies to all data provided by or provided to Sourcewell under this Contract and as it applies to all data created, collected, received, maintained, or disseminated by the Supplier under this Contract.

13. INTELLECTUAL PROPERTY, PUBLICITY, MARKETING, AND ENDORSEMENT

A. INTELLECTUAL PROPERTY

1. *Grant of License.* During the term of this Contract:

   a. Sourcewell grants to Supplier a royalty-free, worldwide, non-exclusive right and license to use the trademark(s) provided to Supplier by Sourcewell in advertising and promotional materials for the purpose of marketing Sourcewell's relationship with Supplier.

DocuSign Envelope ID: 0ECD836D-7E4D-46E6-A1C9-4CF6B24936D4

b. Supplier grants to Sourcewell a royalty-free, worldwide, non-exclusive right and license to use Supplier's trademarks in advertising and promotional materials for the purpose of marketing Supplier's relationship with Sourcewell.

2. *Limited Right of Sublicense*. The right and license granted herein includes a limited right of each party to grant sublicenses to their respective subsidiaries, distributors, dealers, resellers, marketing representatives, and agents (collectively "Permitted Sublicensees") in advertising and promotional materials for the purpose of marketing the Parties' relationship to Participating Entities. Any sublicense granted will be subject to the terms and conditions of this Article. Each party will be responsible for any breach of this Article by any of their respective sublicensees.

3. *Use; Quality Control.*

a. Neither party may alter the other party's trademarks from the form provided and must comply with removal requests as to specific uses of its trademarks or logos.

b. Each party agrees to use, and to cause its Permitted Sublicensees to use, the other party's trademarks only in good faith and in a dignified manner consistent with such party's use of the trademarks. Upon written notice to the breaching party, the breaching party has 30 days of the date of the written notice to cure the breach or the license will be terminated.

4. *Termination*. Upon the termination of this Contract for any reason, each party, including Permitted Sublicensees, will have 30 days to remove all Trademarks from signage, websites, and the like bearing the other party's name or logo (excepting Sourcewell's pre-printed catalog of suppliers which may be used until the next printing). Supplier must return all marketing and promotional materials, including signage, provided by Sourcewell, or dispose of it according to Sourcewell's written directions.

B. PUBLICITY. Any publicity regarding the subject matter of this Contract must not be released without prior written approval from the Authorized Representatives. Publicity includes notices, informational pamphlets, press releases, research, reports, signs, and similar public notices prepared by or for the Supplier individually or jointly with others, or any subcontractors, with respect to the program, publications, or services provided resulting from this Contract.

C. MARKETING. Any direct advertising, marketing, or offers with Participating Entities must be approved by Sourcewell. Send all approval requests to the Sourcewell Supplier Development Administrator assigned to this Contract.

D. ENDORSEMENT. The Supplier must not claim that Sourcewell endorses its Equipment, Products, or Services.

DocuSign Envelope ID: 0ECD836D-7E4D-46E6-A1C9-4CF6B24936D4

14. GOVERNING LAW, JURISDICTION, AND VENUE

The substantive and procedural laws of the State of Minnesota will govern this Contract. Venue for all legal proceedings arising out of this Contract, or its breach, must be in the appropriate state court in Todd County, Minnesota or federal court in Fergus Falls, Minnesota.

15. FORCE MAJEURE

Neither party to this Contract will be held responsible for delay or default caused by acts of God or other conditions that are beyond that party's reasonable control. A party defaulting under this provision must provide the other party prompt written notice of the default.

16. SEVERABILITY

If any provision of this Contract is found by a court of competent jurisdiction to be illegal, unenforceable, or void then both parties will be relieved from all obligations arising from that provision. If the remainder of this Contract is capable of being performed, it will not be affected by such determination or finding and must be fully performed.

17. PERFORMANCE, DEFAULT, AND REMEDIES

A. PERFORMANCE. During the term of this Contract, the parties will monitor performance and address unresolved contract issues as follows:

1. *Notification.* The parties must promptly notify each other of any known dispute and work in good faith to resolve such dispute within a reasonable period of time. If necessary, Sourcewell and the Supplier will jointly develop a short briefing document that describes the issue(s), relevant impact, and positions of both parties.
2. *Escalation.* If parties are unable to resolve the issue in a timely manner, as specified above, either Sourcewell or Supplier may escalate the resolution of the issue to a higher level of management. The Supplier will have 30 calendar days to cure an outstanding issue.
3. *Performance while Dispute is Pending*. Notwithstanding the existence of a dispute, the Supplier must continue without delay to carry out all of its responsibilities under the Contract that are not affected by the dispute. If the Supplier fails to continue without delay to perform its responsibilities under the Contract, in the accomplishment of all undisputed work, the Supplier will bear any additional costs incurred by Sourcewell and/or its Participating Entities as a result of such failure to proceed.

B. DEFAULT AND REMEDIES. Either of the following constitutes cause to declare this Contract, or any Participating Entity order under this Contract, in default:

1. Nonperformance of contractual requirements, or
2. A material breach of any term or condition of this Contract.

DocuSign Envelope ID: 0ECD836D-7E4D-46E6-A1C9-4CF6B24936D4

The party claiming default must provide written notice of the default, with 30 calendar days to cure the default. Time allowed for cure will not diminish or eliminate any liability for liquidated or other damages. If the default remains after the opportunity for cure, the non-defaulting party may:

- Exercise any remedy provided by law or equity, or
- Terminate the Contract or any portion thereof, including any orders issued against the Contract.

18. INSURANCE

A. REQUIREMENTS. At its own expense, Supplier must maintain insurance policy(ies) in effect at all times during the performance of this Contract with insurance company(ies) licensed or authorized to do business in the State of Minnesota having an "AM BEST" rating of A- or better, with coverage and limits of insurance not less than the following:

1. *Workers' Compensation and Employer's Liability.*
Workers' Compensation: As required by any applicable law or regulation.
Employer's Liability Insurance: must be provided in amounts not less than listed below:
Minimum limits:
$500,000 each accident for bodily injury by accident
$500,000 policy limit for bodily injury by disease
$500,000 each employee for bodily injury by disease

2. *Commercial General Liability Insurance.* Supplier will maintain insurance covering its operations, with coverage on an occurrence basis, and must be subject to terms no less broad than the Insurance Services Office ("ISO") Commercial General Liability Form CG0001 (2001 or newer edition), or equivalent. At a minimum, coverage must include liability arising from premises, operations, bodily injury and property damage, independent contractors, products-completed operations including construction defect, contractual liability, blanket contractual liability, and personal injury and advertising injury. All required limits, terms and conditions of coverage must be maintained during the term of this Contract.
Minimum Limits:
$1,000,000 each occurrence Bodily Injury and Property Damage
$1,000,000 Personal and Advertising Injury
$2,000,000 aggregate for products liability-completed operations
$2,000,000 general aggregate

3. *Commercial Automobile Liability Insurance.* During the term of this Contract, Supplier will maintain insurance covering all owned, hired, and non-owned automobiles in limits of liability not less than indicated below. The coverage must be subject to terms

DocuSign Envelope ID: 0ECD836D-7E4D-46E6-A1C9-4CF6B24936D4

no less broad than ISO Business Auto Coverage Form CA 0001 (2010 edition or newer), or equivalent.

Minimum Limits:
$1,000,000 each accident, combined single limit

4. *Umbrella Insurance*. During the term of this Contract, Supplier will maintain umbrella coverage over Employer's Liability, Commercial General Liability, and Commercial Automobile.

Minimum Limits:
$2,000,000

5. *Professional/Technical, Errors and Omissions, and/or Miscellaneous Professional Liability*. During the term of this Contract, Supplier will maintain coverage for all claims the Supplier may become legally obligated to pay resulting from any actual or alleged negligent act, error, or omission related to Supplier's professional services required under this Contract.

Minimum Limits:
$2,000,000 per claim or event
$2,000,000 – annual aggregate

6. *Network Security and Privacy Liability Insurance*. During the term of this Contract, Supplier will maintain coverage for network security and privacy liability. The coverage may be endorsed on another form of liability coverage or written on a standalone policy. The insurance must cover claims which may arise from failure of Supplier's security resulting in, but not limited to, computer attacks, unauthorized access, disclosure of not public data – including but not limited to, confidential or private information, transmission of a computer virus, or denial of service.

Minimum limits:
$2,000,000 per occurrence
$2,000,000 annual aggregate

Failure of Supplier to maintain the required insurance will constitute a material breach entitling Sourcewell to immediately terminate this Contract for default.

B. CERTIFICATES OF INSURANCE. Prior to commencing under this Contract, Supplier must furnish to Sourcewell a certificate of insurance, as evidence of the insurance required under this Contract. Prior to expiration of the policy(ies), renewal certificates must be mailed to Sourcewell, 202 12th Street Northeast, P.O. Box 219, Staples, MN 56479 or sent to the Sourcewell Supplier Development Administrator assigned to this Contract. The certificates must be signed by a person authorized by the insurer(s) to bind coverage on their behalf.

DocuSign Envelope ID: 0ECD836D-7E4D-46E6-A1C9-4CF6B24936D4

Failure to request certificates of insurance by Sourcewell, or failure of Supplier to provide certificates of insurance, in no way limits or relieves Supplier of its duties and responsibilities in this Contract.

C. ADDITIONAL INSURED ENDORSEMENT AND PRIMARY AND NON-CONTRIBUTORY INSURANCE CLAUSE. Supplier agrees to list Sourcewell and its Participating Entities, including their officers, agents, and employees, as an additional insured under the Supplier's commercial general liability insurance policy with respect to liability arising out of activities, "operations," or "work" performed by or on behalf of Supplier, and products and completed operations of Supplier. The policy provision(s) or endorsement(s) must further provide that coverage is primary and not excess over or contributory with any other valid, applicable, and collectible insurance or self-insurance in force for the additional insureds.

D. WAIVER OF SUBROGATION. Supplier waives and must require (by endorsement or otherwise) all its insurers to waive subrogation rights against Sourcewell and other additional insureds for losses paid under the insurance policies required by this Contract or other insurance applicable to the Supplier or its subcontractors. The waiver must apply to all deductibles and/or self-insured retentions applicable to the required or any other insurance maintained by the Supplier or its subcontractors. Where permitted by law, Supplier must require similar written express waivers of subrogation and insurance clauses from each of its subcontractors.

E. UMBRELLA/EXCESS LIABILITY/SELF-INSURED RETENTION. The limits required by this Contract can be met by either providing a primary policy or in combination with umbrella/excess liability policy(ies), or self-insured retention.

19. COMPLIANCE

A. LAWS AND REGULATIONS. All Equipment, Products, or Services provided under this Contract must comply fully with applicable federal laws and regulations, and with the laws in the states and provinces in which the Equipment, Products, or Services are sold.

B. LICENSES. Supplier must maintain a valid and current status on all required federal, state/provincial, and local licenses, bonds, and permits required for the operation of the business that the Supplier conducts with Sourcewell and Participating Entities.

20. BANKRUPTCY, DEBARMENT, OR SUSPENSION CERTIFICATION

Supplier certifies and warrants that it is not in bankruptcy or that it has previously disclosed in writing certain information to Sourcewell related to bankruptcy actions. If at any time during this Contract Supplier declares bankruptcy, Supplier must immediately notify Sourcewell in writing.

DocuSign Envelope ID: 0ECD836D-7E4D-46E6-A1C9-4CF6B24936D4

Supplier certifies and warrants that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from programs operated by the State of Minnesota; the United States federal government or the Canadian government, as applicable; or any Participating Entity. Supplier certifies and warrants that neither it nor its principals have been convicted of a criminal offense related to the subject matter of this Contract. Supplier further warrants that it will provide immediate written notice to Sourcewell if this certification changes at any time.

21. PROVISIONS FOR NON-UNITED STATES FEDERAL ENTITY PROCUREMENTS UNDER UNITED STATES FEDERAL AWARDS OR OTHER AWARDS

Participating Entities that use United States federal grant or FEMA funds to purchase goods or services from this Contract may be subject to additional requirements including the procurement standards of the Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards, 2 C.F.R. § 200. Participating Entities may have additional requirements based on specific funding source terms or conditions. Within this Article, all references to "federal" should be interpreted to mean the United States federal government. The following list only applies when a Participating Entity accesses Supplier's Equipment, Products, or Services with United States federal funds.

A. EQUAL EMPLOYMENT OPPORTUNITY. Except as otherwise provided under 41 C.F.R. § 60, all contracts that meet the definition of "federally assisted construction contract" in 41 C.F.R. § 60-1.3 must include the equal opportunity clause provided under 41 C.F.R. §60-1.4(b), in accordance with Executive Order 11246, "Equal Employment Opportunity" (30 FR 12319, 12935, 3 C.F.R. §, 1964-1965 Comp., p. 339), as amended by Executive Order 11375, "Amending Executive Order 11246 Relating to Equal Employment Opportunity," and implementing regulations at 41 C.F.R. § 60, "Office of Federal Contract Compliance Programs, Equal Employment Opportunity, Department of Labor." The equal opportunity clause is incorporated herein by reference.

B. DAVIS-BACON ACT, AS AMENDED (40 U.S.C. § 3141-3148). When required by federal program legislation, all prime construction contracts in excess of $2,000 awarded by non-federal entities must include a provision for compliance with the Davis-Bacon Act (40 U.S.C. § 3141-3144, and 3146-3148) as supplemented by Department of Labor regulations (29 C.F.R. § 5, "Labor Standards Provisions Applicable to Contracts Covering Federally Financed and Assisted Construction"). In accordance with the statute, contractors must be required to pay wages to laborers and mechanics at a rate not less than the prevailing wages specified in a wage determination made by the Secretary of Labor. In addition, contractors must be required to pay wages not less than once a week. The non-federal entity must place a copy of the current prevailing wage determination issued by the Department of Labor in each solicitation. The decision to award a contract or subcontract must be conditioned upon the acceptance of the wage determination. The non-federal entity must report all suspected or reported violations to the federal awarding agency. The contracts must also include a provision for compliance with

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the Copeland "Anti-Kickback" Act (40 U.S.C. § 3145), as supplemented by Department of Labor regulations (29 C.F.R. § 3, "Contractors and Subcontractors on Public Building or Public Work Financed in Whole or in Part by Loans or Grants from the United States"). The Act provides that each contractor or subrecipient must be prohibited from inducing, by any means, any person employed in the construction, completion, or repair of public work, to give up any part of the compensation to which he or she is otherwise entitled. The non-federal entity must report all suspected or reported violations to the federal awarding agency. Supplier must be in compliance with all applicable Davis-Bacon Act provisions.

C. CONTRACT WORK HOURS AND SAFETY STANDARDS ACT (40 U.S.C. § 3701-3708). Where applicable, all contracts awarded by the non-federal entity in excess of $100,000 that involve the employment of mechanics or laborers must include a provision for compliance with 40 U.S.C. §§ 3702 and 3704, as supplemented by Department of Labor regulations (29 C.F.R. § 5). Under 40 U.S.C. § 3702 of the Act, each contractor must be required to compute the wages of every mechanic and laborer on the basis of a standard work week of 40 hours. Work in excess of the standard work week is permissible provided that the worker is compensated at a rate of not less than one and a half times the basic rate of pay for all hours worked in excess of 40 hours in the work week. The requirements of 40 U.S.C. § 3704 are applicable to construction work and provide that no laborer or mechanic must be required to work in surroundings or under working conditions which are unsanitary, hazardous or dangerous. These requirements do not apply to the purchases of supplies or materials or articles ordinarily available on the open market, or contracts for transportation or transmission of intelligence. This provision is hereby incorporated by reference into this Contract. Supplier certifies that during the term of an award for all contracts by Sourcewell resulting from this procurement process, Supplier must comply with applicable requirements as referenced above.

D. RIGHTS TO INVENTIONS MADE UNDER A CONTRACT OR AGREEMENT. If the federal award meets the definition of "funding agreement" under 37 C.F.R. § 401.2(a) and the recipient or subrecipient wishes to enter into a contract with a small business firm or nonprofit organization regarding the substitution of parties, assignment or performance of experimental, developmental, or research work under that "funding agreement," the recipient or subrecipient must comply with the requirements of 37 C.F.R. § 401, "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements," and any implementing regulations issued by the awarding agency. Supplier certifies that during the term of an award for all contracts by Sourcewell resulting from this procurement process, Supplier must comply with applicable requirements as referenced above.

E. CLEAN AIR ACT (42 U.S.C. § 7401-7671Q.) AND THE FEDERAL WATER POLLUTION CONTROL ACT (33 U.S.C. § 1251-1387). Contracts and subgrants of amounts in excess of $150,000 require the non-federal award to agree to comply with all applicable standards, orders or regulations issued pursuant to the Clean Air Act (42 U.S.C. § 7401- 7671q) and the Federal Water Pollution Control Act as amended (33 U.S.C. § 1251- 1387). Violations must be reported to the Federal awarding agency and the Regional Office of the Environmental Protection Agency (EPA).

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Supplier certifies that during the term of this Contract will comply with applicable requirements as referenced above.

F. DEBARMENT AND SUSPENSION (EXECUTIVE ORDERS 12549 AND 12689). A contract award (see 2 C.F.R. § 180.220) must not be made to parties listed on the government wide exclusions in the System for Award Management (SAM), in accordance with the OMB guidelines at 2 C.F.R. §180 that implement Executive Orders 12549 (3 C.F.R. § 1986 Comp., p. 189) and 12689 (3 C.F.R. § 1989 Comp., p. 235), "Debarment and Suspension." SAM Exclusions contains the names of parties debarred, suspended, or otherwise excluded by agencies, as well as parties declared ineligible under statutory or regulatory authority other than Executive Order 12549. Supplier certifies that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation by any federal department or agency.

G. BYRD ANTI-LOBBYING AMENDMENT, AS AMENDED (31 U.S.C. § 1352). Suppliers must file any required certifications. Suppliers must not have used federal appropriated funds to pay any person or organization for influencing or attempting to influence an officer or employee of any agency, a member of Congress, officer or employee of Congress, or an employee of a member of Congress in connection with obtaining any federal contract, grant, or any other award covered by 31 U.S.C. § 1352. Suppliers must disclose any lobbying with non-federal funds that takes place in connection with obtaining any federal award. Such disclosures are forwarded from tier to tier up to the non-federal award. Suppliers must file all certifications and disclosures required by, and otherwise comply with, the Byrd Anti-Lobbying Amendment (31 U.S.C. § 1352).

H. RECORD RETENTION REQUIREMENTS. To the extent applicable, Supplier must comply with the record retention requirements detailed in 2 C.F.R. § 200.333. The Supplier further certifies that it will retain all records as required by 2 C.F.R. § 200.333 for a period of 3 years after grantees or subgrantees submit final expenditure reports or quarterly or annual financial reports, as applicable, and all other pending matters are closed.

I. ENERGY POLICY AND CONSERVATION ACT COMPLIANCE. To the extent applicable, Supplier must comply with the mandatory standards and policies relating to energy efficiency which are contained in the state energy conservation plan issued in compliance with the Energy Policy and Conservation Act.

J. BUY AMERICAN PROVISIONS COMPLIANCE. To the extent applicable, Supplier must comply with all applicable provisions of the Buy American Act. Purchases made in accordance with the Buy American Act must follow the applicable procurement rules calling for free and open competition.

K. ACCESS TO RECORDS (2 C.F.R. § 200.336). Supplier agrees that duly authorized representatives of a federal agency must have access to any books, documents, papers and

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records of Supplier that are directly pertinent to Supplier's discharge of its obligations under this Contract for the purpose of making audits, examinations, excerpts, and transcriptions. The right also includes timely and reasonable access to Supplier's personnel for the purpose of interview and discussion relating to such documents.

L. PROCUREMENT OF RECOVERED MATERIALS (2 C.F.R. § 200.322). A non-federal entity that is a state agency or agency of a political subdivision of a state and its contractors must comply with Section 6002 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act. The requirements of Section 6002 include procuring only items designated in guidelines of the Environmental Protection Agency (EPA) at 40 C.F.R. § 247 that contain the highest percentage of recovered materials practicable, consistent with maintaining a satisfactory level of competition, where the purchase price of the item exceeds $10,000 or the value of the quantity acquired during the preceding fiscal year exceeded $10,000; procuring solid waste management services in a manner that maximizes energy and resource recovery; and establishing an affirmative procurement program for procurement of recovered materials identified in the EPA guidelines.

M. FEDERAL SEAL(S), LOGOS, AND FLAGS. The Supplier cannot use the seal(s), logos, crests, or reproductions of flags or likenesses of Federal agency officials without specific pre-approval.

N. NO OBLIGATION BY FEDERAL GOVERNMENT. The U.S. federal government is not a party to this Contract or any purchase by a Participating Entity and is not subject to any obligations or liabilities to the Participating Entity, Supplier, or any other party pertaining to any matter resulting from the Contract or any purchase by an authorized user.

O. PROGRAM FRAUD AND FALSE OR FRAUDULENT STATEMENTS OR RELATED ACTS. The Contractor acknowledges that 31 U.S.C. 38 (Administrative Remedies for False Claims and Statements) applies to the Supplier's actions pertaining to this Contract or any purchase by a Participating Entity.

P. FEDERAL DEBT. The Supplier certifies that it is non-delinquent in its repayment of any federal debt. Examples of relevant debt include delinquent payroll and other taxes, audit disallowance, and benefit overpayments.

Q. CONFLICTS OF INTEREST. The Supplier must notify the U.S. Office of General Services, Sourcewell, and Participating Entity as soon as possible if this Contract or any aspect related to the anticipated work under this Contract raises an actual or potential conflict of interest (as described in 2 C.F.R. Part 200). The Supplier must explain the actual or potential conflict in writing in sufficient detail so that the U.S. Office of General Services, Sourcewell, and Participating Entity are able to assess the actual or potential conflict; and provide any additional information as necessary or requested.

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R. U.S. EXECUTIVE ORDER 13224. The Supplier, and its subcontractors, must comply with U.S. Executive Order 13224 and U.S. Laws that prohibit transactions with and provision of resources and support to individuals and organizations associated with terrorism.

S. PROHIBITION ON CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT. To the extent applicable, Supplier certifies that during the term of this Contract it will comply with applicable requirements of 2 C.F.R. § 200.216.

T. DOMESTIC PREFERENCES FOR PROCUREMENTS. To the extent applicable, Supplier certifies that during the term of this Contract will comply with applicable requirements of 2 C.F.R. § 200.322.

22. CANCELLATION

Sourcewell or Supplier may cancel this Contract at any time, with or without cause, upon 60 days' written notice to the other party. However, Sourcewell may cancel this Contract immediately upon discovery of a material defect in any certification made in Supplier's Proposal. Cancellation of this Contract does not relieve either party of financial, product, or service obligations incurred or accrued prior to cancellation.

Sourcewell	IC Bus, LLC
DocuSigned by: Jeremy Schwartz C0FD2A139D06489...	DocuSigned by: Alec Borror F4C6D3891EED4C2...
By: _____	By: _____
Jeremy Schwartz	Alec Borror
Title: Chief Procurement Officer	Title: Sales Director, IC Bus
Date: 12/13/2023 | 9:35 PM CST	Date: 12/13/2023 | 7:22 PM CST

Approved:

DocuSigned by: Chad Coauette 48BAF71B0894454...

By: _____

Chad Coauette

Title: Executive Director/CEO

Date: 12/14/2023 | 6:58 AM CST

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RFP 102623 - School Buses with Related Accessories, Supplies, Parts, and Services

Vendor Details

Company Name:	IC Bus
Does your company conduct business under any other name? If yes, please state:	IL
Address:	2701 Navistar Dr Lisle, IL 60532
Contact:	Alec Borror
Email:	alec.borror@navistar.com
Phone:	847-313-1544
Fax:	847-313-1544
HST#:	

Submission Details

Created On:	Monday September 11, 2023 16:23:09
Submitted On:	Thursday October 26, 2023 14:53:23
Submitted By:	Alec Borror
Email:	alec.borror@navistar.com
Transaction #:	4a3068fb-81ac-4b10-877d-43c851b71523
Submitter's IP Address:	136.226.80.205

Specifications

Table 1: Proposer Identity & Authorized Representatives

General Instructions (applies to all Tables) Sourcewell prefers a brief but thorough response to each question. Do not merely attach additional documents to your response without also providing a substantive response. Do not leave answers blank; respond “N/A” if the question does not apply to you (preferably with an explanation).

Line Item	Question	Response *	
1	Proposer Legal Name (one legal entity only): (In the event of award, will execute the resulting contract as "Supplier")	IC Bus, LLC	*
2	Identify all subsidiary entities of the Proposer whose equipment, products, or services are included in the Proposal.	N/A	*
3	Identify all applicable assumed names or DBA names of the Proposer or Proposer's subsidiaries in Line 1 or Line 2 above.	Navistar, Inc; IC Bus; IC	*
4	Provide your CAGE code or Unique Entity Identifier (SAM):	CAGE 526V0 UEI MV36U3JR39Y8	*
5	Proposer Physical Address:	2701 Navistar Dr. Lisle, IL 60532	*
6	Proposer website address (or addresses):	www.ICBus.com	*
7	Proposer's Authorized Representative (name, title, address, email address & phone) (The representative must have authority to sign the “Proposer’s Assurance of Compliance” on behalf of the Proposer and, in the event of award, will be expected to execute the resulting contract):	Alec Borror Sales Director, IC Bus 2701 Navistar Dr. Lisle, IL 60532 331-332-4037	*
8	Proposer's primary contact for this proposal (name, title, address, email address & phone):	Alec Borror Sales Director, IC Bus 2701 Navistar Dr. Lisle, IL 60532 331-332-4037	*
9	Proposer's other contacts for this proposal, if any (name, title, address, email address & phone):	Ryan Kauffman Vice President Sales, IC Bus 2701 Navistar Dr. Lisle, IL 60532 ryan.kauffman@navistar.com	

Table 2: Company Information and Financial Strength

Line Item	Question	Response *	

10	Provide a brief history of your company, including your company's core values, business philosophy, and industry longevity related to the requested equipment, products or services.	IC Bus, LLC is a wholly owned subsidiary of Navistar, Inc. and is the school bus arm of Navistar. For purposes of this document, the terms IC BUS LLC, IC Bus, or simply IC may be used interchangeably. Navistar and under its previous corporate name, International Harvester Company, had produced school buses beginning in the early 1900's. Navistar itself has roots back to Cyrus McCormick and the invention of the mechanical reaping machine in 1831. The key piece of agricultural equipment allowed expansion into more pieces of farm equipment and industrial growth throughout the 1800's. As the 20th Century dawned McCormick merged with other farm equipment manufacturers to form the International Harvester Company headquartered in Chicago, IL. Quickly they saw the need for further expansion and market need developing the International branded truck, including school buses. In more modern history, the farm equipment business was sold, and Navistar was chosen for the new corporate name which focused on trucks, buses, and engines. On July 31, 2021, Traton, Volkswagen AG's commercial truck division, closed on its merger with Navistar International. With this merger, Navistar joined Traton brands Sania, MAN, and Volkswagen Caminhoes e Onibusbrands to create one of the world's largest truck manufactures. Navistar is now a wholly owned entity within the Traton group of brands owned by Volkswagen. There are many things IC Bus is doing to continue to be a leader in the market. These include On Command Connection (OCC) that takes signals from the vehicle and allows users to see and monitor their fleet via Health reports detailing potential service and maintenance issues. IC Bus launched a brand new NextGen bus in July of 2023 with a focus on safety enhancements, all new front-end body, and a driver first interior. Additionally, we have a strong presence in the BEV market with our electric bus. The launch of the NextGen Electric Bus is planned for 2024. Navistar's mission statement is to become leaders in sustainable transportation and the Company goals outline a strategy that 50% of vehicles sold by 2030 will be Electric and 100% by 2035. Additional details around Navistar and our partnership with Traton can be found at our investor relations website https://ir.navistar.com/investor-home/default.aspx	*
11	What are your company's expectations in the event of an award?	IC Bus expectations are to be the preferred supplier for school buses within the Sourcewell network. We have had a breakthrough in Dealer engagement within Sourcewell over the past few years and will continue to build on that to make this award successful.	*
12	Demonstrate your financial strength and stability with meaningful data. This could include such items as financial statements, SEC filings, credit and bond ratings, letters of credit, and detailed reference letters. Upload supporting documents (as applicable) in the document upload section of your response.	IC Bus is a wholly owned subsidiary of Navistar, Inc. As of July 1, 2021, Navistar merged and became a wholly owned subsidiary of Traton E, and therefore part of the Traton Group. All financial information of Navistar is reported through Traton, which is a publicly traded on the Frankfurt and Stockholm stock exchange. For FY 2022, Traton reported over $40 billion in total revenues and over 100,000 employees worldwide. The most recent 2022 annual report and 2023 half year financial report is attached is supporting documents, and further financial information can be found at the Traton investor relations website https://ir.traton.com/en/. Bond rating can be found at: https://ir.traton.com/en/rating/	*
13	What is your US market share for the solutions that you are proposing?	IC Bus had 40% total US market share in 2022.	*
14	What is your Canadian market share for the solutions that you are proposing?	IC Bus had 34% Total Canadian market share in 2022.	*
15	Has your business ever petitioned for bankruptcy protection? If so, explain in detail.	No.	*

16	How is your organization best described: is it a manufacturer, a distributor/dealer/reseller, or a service provider? Answer whichever question (either a) or b) just below) best applies to your organization. a) If your company is best described as a distributor/dealer/reseller (or similar entity), provide your written authorization to act as a distributor/dealer/reseller for the manufacturer of the products proposed in this RFP. If applicable, is your dealer network independent or company owned? b) If your company is best described as a manufacturer or service provider, describe your relationship with your sales and service force and with your dealer network in delivering the products and services proposed in this RFP. Are these individuals your employees, or the employees of a third party?	IC Bus and its parent company Navistar is a Truck and Bus manufacturer. We distribute our Trucks and Buses through our Dealer network who would be the Member selling point. IC Bus Dealers are independently owned and operated. they operate with a Sales and Service agreement administered by Navistar. The agreement sets forth standards and conditions that they agree to operate within. Sales representatives of the dealerships are employees of the dealership and hold all necessary licenses required by local authorities. IC bus employs Regional Sales Managers to work with the dealers in a state of continuous improvement to augment the dealer capability.	*
17	If applicable, provide a detailed explanation outlining the licenses and certifications that are both required to be held, and actually held, by your organization (including third parties and subcontractors that you use) in pursuit of the business contemplated by this RFP.	State and Local governments regulate our dealer businesses and their legal ability to go to market. Navistar requires the IC bus dealer to meet these requirements in order to sell buses within their defined territory. All IC Bus dealerships hold the required licenses and requirements to conduct business.	*
18	Provide all “Suspension or Debarment” information that has applied to your organization during the past ten years.	Traton, Navistar, and IC Bus has not been subject to "Suspension and Debarment" in the past 10 years.	*

Table 3: Industry Recognition & Marketplace Success

Line Item	Question	Response *	
19	Describe any relevant industry awards or recognition that your company has received in the past five years	IC Bus recognized Cumberland CEO Terry Minor as the 2022 IC Bus Dealer of the Year. Every year, IC Bus awards one dealer for their top performance, leadership within the industry and support of their surrounding communities. Supporting both International Truck and IC Bus school bus customers, Cumberland was founded in 2007 by Minor and named after the Cumberland River that runs through downtown Nashville, Tenn. With ten locations in Florida and Tennessee, Cumberland operates around its core values of honor, readiness, victory and loyalty. The dealership promises customers access to the latest technologies, continuous improvement and flawless business execution. ISO 14001 Comkpliant: Tulsa, OK Bus Plant ISO 9001 2015 Certification: Lisle Il- Navistar Inc. World Headquarters Navistar achieved US Dept of Energy Better Buildings award in 2019 Navistar's company vision is to accelerate the impact of sustainable mobility. Navistar Sustainability report in attachments.	*
20	What percentage of your sales are to the governmental sector in the past three years	2020-73% 2021- 70% 2022- 67%	*
21	What percentage of your sales are to the education sector in the past three years	2020- 98% 2021- 98% 2022- 98%	*
22	List any state, provincial, or cooperative purchasing contracts that you hold. What is the annual sales volume for each of these contracts over the past three years?	The following list of all states where our dealers participate in either a state bid or consortium. Listed are our annual unit averages for the 3 year period 2020-2022 State Avg per year FL 365 GA 223 IN 204 KS 33 KY 213 MI 331 MN 152 MS 199 NC 130 NY 735 OH 512 SC 7 UT 64 VA 300 WA 67 WV 72	*
23	List any GSA contracts or Standing Offers and Supply Arrangements (SOSA) that you hold. What is the annual sales volume for each of these contracts over the past three years?	Our MD dealer, K. Neal International is the GSA Contractor for IC Bus.	*

Table 4: References/Testimonials

Line Item 24. Supply reference information from three customers who are eligible to be Sourcewell participating entities.

Entity Name *	Contact Name *	Phone Number *	
Putnam County Bus Garage 515 East Veterans Dr Cookeville, TN	Ron Chaffin Director of Transportation	931-510-4242	*
Bledsoe County School 244 Sequatchie Rd Pikeville, TN 37367	Brian Turner Director of Transportation	423-447-2945	*
Cypress Fairbanks ISD 21330 W Campus Dr Cypress, TX 77433	Dr. Kayne M. Smith Director of Transportation	346-205-8434	*

Table 5: Top Five Government or Education Customers

Line Item 25. Provide a list of your top five government, education, or non-profit customers (entity name is optional), including entity type, the state or province the entity is located in, scope of the project(s), size of transaction(s), and dollar volumes from the past three years.

Entity Name	Entity Type *	State / Province *	Scope of Work *	Size of Transactions *	Dollar Volume Past Three Years *	
Confidential	Education	Texas - TX	School Buses	455 units	Confidential	*
Confidential	Education	Maryland - MD	School Buses	321 units	Confidential	*
Confidential	Education	Texas - TX	School Buses	284 units	Confidential	*
Confidential	Education	Virginia - VA	School Buses	256 units	Confidential	*
Confidential	Education	Florida - FL	School Buses	139 units	Confidential	*

Table 6: Ability to Sell and Deliver Service

Describe your company's capability to meet the needs of Sourcewell participating entities across the US and Canada, as applicable. Your response should address in detail at least the following areas: locations of your network of sales and service providers, the number of workers (full-time equivalents) involved in each sector, whether these workers are your direct employees (or employees of a third party), and any overlap between the sales and service functions.

Line Item	Question	Response *	
26	Sales force.	IC Bus has its own dedicated assembly plant in Tulsa, OK where all IC buses are manufactured. IC Bus also employes its own engineers, sales and management team. Additionally, IC Bus has a sales team of over 10 individuals who have specific functions that cover National Accounts, ICE sales, EV sales, and grant writing. The sales team helps facilitate with our dealer network and are available to work with Sourcewell Members.	*
27	Dealer network or other distribution methods.	The IC Bus dealer network spans across every US State and Canadian Province with over 150 physical locations. Our strong dealer network comprises of an extensive sales and service team that is best in class in the industry. This capability is enhanced by the wider Navistar dealer network which includes 720 locations, 8,474 technicians, and 7,668 service bays available to work on all international products, including IC Bus.	*
28	Service force.	IC Bus has a field service team that exists within the larger service organization responsible for dealer performance, customer satisfaction, and customer fitness. As service issues arise, this team ensures best in class service is provided to our dealer network and end customers. Our internal IC Bus service team is enhanced by having the largest dealer network available across both IC Bus and International Truck Dealerships. All of these combined 720+ Navistar dealer locations can provide service work for our end customers.	*

29	Describe the ordering process. If orders will be handled by distributors, dealers or others, explain the respective roles of the Proposer and others.	The IC Bus Dealer will verify the requesting entity is a Sourcewell Member. If the requesting entity is not a member the dealer will assist them in becoming one. Once the member has determined the specifications of the bus, the IC Bus Dealer will price the bus using the Sourcewell IC Bus workbook developed for this contract. It assures the Member obtains the bus priced properly as prescribed in the contract and provides an easy to read template laying out prices and discounts. The IC Bus dealer will submit the information to our Finance Team who provides them an authorized number. Upon receipt of the Member PO, the selling dealer sends the workbook and the PO and sends the order to the factory. The selling dealer will receive a job number and VIN. The unit will be identified by a special feature code so they can easily be tracked in the system. If purchased from stock, the authorization number will be utilized for tracking purposes. Order to build timing will vary based on seasonality and is generally in the 120-150 day timeline, but this can vary widely based on supplier shortages on specific options.	*
30	Describe in detail the process and procedure of your customer service program, if applicable. Include your response-time capabilities and commitments, as well as any incentives that help your providers meet your stated service goals or promises.	Customer service is provided by our Dealer network, who handles all direct relationships with our end customers. Navistar implements a system names Diamond Edge with our dealers to measure performance and key operations that impact a dealerships overall performance score. Diamond Edge includes the following components and metrics to measure success: 1. Diamond Edge Certification, which allows customers to experience faster service, immediate parts availability, and a higher level of servicing expertise. 2. Technician education and certification 3. Vehicle write up within 15 minutes 4. Vehicle diagnosed and communicated back to the customer with 2 hours 5. Predictive parts stocking logic to ensure parts are on the shelf for unplanned service events 6. Velocity metrics to ensure for repairs to be completed within 24/48 hours of arrival at a dealership	*
31	Describe your ability and willingness to provide your products and services to Sourcewell participating entities in the United States.	IC Bus school buses are readily available and supported in the United States.	*
32	Describe your ability and willingness to provide your products and services to Sourcewell participating entities in Canada.	IC Bus school buses are readily available and supported in Canada.	*
33	Identify any geographic areas of the United States or Canada that you will NOT be fully serving through the proposed contract.	IC Bus will not be including Puerto Rico, the Pacific US Territories, or the US Virgin Islands.	*
34	Identify any Sourcewell participating entity sectors (i.e., government, education, not-for-profit) that you will NOT be fully serving through the proposed contract. Explain in detail. For example, does your company have only a regional presence, or do other cooperative purchasing contracts limit your ability to promote another contract?	IC Bus will serve all Sourcewell Members within the 48 contiguous United States, plus the US States of Hawaii and Alaska, and the Canadian Provinces and Territories.	*
35	Define any specific contract requirements or restrictions that would apply to our participating entities in Hawaii and Alaska and in US Territories.	No restrictions for Hawaii and Alaksa. IC Bus does not have representation in Puerto Rico or the US territories and would preclude any Members in those areas.	*

Table 7: Marketing Plan

Line Item	Question	Response *	
36	Describe your marketing strategy for promoting this contract opportunity. Upload representative samples of your marketing materials (if applicable) in the document upload section of your response.	We plan to continue to actively market our Sourcewell partnership on Social Media, through traditional media, as well as during dealer and customer communications. This includes education on the Sourcewell partnership during trade shows, dealer town halls, as well as from our sales staff actively promoting during dealer and customer visits. In addition, after the award of a new contract we will: 1) Issue a press release upon notification of the award 2) This will generate new interest from our dealer network, we will host a dealer webinar to re-introduce dealers who may be less familiar with Sourcewell 3) Sourcewell banners and materials are a staple at our trade shows and regional events 4) After webinar, dealers will be provided a list of all customers in their territory who are Sourcewell members 5) Our internal sales team will be tasked with following up with dealers to select customers to target 6) Sourcewell will be included at future sales training events 7) Selected sales staff will be tasked with further engagement with Sourcewell based on dealers who are not currently active with the program 8) IC Bus will participate in Sourcewell sponsored events in order to support Sourcewell and continue to find ways to be further engaged with the program 9) A dealer communication letter will be sent to all dealers to re-introduce the program and process details 10) Further collaboration with Sourcewell to find ways to continue to work with our dealers to further engage their future participation in the program	*
37	Describe your use of technology and digital data (e.g., social media, metadata usage) to enhance marketing effectiveness.	IC Bus currently has a landing page for Sourcewell information within the IC Bus website which we periodically include as a reminder in our weekly newsletters to the dealer network. Landing Page can be found at : https://www.icbus.com/sourcewell	*
38	In your view, what is Sourcewell's role in promoting contracts arising out of this RFP? How will you integrate a Sourcewell-awarded contract into your sales process?	We will continue to collaborate with Sourcewell to establish best practices in promoting contracts from this award. Working together to better understanding what is working on the Sourcewell side combined with continuing to understand the IC Bus sales process will be key in continued promotion. Sourcewell will have access to the sales team as well as the dealer network. The program will be promoted by all sales members at IC Bus. Every dealer should understand the benefits of the program and understand how to identify a customer that is a good fit to use the program. We have seen some dealers integrate Sourcewell as a standard within the sales process, and we will look to replicate that process across the dealer network.	*
39	Are your products or services available through an e-procurement ordering process? If so, describe your e-procurement system and how governmental and educational customers have used it.	IC Buses are not available through an e-procurement process. Members will need to work directly with their selling dealer to better understand the process at the dealer level. Our dealer network is sophisticated in facilitating customer needs including doing business electronically to meet customer needs.	*

Table 8: Value-Added Attributes

Line Item	Question	Response *	

40	Describe any product, equipment, maintenance, or operator training programs that you offer to Sourcewell participating entities. Include details, such as whether training is standard or optional, who provides training, and any costs that apply.	Product training is available to customers, specific around our new Electric Bus. Upon delivery of a unit, our internal sales team or dealer personnel will set up a training session with the customer including their drivers, maintenance staff, and first responders in the area. The goal of this training is the educate anyone who may interact with the electric vehicle an understanding of the vehicle and being comfortable with the vehicle. Service training is not standard or included with the product for either ICE or the EV Bus. The intent is that any warranty repairs should be done through the local dealership service team in order to minimize customer impact. IC Bus hosts IC University, a weeklong training conducted at our plant and related facilities. IC holds multiple sessions of IC University throughout the summer in order to facilitate customer schedules. IC University is widely appreciated across the customer network. IC Bus offers many tools that inform a user of vehicle health and can inform users on vehicle health and fault codes. IC also utilizes IC 360 which allows customers to communicate with their local dealer on service being done in the shop. IC 360 allows customers to see live updates on what service is being performed on the vehicle and provide feedback directly to the delaer.	*
41	Describe any technological advances that your proposed products or services offer.	In July 2023, IC Bus released it's Next Generation vehicle which includes many technological advances. The focus of the Next Gen bus was around the safety of the vehicle as well as driver first, ensuring drivers have all the tools they need for a safe and comfortable ride. Some of the technological advances include: Safety: - Bendix® Intellipark® electronic parking brake standard (on air brake units) - Bendix® Wingman® Advanced™ Safety Package (air brake units) – including active braking capabilities for collision avoidance, following distance alerts, adaptive cruise and more - No Student Left Behind child monitoring system - Single-panel glass on entrance door for improved driver visibility - Entrance doors integrated into dash cluster, providing ‘Door Ajar’ warning if bus reaches certain speed prior to door being fully closed - Daytime running headlights with automatic twilight sensor - Electronic stability control - Enhanced Visibility - Designed with Drivers in mind Technology - All buses are equipped with OnCommand Connection, which allows 24/7 access and visibility to real time vehicle diagnostic and predictive maintenance tools. It also allows visibility to current vehicle location and route history, as well as provides driver monitoring. A full breakdown of the NextGen bus can be found at : https://www.icbus.com/buses/school/ceseries Spec sheets for both the Diesel CE Series and Electric CE Series are available in the attachments.	*

42	Describe the safety features and innovations incorporated in the manufacturing of your buses that impact student safety.	IC Bus always puts safety first, as the children we transport are the most precious cargo. We continue to make strides in increasing the safety of our vehicle, and have done that with our NextGen bus launched in July 2023. Safety Features Include: - Bendix® Intellipark® electronic parking brake standard (on air brake units) - Bendix® Wingman® Advanced™ Safety Package (air brake units) – including active braking capabilities for collision avoidance, following distance alerts, adaptive cruise and more - No Student Left Behind child monitoring system - Single-panel glass on entrance door for improved driver visibility - Entrance doors integrated into dash cluster, providing 'Door Ajar' warning if bus reaches certain speed prior to door being fully closed - Daytime running headlights with automatic twilight sensor - Electronic stability control - Enhanced Visibility Additionally, durable construction of the bus is key to safety. Some key features inlcude: - 16-gauge steel body and interior panels for longevity and structural integrity - 14-gauge steel threaded body bows with continuous runners connecting all roof bows for ruggedness and superior strength - Stamped parts used wherever possible during construction provides increased strength and tighter tolerances -Meets or exceeds FMVSS/CMVSS A full list of safety features and innovations can be found at: https://www.icbus.com/buses/school/ceseries	*

43	Describe any “green” initiatives that relate to your company or to your products or services, and include a list of the certifying agency for each.	Navistar's mission statement is to 'accelerate the impact of sustainable mobility.' Our Tulsa Bus Plant facility is ISO 14001 Certified. IC Bus and Navistar have many green initiatives including the following: - Path to zero emissions. We strive to achieve 50% new battery electric vehicle sales by 2030 and 100% by 2040 for the US market. - Decarbonization. Navistar’s decarbonization effort to move away from product fossil fuels began in 2021. Navistar’s work through 2022 and into 2023, is leading to the development of targets to be submitted to the SBTi. This target will encompass Scope 1 and Scope 2 emissions and a target for Scope 3 emissions from the use of products Energy Usage - Electrical energy usage, therefore, continues to be a key area of focus. Our production increased by 32% in 2022, yet the purchased utility energy used by our facilities increased only slightly, less than 2% over 2021; evidence of the energy efficiency gains and reduction of wasted energy in our operations Circular Business - Circularity not only saves raw resources from being used in the production of a new product, but uses less energy, causes less emissions and creates less waste than a new product. Navistar is early in its journey toward a circular business model but is committed to moving in that direction. Remanufacturing - The energy and emissions impacts of a remanufactured vehicle part can be on average as low as 35% compared with a new part and the waste impacts can be less than 10% compared with a new vehicle part according to a 2018 United Nations Environment Program report.1 As a result, remanufacturing can have a significant impact. Navistar sells and distributes remanufactured parts under the ReNEWed® and Fleetrite® brands, with approximately 3,000 different parts regularly remanufactured. Recycle - n 2022, 64% of all waste generated was recycled, compared to 67% in 2021 – which represents a slight decrease likely related to the impacts of the COVID-19 pandemic affecting waste segregation and recycling. We have programs to recycle cardboard, pallets and other packaging material. We aim to shape the circular economy, continuously improve toward our goal of a 75% recycling rate, and create a less resource-intensive company. Conserving Water Resources - In 2022, we used 0.51 million cubic meters of water in our operations, a 9.1% increase from 0.47 million cubic meters in 2021. Our overall water usage has been trending lower during the years prior to the start of the pandemic but increased slightly compared to 2021. However, the total water use per vehicle decreased due to improved efficiency at higher production levels. Environmental Compliance - Environmental compliance remains a baseline value for us. Our manufacturing facilities are certified by outside auditors to comply with the ISO 14001 environmental management system standard, except for the new San Antonio plant, which is planned to achieve certification in 2024. Further details on each of these initiatives can be found in the attached Navistar 2022 Sustainability Report.	*
44	Identify any third-party issued eco-labels, ratings or certifications that your company has received for the equipment or products included in your Proposal related to energy efficiency or conservation, life-cycle design (cradle-to-cradle), or other green/sustainability factors.	Navistar does not have any third-party eco-labels beyond ESEPA compliance on all vehicles and engines manufactured.	*

45	Describe any Women or Minority Business Entity (WMBE), Small Business Entity (SBE), or veteran owned business certifications that your company or hub partners have obtained. Upload documentation of certification (as applicable) in the document upload section of your response.	Navistar and IC Bus are committed to diversity both internally within our workforce and externally with our supply base. We have a supplier diversity program that has been in place for 40 years to bring awareness and emphasis to our business practices. We continue to grow our commitment and purchases from our diversity business partners and embrace diversity as a way of business. Our supplier diversity program is designed to develop and strenghten strategic supplier relationships with companies owned by minorities, women, veterans, and small businesses. As a result of our efforts to sustain a robust and diverse supplier base, Navistar finished 2022 having spent: ~$266.4 million on purchases from Minority Business Enterprises (MBE) and Women Business Enterprises (WBE) ~$608 million with Small Business Enterprises (SBE) ~$25 million Veteran Business Enterprises (VBE) ~$78.7 million – Small Disadvantaged Business Enterprises ~$12 million with enterprises in Historically Underutilized Business Zones (HUB Further details can be found in our attached 2022 Sustainability report.	*
46	What unique attributes does your company, your products, or your services offer to Sourcewell participating entities? What makes your proposed solutions unique in your industry as it applies to Sourcewell participating entities?	IC Bus has the largest school bus dealer network in the US and Canada to sell and service the buses we build and sell to our customers and Sourcewell Members. The Dealer network is important for Sourcewell Members because it allows Members to have access to service and parts as needed. Additionally, our Next Generation bus leads the industry in both safety and technology, while also creating a driver first environment. Navistar and IC Bus have a bold vision to accelerate the impact of sustainable mobility and both short term and long term goals to meet that vision outlined in this RFP. Additional information can be found in the attached 2022 Sustainability Report.	*

Table 9: Warranty

Describe in detail your manufacturer warranty program, including conditions and requirements to qualify, claims procedure, and overall structure. You may upload representative samples of your warranty materials (if applicable) in the document upload section of your response in addition to responding to the questions below.

Line Item	Question	Response *	
47	Do your warranties cover all products, parts, and labor?	IC Bus base warranty covers all products, parts, and labor, less maintenance, parts and/or abuse for the first 12 months of service. Many components, especially key components such as engines, transmissions, frame rails, axles, and seat frames and foams have significantly longer warranty periods.	*
48	Do your warranties impose usage restrictions or other limitations that adversely affect coverage?	The IC Warranty document (attached) will clarify. 1. the warranty coverage document also covers restrictions of coverage, competitive with the rest of the industry restrictions and limitations. 2. External influence, damage, modifications, etc. 3. Failure due to improper use, misapplication or abuse could be denied. 4. Failure to improper maintenance, storage, deterioration, etc. 5. Supplier Direct warranty requirements i.e. Cummins/Allison etc.	*
49	Do your warranties cover the expense of technicians' travel time and mileage to perform warranty repairs?	1. On road vehicles that are still under towing coverage have a unit disabling failure, and covered by towing coverage can be repaired at failure site. When this is more cost effective and can be properly repaired without towing the unit back to a dealer, we will reimburse for the road call in lieu of the tow expense. This is not covered under the standard warranty period.	*
50	Are there any geographic regions of the United States or Canada (as applicable) for which you cannot provide a certified technician to perform warranty repairs? How will Sourcewell participating entities in these regions be provided service for warranty repair?	All 50 US States and the Canadian Provinces and Territories are included for coverage.	*
51	Will you cover warranty service for items made by other manufacturers that are part of your proposal, or are these warranties issues typically passed on to the original equipment manufacturer?	Navistar does cover many supplier based components through the standard warranty period. However, as indicated above there are a few suppliers such as Cummins / Allison that require their concerns to return to their distributers for repair and warranty. Additionally, supplier direct warranties may be available from the supplier subsequent to the 12 month IC Bus warranty. Equipment installed at the dealer, or an aftermarket modification center are not covered by the IC Bus warranty. These items would be warranted by the selling dealer and / or the aftermarket modification center itself.	*
52	What are your proposed exchange and return programs and policies?	Our vehicles will be delivered as ordered and warranted free of defects and workmanship. If a vehicle is not performing to the level expected, we will engage the appropriate Field Service Manger to expedite a repair plan. Our expectation is to not only resolve your concern fully but do it in a timely fashion.	*
53	Describe any service contract options for the items included in your proposal.	IC Bus offers many extended service contracts including: Towing @ $550 per incident Towing @ $1,100 per incident Extended Vehicle coverage including body Extended Vehicle coverage excluding body Pre Packaged component systems - start and alternator Pre Packaged component systems - Electrical Cummins Full Engine Cummins Full Engine Minus Maintenance Cummins Major Components Cummins Full Engine Minus Injectors Cummins Full Engine + Aftertreatment	*

Table 10: Payment Terms and Financing Options

Line Item	Question	Response *	
54	Describe your payment terms and accepted payment methods.	Payment terms are as specified by the selling dealer, the school bus industry is characterized typically by payment upon delivery.	*
55	Describe any leasing or financing options available for use by educational or governmental entities.	IC Bus has a captive finance company in Navistar Financial Corporation which offers a wide variety of leasing and financing options for our vehicles. The selling dealer will be able to provide all options available specific to each market.	*
56	Describe any standard transaction documents that you propose to use in connection with an awarded contract (order forms, terms and conditions, service level agreements, etc.). Upload a sample of each (as applicable) in the document upload section of your response.	The IC Bus dealer will verify the requesting entity is a Sourcewell Member. If the requesting entity is not a Sourcewell Member, the dealer will assist them in becoming a member. The IC sales team will help in this process as necessary. Once the Member ahs determined the specs of the bus, the IC BUS Dealer will price the Bus using the Sourcewell IC Bus workbook developed for this contract. This assures the Member obtains the bus priced properly as prescribed in the contract and provides an easy to read template laying out prices and discounts. The IC Bus dealer will submit the information to our Finance Team who provides them an authorization number. Upon receipt of the Member PO, the selling dealer sends the workbook and PO and sends the order to the factory. The selling dealer will receive a job number and VIN. the unit will be identified by a special feature code so they can easily be tracked in the system. If purchased from stock, the authorization number will be utilized for tracking purposes. Order to build timing will vary based on seasonality and suppliers but is generally in the 120-day timeframe.	*
57	Do you accept the P-card procurement and payment process? If so, is there any additional cost to Sourcewell participating entities for using this process?	P-Card usage and terms would be specified by the selling dealer. Generally, school bus vehicle purchases are outside the scope of P-Card usage. Any fees imposed by the process would be above the discount and selling structure described in this RFP.	*

Table 11: Pricing and Delivery

Provide detailed pricing information in the questions that follow below. Keep in mind that reasonable price and product adjustments can be made during the term of an awarded Contract as described in the RFP, the template Contract, and the Sourcewell Price and Product Change Request Form.

Line Item	Question	Response *	
58	Describe your pricing model (e.g., line-item discounts or product-category discounts). Provide detailed pricing data (including standard or list pricing and the Sourcewell discounted price) on all of the items that you want Sourcewell to consider as part of your RFP response. If applicable, provide a SKU for each item in your proposal. Upload your pricing materials (if applicable) in the document upload section of your response.	IC Bus will utilize a pricing program for the IC Bus dealers that defines a percentage of discount off the list price to all vehicles inclusive of base chassis and options. Total chassis and options list, less percentage discount equals the selling price. The spreadsheet used for pricing is include in the related documents section of this RFP. IC Bus pricing for the Sourcewell RFP for school buses with related accessories is based on the US Dollar. For units purchased by Sourcewell Members in Canada an exchange rate will be added to the pricing on the proposal. IC Bus will provide the selling dealer with the appropriate exchange rate when the unit is quoted and that exchange rate will be honored for 60 days.	*
59	Quantify the pricing discount represented by the pricing proposal in this response. For example, if the pricing in your response represents a percentage discount from MSRP or list, state the percentage or percentage range.	There are unique discount precents for the CE with Diesel and CE Electric. Model — MSRP — Discount CE w/ Diesel — $253,146 — 53% — $118,179 CE Electric 2 — $376,268 — 5.2% — $356,702 CE Electric 3 — $430,763 — 4.7% — $410,517 Federally Mandated Surcharges and emissions will be added as required.	*
60	Describe any quantity or volume discounts or rebate programs that you offer.	Orders of 5 or more will receive an additional $1500 discount per unit. Orders of 20 or more will receive an incremental $1500 per unit.	*
61	Propose a method of facilitating “sourced” products or related services, which may be referred to as “open market” items or “nonstandard options”. For example, you may supply such items “at cost” or “at cost plus a percentage,” or you may supply a quote for each such request.	IC Bus dealers have access to the IC Bus custom bus center where additional non-stock goods can be added. These goods would be quoted from the IC Dealer to the Sourcewell Member. CBC added good carries a 12 month warranty. Goods purchased outside of the bus assembly process, including the CBS can be added to the Member's proposal with a handling fee not to exceed 5% of these goods and modifications.	*
62	Identify any element of the total cost of acquisition that is NOT included in the pricing submitted with your response. This includes all additional charges associated with a purchase that are not directly identified as freight or shipping charges. For example, list costs for items like pre-delivery inspection, installation, set up, mandatory training, or initial inspection. Identify any parties that impose such costs and their relationship to the Proposer.	IC Bus charges the dealers a storage fund fee of $150 and as such would be added below the vehicle price line and be included with the total cost quoted to the Sourcewell Member.	*
63	If freight, delivery, or shipping is an additional cost to the Sourcewell participating entity, describe in detail the complete freight, shipping, and delivery program.	IC Bus dealers contract their own freight and as such would be added below the vehicle price line and be included within the total cost quoted to the Sourcewell Member.	*
64	Specifically describe freight, shipping, and delivery terms or programs available for Alaska, Hawaii, Canada, or any offshore delivery.	IC Bus dealers contract freight independent of IC Bus, as such freight chargers will be added into the total cost and quoted to the Sourcewell Member.	*
65	Describe any unique distribution and/or delivery methods or options offered in your proposal.	IC Bus dealers can arrange delivery options with the Sourcewell Member that may be more suitable for local conditions or needs. These unique delivery options would be a matter for the Sourcewell Member and IC dealer.	*

Table 12: Pricing Offered

Line Item	The Pricing Offered in this Proposal is: *	Comments
66	a. the same as the Proposer typically offers to an individual municipality, university, or school district.	IC Bus has offered additional incentives for larger awards

Table 13: Audit and Administrative Fee

Line Item	Question	Response *	
67	Specifically describe any self-audit process or program that you plan to employ to verify compliance with your proposed Contract with Sourcewell. This process includes ensuring that Sourcewell participating entities obtain the proper pricing, that the Vendor reports all sales under the Contract each quarter, and that the Vendor remits the proper administrative fee to Sourcewell. Provide sufficient detail to support your ability to report quarterly sales to Sourcewell as described in the Contract template.	We have established a feature code added to Sourcewell orders that allows us to monitor and report out sales with Sourcewell. Additionally, the dealer pricing will need to be submitted for verification. This will ensure member pricing is correct and provide a secondary audit trail.	*
68	If you are awarded a contract, provide a few examples of internal metrics that will be tracked to measure whether you are having success with the contract.	IC Bus is determined to ensure the success of being awarded a Sourcewell contract. Internal metrics we will track include quarterly sales, annual sales, and comparisons from previous years to ensure growth within the program. IC Bus has ambitious goals to continue to grow the Sourcewell program, and if the metrics are not showing that growth, we will work with Sourcewell to find best practices to improve the metrics.	*
69	Identify a proposed administrative fee that you will pay to Sourcewell for facilitating, managing, and promoting the Sourcewell Contract in the event that you are awarded a Contract. This fee is typically calculated as a percentage of Vendor's sales under the Contract or as a per-unit fee; it is not a line-item addition to the Member's cost of goods. (See the RFP and template Contract for additional details.)	IC Bus is pleased to provide Sourcewell with the following administrative fee schedule: CE School Bus - $750 EV School Bus - $1,000 These rebates will be paid quarterly from IC Bus along with the detailed summary sheet.	*

Table 14A: Depth and Breadth of Offered Equipment Products and Services

Line Item	Question	Response *	
70	Provide a detailed description of the equipment, products, and services that you are offering in your proposal.	IC Bus is a Bus manufacturer and the primary equipment we offer through the Sourcewell program is busses. Also, we also provide extended service contracts for our buses, and the option to add charging bundles to our Electric bus option.	*
71	Within this RFP category there may be subcategories of solutions. List subcategory titles that best describe your products and services.	IC Bus wants to serve the Sourcewell Members. In the event a member needs a special feature or chassis configuration that may not be readily apparent, please reach out to your local IC dealer for assistance.	*

Table 14B: Depth and Breadth of Offered Equipment Products and Services

Indicate below if the listed school bus type is offered within your proposal and, for each available bus type, the engine or power alternatives that you offer within the type. Provide additional comments in the text box provided, as necessary.

Line Item	Bus Type	Offered *	Engine - Gas & Diesel *	Engine - CNG or Propane *	Engine - Hybrid or Alt Fuel *	Electric Powered *	Comments	
72	Type A School Bus	○ Yes ◉ No	○ Yes ◉ No	○ Yes ◉ No	○ Yes ◉ No	○ Yes ◉ No	IC Bus does not offer a Type A bus.	*
73	Type C School Bus	◉ Yes ○ No	◉ Yes ○ No	○ Yes ◉ No	○ Yes ◉ No	◉ Yes ○ No	The IC Bus CE is a Type C that is offered with either a diesel engine or is electric powered.	*
74	Type D School Bus	○ Yes ◉ No	◉ Yes ○ No	○ Yes ◉ No	○ Yes ◉ No	◉ Yes ○ No	IC Bus does not offer a Type D bus.	*
75	School Activity Bus	◉ Yes ○ No	◉ Yes ○ No	○ Yes ◉ No	○ Yes ◉ No	◉ Yes ○ No	IC Bus offers a school activity bus as a Type C with either a diesel engine or electric powered.	*
76	Prison Bus	◉ Yes ○ No	◉ Yes ○ No	○ Yes ◉ No	○ Yes ◉ No	◉ Yes ○ No	IC Bus offers a Prison Bus as a Type C with either a diesel engine or electric powered.	
77	Accessories, Parts, and Services	◉ Yes ○ No	◉ Yes ○ No	○ Yes ◉ No	○ Yes ◉ No	◉ Yes ○ No	Accessories, parts, and service are available throughout the IC Bus Dealer network and beyond that within the Internatioanl Dealer network.	

Table 15: Exceptions to Terms, Conditions, or Specifications Form

Line Item 78. **NOTICE**: To identify any exception, or to request any modification, to Sourcewell standard Contract terms, conditions, or specifications, a Proposer must submit the proposed exception(s) or requested modification(s) via redline in the Contract Template provided in the “Bid Documents” section. Proposer must upload the redline in the “Requested Exceptions” upload field. All exceptions and/or proposed modifications are subject to review and approval by Sourcewell and will not automatically be included in the Contract.

Do you have exceptions or modifications to propose?	Acknowledgement *
	○ Yes ◉ No

Documents

Ensure your submission document(s) conforms to the following:

1. Documents in PDF format are preferred. Documents in Word, Excel, or compatible formats may also be provided.

2. Documents should NOT have a security password, as Sourcewell may not be able to open the file. It is your sole responsibility to ensure that the uploaded document(s) are not either defective, corrupted or blank and that the documents can be opened and viewed by Sourcewell.

3. Sourcewell may reject any response where any document(s) cannot be opened and viewed by Sourcewell.

4. If you need to upload more than one (1) document for a single item, you should combine the documents into one zipped file. If the zipped file contains more than one (1) document, ensure each document is named, in relation to the submission format item responding to. For example, if responding to the Marketing Plan category save the document as “Marketing Plan.”

- Pricing - 2023 Sourcewell IC Bus Workbook.xlsx - Thursday October 26, 2023 14:52:02
- Financial Strength and Stability - Traton 2023 Half-Year Financial report.pdf - Wednesday October 25, 2023 22:07:15
- Marketing Plan/Samples (optional)
- WMBE/MBE/SBE or Related Certificates - Navistar Sustainability Report 2022.pdf - Wednesday October 25, 2023 22:15:09
- Warranty Information - VehicleWarranty_eBus.pdf - Thursday October 26, 2023 13:36:12
- Standard Transaction Document Samples (optional)
- Requested Exceptions (optional)
- Upload Additional Document - Traton 2022 Annual Report.pdf - Wednesday October 25, 2023 22:11:33

Addenda, Terms and Conditions

PROPOSER AFFIDAVIT AND ASSURANCE OF COMPLIANCE

I certify that I am the authorized representative of the Proposer submitting the foregoing Proposal with the legal authority to bind the Proposer to this Affidavit and Assurance of Compliance:

1. The Proposer is submitting this Proposal under its full and complete legal name, and the Proposer legally exists in good standing in the jurisdiction of its residence.

2. The Proposer warrants that the information provided in this Proposal is true, correct, and reliable for purposes of evaluation for contract award.

3. The Proposer, including any person assisting with the creation of this Proposal, has arrived at this Proposal independently and the Proposal has been created without colluding with any other person, company, or parties that have or will submit a proposal under this solicitation; and the Proposal has in all respects been created fairly without any fraud or dishonesty. The Proposer has not directly or indirectly entered into any agreement or arrangement with any person or business in an effort to influence any part of this solicitation or operations of a resulting contract; and the Proposer has not taken any action in restraint of free trade or competitiveness in connection with this solicitation. Additionally, if Proposer has worked with a consultant on the Proposal, the consultant (an individual or a company) has not assisted any other entity that has submitted or will submit a proposal for this solicitation.

4. To the best of its knowledge and belief, and except as otherwise disclosed in the Proposal, there are no relevant facts or circumstances which could give rise to an organizational conflict of interest. An organizational conflict of interest exists when a vendor has an unfair competitive advantage or the vendor's objectivity in performing the contract is, or might be, impaired.

5. The contents of the Proposal have not been communicated by the Proposer or its employees or agents to any person not an employee or legally authorized agent of the Proposer and will not be communicated to any such persons prior to Due Date of this solicitation.

6. If awarded a contract, the Proposer will provide to Sourcewell Participating Entities the equipment, products, and services in accordance with the terms, conditions, and scope of a resulting contract.

7. The Proposer possesses, or will possess before delivering any equipment, products, or services, all applicable licenses or certifications necessary to deliver such equipment, products, or services under any resulting contract.

8. The Proposer agrees to deliver equipment, products, and services through valid contracts, purchase orders, or means that are acceptable to Sourcewell Members. Unless otherwise agreed to, the Proposer must provide only new and first-quality products and related services to Sourcewell Members under an awarded Contract.

9. The Proposer will comply with all applicable provisions of federal, state, and local laws, regulations, rules, and orders.

10. The Proposer understands that Sourcewell will reject RFP proposals that are marked "confidential" (or "nonpublic," etc.), either substantially or in their entirety. Under Minnesota Statutes Section 13.591, subdivision 4, all proposals are considered nonpublic data until the evaluation is complete and a Contract is awarded. At that point, proposals become public data. Minnesota Statutes Section 13.37 permits only certain narrowly defined data to be considered a "trade secret," and thus nonpublic data under Minnesota's Data Practices Act.

11. Proposer its employees, agents, and subcontractors are not:
    1. Included on the "Specially Designated Nationals and Blocked Persons" list maintained by the Office of Foreign Assets Control of the United States Department of the Treasury found at: https://www.treasury.gov/ofac/downloads/sdnlist.pdf;

    2. Included on the government-wide exclusions lists in the United States System for Award Management found at: https://sam.gov/SAM/; or

    3. Presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from programs operated

by the State of Minnesota; the United States federal government or the Canadian government, as applicable; or any Participating Entity. Vendor certifies and warrants that neither it nor its principals have been convicted of a criminal offense related to the subject matter of this solicitation.

☑ By checking this box I acknowledge that I am bound by the terms of the Proposer's Affidavit, have the legal authority to submit this Proposal on behalf of the Proposer, and that this electronic acknowledgment has the same legal effect, validity, and enforceability as if I had hand signed the Proposal. This signature will not be denied such legal effect, validity, or enforceability solely because an electronic signature or electronic record was used in its formation. - Alec Borror, Sales Director, Navistar, Inc.

The Proposer declares that there is an actual or potential Conflict of Interest relating to the preparation of its submission, and/or the Proposer foresees an actual or potential Conflict of Interest in performing the contractual obligations contemplated in the bid.

○ **Yes** ◉ **No**

The Bidder acknowledges and agrees that the addendum/addenda below form part of the Bid Document.

Check the box in the column "**I have reviewed this addendum"** below to acknowledge each of the addenda.

File Name	I have reviewed the below addendum and attachments (if applicable)	Pages
Addendum_7_School_Buses_RFP_102623 Wed September 27 2023 02:29 PM	☑	1
Addendum_6_School_Buses_RFP_102623 Mon September 25 2023 02:59 PM	☑	1
Addendum_5_School_Buses_RFP_102623 Fri September 22 2023 02:08 PM	☑	1
Addendum_4_School_Buses_RFP_102623 Mon September 18 2023 04:54 PM	☑	1
Addendum_3_School_Buses_RFP_102623 Thu September 14 2023 01:37 PM	☑	3
Addendum_2_School_Buses_RFP_102623 Mon September 11 2023 11:20 AM	☑	1
Addendum_1_School_Buses_RFP_102623 Fri September 8 2023 03:20 PM	☑	1

DocuSign Envelope ID: 619AD054-387D-4F84-A8D7-C5B989EC8CAB

AMENDMENT #1
TO
CONTRACT # 102623-ICB

THIS AMENDMENT is effective upon the date of the last signature below by and between **Sourcewell** and **IC Bus, LLC** (Supplier).

Sourcewell awarded a contract to the Supplier to provide School Buses with Related Accessories, Supplies, Parts, and Services to Sourcewell and its Participating Entities, effective December 14, 2023, through December 22, 2027 (Contract).

Supplier's terms related to pricing discounts, found in Supplier's Proposal line item 59 under "Table 11: Pricing and Delivery" are deleted and replaced with the following:

- Percent discounts are calculated off the MSRP price, ranging from 4.7% to 53%, for CE Series, depending on Power Train (Electric, Diesel).
- Federally-mandated surcharges and emissions will be added as required.

Except as amended above, the Contract remains in full force and effect.

Sourcewell

DocuSigned by:
By: Jeremy Schwartz
C0FD2A139D06489...
Jeremy Schwartz, Director of Operations/CPO

Date: 4/26/2024 | 10:42 AM CDT

IC Bus, LLC

DocuSigned by:
By: Alec Borror
F4C6D3891EED4C2...
Alec Borror

Title: Sales Director

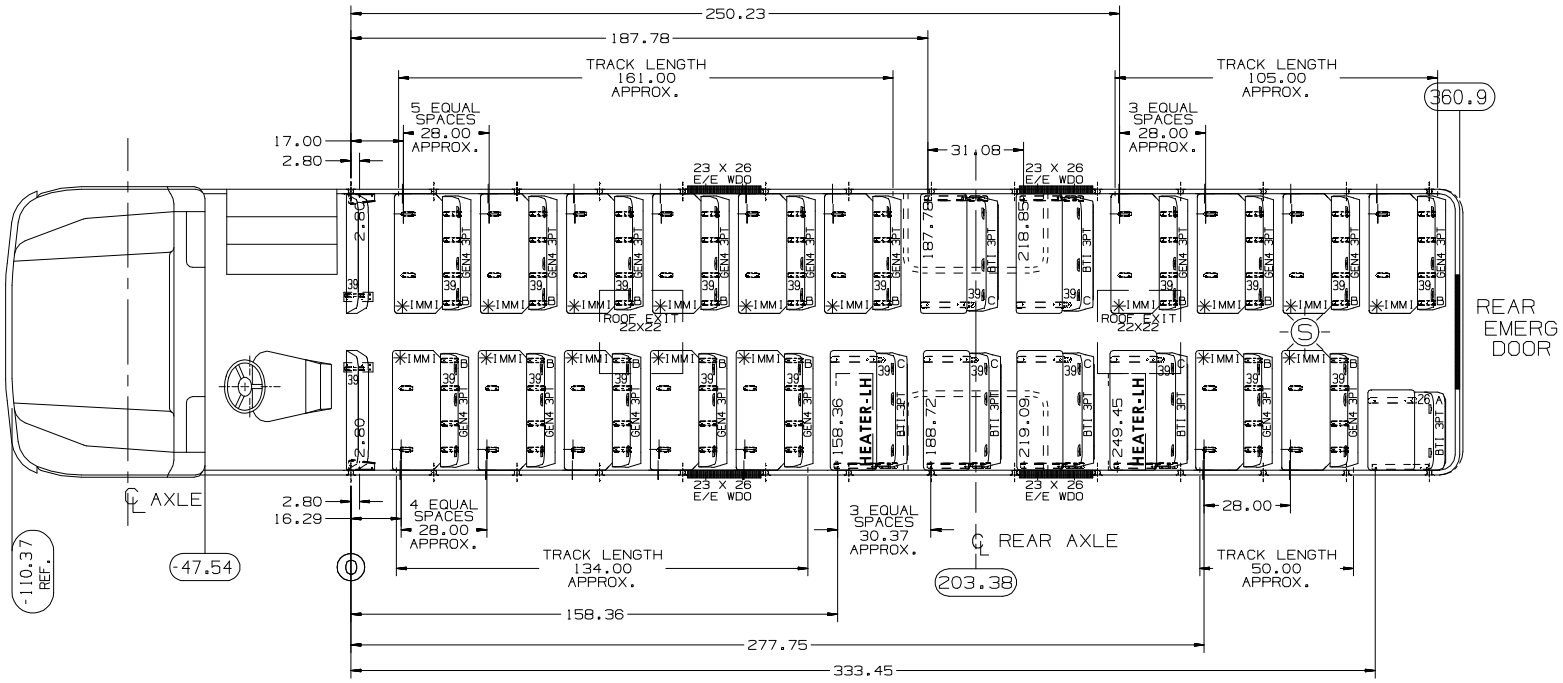
Date: 4/26/2024 | 9:41 AM CDT

SPACING IS BTI/
GEN4 COMPATIBLE

BODY PLAN

WHEELBASE 276"

PB10E00, 34 FT. 2 IN., CAP 71



PURCHASED SEATS IN THIS UNIT ARE:
BTI (3P) / GEN4 (3P)

✳ 450": TOTAL TRACK LENGTH (APPROXIMATELY)

THIS UNIT CONFORMS TO APPLICABLE FMVSS

THIS DOCUMENT IS IN ACCORDANCE WITH ASME Y14.5M-1994 AS AMENDED BY THE INTERNATIONAL TRUCK DIVISION DIMENSIONING AND TOLERANCING ADDENDUM-2000.

CHK	DATE	CHANGE	REV	REFERENCE

50000/49000

REVISE ONLY ON LOGIC SYSTEM

INTERNATIONAL TRUCK AND ENGINE CORPORATION

INTERNATIONAL® CONFIDENTIAL PROPRIETARY

REFERENCE 000

LINEAR MEASURE: mm ☐ in ☒

UNLESS SPECIFIED DIM TOLERANCES ARE

	mm	in
ONE PLACE (.X)	±1.5	±.06
TWO PLACE (.XX)	±0.8	±.03
THREE PLACE (.XXX)	±0.25	±.010
ANGLES	±1°	

APPROX. MASS (WEIGHT)
ROUGH PART
FINISH PART

THIRD ANGLE PROJECTION

INTERNAL CONTROL

NAME: BODY PLAN PB10E00 — CONTROL: E 50

NAME (TRANSLATION) — VERSION: E

DRAWN: U02A557 — MATERIAL — APPD/REV DATE

DATE: 31JAN23

CHECKED — DATE

APPROVED — PIRS NOUN CODE — PART TYPE CODE — SCALE: NONE — SIZE: 4

DATE — PART NO.: CLAND-438 — SHEET: 01

RELEASE NO. — FRAME

CUMBERLAND INTL TRUCKS, INC

640 MASSMAN DR.
NASHVILLE, TN 37210
PHONE: 615 256-4633 - FAX: 255-8318

Purchase Order # 37743

BILL TO:

Greeneville City Schools Sourcewell Member ID 11301
312 Floral Street
Greeneville, TN 37743
423-787-8003

DELIVER TO

Greeneville City Schools
312 Floral Street
Greeneville, T 37743 37367
423-787-8003

DATE	CUST. PO NO.	SALES
03/01/23	EPA Clean School Rebate 37743	ASHLEY SCURLOCK

QTY	ITEM	DESCRIPTION	UNIT PRICE	TOTALS
1	ELECTRIC BUS	IC Bus, PB10E, 2025, Electric, 33,000 lb lap and shoulder belts Air Conditioning	$401,410.04	$401,410.04

Sourcewell

Awarded Contract

Contract # 102623-ICB

Kristie Rollins

Transportation Supervisor

SUB-TOTAL $401,410.04

TOTAL $401,410.04

Please Remit Payment to:
CUMBERLAND INTL TRUCKS, INC.
P.O. BOX 100266
NASHVILLE, TN 37244-0266
Phone: 615 256-4633

SIGNATURE X

Content Keeper 3 Year

Quote #220992 v1



Prepared For:

Greeneville City Schools
Larry Jones
129 W DEPOT ST
GREENEVILLE, TN 37743-1102

P: 4237878000
E: jonesl@gcschools.net

Prepared by:

Headquarters
Cathy Young
1720 Topside Road
Louisville, TN 37777

P: 865.273.1960
E: cyoung@pcsknox.com

Date Issued:
11.12.2024
Expires:
12.20.2024

Content Keeper 3 Yr

Description		Price	Qty	Ext. Price
CKWFPLAT	**CK Web Filter & Reporter Platform SUB (3 Year(s))**	$8.75	3000	$26,250.00
CKAPD	**CK App Defender Subscription (3 Year(s))**	$2.90	3000	$8,700.00
SL-FR	**CK Hybrid Gateway (SL-FR) (1 Year(s))**	$9,109.00	1	$9,109.00
			Subtotal:	**$44,059.00**

Quote Summary	Amount
Content Keeper 3 Yr	$44,059.00
Total:	**$44,059.00**

Taxes, shipping, handling and other fees may apply. We reserve the right to cancel orders arising from pricing or other errors.

Acceptance

Headquarters

C Young

Cathy Young
Signature / Name

11/12/2024
Date

Greeneville City Schools

Larry Jones
Signature / Name Initials

Date