



IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

THE STATE OF DELAWARE *ex rel.*
KATHLEEN JENNINGS, Attorney
General for the State of Delaware

PLAINTIFF,

v.

ELI LILLY AND COMPANY; NOVO
NORDISK INC.; SANOFI-AVENTIS
U.S. LLC; EVERNORTH HEALTH,
INC. (FORMERLY EXPRESS SCRIPTS
HOLDING COMPANY); EXPRESS
SCRIPTS, INC.; EXPRESS SCRIPTS
ADMINISTRATORS, LLC; ESI MAIL
PHARMACY SERVICE, INC.;
EXPRESS SCRIPTS PHARMACY, INC.;
MEDCO HEALTH SOLUTIONS, INC.;
CVS HEALTH CORPORATION; CVS
PHARMACY, INC.; CAREMARK RX,
LLC; CAREMARKPCS HEALTH, LLC;
CAREMARK, LLC; UNITEDHEALTH
GROUP, INC.; OPTUM, INC.;
OPTUMRX, INC.; OPTUMINSIGHT
LIFE SCIENCES, INC.; AND
OPTUMINSIGHT, INC.

DEFENDANTS.

Case No.

VERIFIED COMPLAINT

VERIFIED COMPLAINT FOR
THE STATE OF DELAWARE *ex rel.* KATHLEEN JENNINGS

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I. INTRODUCTION

1. Diabetes is a serious public health concern in Delaware as approximately 112,000 Delaware residents are living with diabetes. An additional 130,000 Delaware residents have prediabetes, which is when a person's blood sugar level is higher than it should be and signifies that the person is at greater risk for developing diabetes.

2. Diabetes is one of the leading causes of blindness, kidney failure, and lower limb amputations despite the availability of effective treatment.

3. The economic impact of diabetes is staggering. The total estimated cost of diagnosed diabetes in Delaware is \$1.1 billion per year.

4. Nearly all diabetics in Delaware rely on daily insulin treatments to survive, Type 2 diabetic treatments such as glucagon-like peptide-1 (GLP-1) drugs, or use a combination of both to treat and control diabetes.

5. Defendants Eli Lilly, Novo Nordisk and Sanofi (collectively, "Manufacturer Defendants" or "Manufacturers") manufacture the vast majority of insulins and other diabetic medications available in Delaware.

6. Defendants CVS Caremark, Express Scripts, and OptumRx ("PBM Defendants" or "PBMs") act as the gatekeepers to the pharmaceutical market, as these three corporate actors are at once: (1) the largest pharmacy benefit managers in the United States and in Delaware (controlling approximately 80% of the PBM market); and (2) the largest pharmacies in the United States (making up 3 of the top 5 dispensing pharmacies in the U.S.). These PBM conglomerates sit at 4th

(Optum/UHG), 6th (CVS Health), and 16th (Express Scripts) on the Fortune 500 list of the largest corporations by revenue.

7. Because of their size and the roles their affiliated entities play in the pharmaceutical system, CVS Caremark, OptumRx, and Express Scripts have near complete and ubiquitous control of the pricing, dispensing, and reimbursement systems for the at-issue diabetes medications for their covered lives.¹ The PBM Defendants affect nearly every diabetic drug transaction in Delaware.

8. While the PBM Defendants represent that they perform their services on behalf of their clients (including Delaware payors)² and diabetics to lower drug prices, increase access to affordable drugs, and promote diabetic health, these representations are false.

9. Rather, the PBM Defendants have worked in coordination with the Manufacturer Defendants to distort the market for diabetic treatments to their benefit at the expense of Delaware diabetics.

10. As part of their work, PBM Defendants design and implement drug formularies (i.e., approved drug lists).

11. Drug formularies are tiered lists which determine which drugs are available, at what out-of-pocket costs, and with what restrictions for insured consumers.

¹ “Covered lives” refer to patients that are enrolled in health plans covered by a PBM.

² The PBM Defendants’ clients in Delaware, referred to herein as “payors,” include health insurers, employers, state and local governments, and unions who provide prescription benefits for their employees and/or members.

12. The PBM Defendants' formularies play a crucial role in their ability to control drug availability and price.

13. If a drug is not included on a formulary, then it is not covered by health insurance.

14. PBM Defendants understand that their standard formulary offerings drive drug utilization and control access.

15. Because the three PBM Defendants control 80% of the pharmacy benefit market, unless they include a drug on one of their standard formulary offerings, it functionally is not available to an estimated 80% of Delaware's insured citizens.

16. The Manufacturers likewise understand that PBMs' standard formularies drive drug utilization—if Manufacturers want their drugs to be prescribed and paid for, they must obtain preferable formulary positions on the PBM Defendants' formularies.

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

18. The unfair and deceptive scheme described herein—referred to as the Insulin Pricing Scheme—was born from this mutual understanding.

19. Over the course of the last fifteen years, and pursuant to the Insulin Pricing Scheme, Manufacturer Defendants have dramatically raised the list prices of

their respective diabetes drugs despite the fact that the cost to produce these drugs has decreased during that same time period.

20. The price for diabetes medications, which cost Manufacturer Defendants less than \$2 to produce and which were originally priced at \$20 when released in the late 1990s, skyrocketed during the relevant time period to prices between \$300 and \$700, and sometimes even more.

21. Remarkably, nothing about these medications has changed; Defendants' \$350 insulin is the exact drug Defendants originally sold for \$20.

22. The current unlawfully inflated price stands in stark contrast to insulin's origins: the discoverers sold the original patent for \$1 to ensure that the medication would remain affordable. Today, insulin has become the poster child for skyrocketing and inflated drug prices.

23. Both Manufacturer and PBM Defendants play vital roles in and profit immensely from the Insulin Pricing Scheme and the artificially inflated prices produced by it.

24. Specifically, the Insulin Pricing Scheme works as follows: first, to gain formulary access from the PBM Defendants for their diabetic treatments, Manufacturer Defendants artificially and willingly raise their list prices, and then pay a significant, yet undisclosed, portion of that price back to the PBMs. These Manufacturer Payments³ are provided under a variety of labels, yet, however they are

³ In the context of this Complaint, the term "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

described, these Manufacturer Payments, along with the inflated list prices, are *quid pro quo* for formulary inclusion on the PBMs' standard offerings.

25. The PBM Defendants then grant preferred status⁴ on their standard formularies to the drugs with the largest Manufacturer Payments and the highest list price, while at the same time excluding lower priced diabetic treatments.

26. To make matters worse, rather than fully pass through these Manufacturer Payments to diabetics or their clients to lower the prices, the PBM Defendants instead obfuscate and retain significant amounts of these Manufacturer Payments as profit.

27. Moreover, around 2012, PBM Defendants began to implement a bold new formulary strategy by creating so-called "exclusionary" formularies which entirely exclude (*i.e.*, do not cover or list) one or more drugs used to treat the same condition. The PBM Defendants created exclusionary formularies to further drive up their own profits. As a result of exclusionary formularies, the PBM Defendants were able to

aggregator acting on the PBM's behalf), either directly via contract or indirectly via Manufacturer-controlled intermediaries. Manufacturer Payments include rebates, administrative fees, inflation fees, pharmacy supplemental discounts, volume discounts, price or margin guarantees, price concessions, indirect purchase fees and rebates, and any other form of consideration exchanged. This broad definition is necessary because PBMs historically have continued to change and evolve the nature of their payment streams to avoid disclosure to clients and disclosure pursuant to state transparency laws. While the route by which the payment streams reach the PBMs has evolved, the fact that the payments do, in fact, reach the PBMs has remained the same.

⁴ "Preferred status" on a formulary refers to a lower tier. The lower the tier a drug is on, the less the out of pocket costs the patient has to pay. Achieving lower tiered status for manufacturers often increases sales because prescribers are more likely to prescribe the drug with a lower out of pocket payment and the patient is more likely to choose that drug.

significantly increase the amount of Manufacturer Payments that they were receiving from the Manufacturer Defendants.

28. In order to maintain their profit margins, the Manufacturer Defendants further raised their list prices in order to make larger and larger Manufacturer Payments to the PBM Defendants.

29. The list prices for the at-issue drugs have become so untethered from the net prices realized by the Manufacturers as to constitute an unlawful price.⁵

30. The Insulin Pricing Scheme creates a “best of both worlds” scenario for Defendants. Manufacturer Defendants are able to make these undisclosed Manufacturer Payments to buy preferred formulary position—which significantly increases their revenue and protects their market share—without sacrificing their profits.

31. For the PBM Defendants—contrary to their representations—they make more money from diabetic drugs with higher list prices and higher Manufacturer Payment amounts.

32. In particular, the PBM Defendants profit off the inflated list prices that result from the Scheme in numerous ways, including: (1) retaining a significant—yet undisclosed—percentage of the Manufacturer Payments, either directly or through their affiliated rebate aggregators; (2) using the inflated list prices produced by the Insulin Pricing Scheme to generate profits from pharmacies in their networks; and (3)

⁵ “Net price” refers to the Manufacturer Defendants’ list price minus all the Manufacturer Payments made to the PBM Defendants.

relying on those same inflated list prices to drive up the PBMs' profits through their own retail, specialty, and mail order pharmacies.

33. With respect to their affiliated pharmacies, the PBM Defendants steer their clients' prescription-drug plans to those pharmacies, including Defendant CVS Pharmacy and the PBM Defendants' affiliated mail order pharmacies, and then overcharge for the at-issue drugs dispensed at those pharmacies to further profit from the Insulin Pricing Scheme. PBM Defendants also collect additional Manufacturer Payments (again tied to list price) from the Manufacturer Defendants for the at-issue drugs sold through their captive pharmacies.

34. Thus, while the PBM Defendants represent both publicly and to their clients that they use their market power to drive down prices for diabetes medications and increase access to affordable drugs, these representations are misleading and deceptive.

35. Rather, the PBM and Manufacturer Defendants are working together to drive up drug prices for Delaware diabetics and to foreclose access to lower priced diabetic treatments in order to increase their profits.

36. Because the PBM Defendants control which drugs are available for the vast majority of Delaware diabetics and because the price paid by nearly every diabetic and payor is based upon the artificially inflated list prices generated by Defendants' scheme, the Insulin Pricing Scheme directly harms every diabetic and payor in Delaware who purchase these life-sustaining drugs.

37. The consequences to Delaware public health caused by the Insulin Pricing Scheme cannot be overstated.

38. Delaware diabetics and payors have been overcharged millions of dollars a year as a result of the Insulin Pricing Scheme.

39. Further, the Insulin Pricing Scheme and the PBM Defendants' formulary exclusions have cut off access for Delaware diabetics to lower priced, affordable diabetic treatments.

40. For Delaware diabetics, the physical, emotional, and financial tolls caused by the Insulin Pricing Scheme have been significant. Unable to afford the drugs they need to stay alive, many diabetics across the country ration or under-dose their diabetes medications, inject expired insulin, reuse needles, and starve themselves to control their blood sugars. This behavior is extremely dangerous and has led to serious complications or even death.

41. In addition to the immeasurable human costs, the Insulin Pricing Scheme also substantially increases healthcare costs for Delaware diabetics by increasing preventable complications. For example, one national model found that all people with diabetes adhering to their diabetes medications would save \$8.3 billion in direct medical costs per year by averting one million emergency department visits and 618,000 hospitalizations.

42. Notably, on January 14, 2021, the US Senate Finance Committee released a Staff Report titled "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug" ("January 2021 Senate Insulin Report"). This report was the

culmination of a two-year investigation based on hundreds of thousands of pages of confidential Manufacturer and PBM documents. For the first time, these confidential documents revealed key information demonstrating that it was the Defendants' misconduct in furtherance of the Insulin Pricing Scheme that was the driving force behind the precipitous price increases for diabetes medications.

43. A year after the release of the January 2021 Senate Insulin Report, the Federal Trade Commission ("FTC") began an investigation into PBM Defendant practices ("PBM FTC Inquiry"). In its policy statement announcing this investigation, the FTC cited specifically to the effect that Manufacturer Payments have in the context of the exorbitant insulin prices and the devastating impact such practices have on the lives of diabetics.

44. Following this investigation, on September 20, 2024, the FTC brought an action against the PBM Defendants and their affiliated rebate aggregators (Ascent (Express Scripts), Emisar (OptumRx), Zinc (CVS Caremark)) for engaging in the Insulin Pricing Scheme.

45. The State of Delaware ("State"), through its Attorney General, now brings this action pursuant to the Delaware Consumer Fraud Act, 6 Del. C. § 2511, *et seq.* (hereafter referred to as the "CFA"); the Delaware Deceptive Trade Practices Act, 6 Del. C. § 2531, *et seq.* (the "DTPA"); and the Delaware common law on behalf of Delaware consumers to protect the health and economic well-being of Delaware residents.

46. This action asserts causes for Defendants' violations of the CFA, DTPA, unjust enrichment, and civil conspiracy.

47. This action seeks all available relief, including without limitation injunctive relief, restitution, disgorgement, actual damages, civil penalties, and attorneys' fees to address and abate the harm caused by the Insulin Pricing Scheme.

II. PARTIES

A. Plaintiff

48. **Plaintiff Kathleen Jennings is the Attorney General of the State of Delaware.** Plaintiff brings this action in her enforcement capacity and in her *parens patriae* capacity to protect the health and financial wellbeing of Delaware consumers. The Attorney General has standing to enforce the CFA and DTPA under 29 Del. C. § 2520(a)(4), 6 Del. C. § 2522(a), 29 Del. C. § 2522(a) and 6 Del. C. § 2533(d). This action is also maintained pursuant to the Attorney General's common law *parens patriae* powers.

B. Manufacturer Defendants

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

50. Eli Lilly is registered to do business in Delaware and may be served through its registered agent: National Registered Agents, Inc., 1209 Orange Street, Wilmington, Delaware 19801.

51. In Delaware, Eli Lilly promotes and distributes several at-issue diabetes medications: Humulin N, Humulin R, Humalog, Mounjaro, Trulicity, and Basaglar.

52. Eli Lilly's global revenues in 2023 were \$7.13 billion from Trulicity, \$1.66 billion from Humalog, \$852 million from Humulin, \$5.16 billion from Mounjaro, and \$728 million from Basaglar.

53. Eli Lilly's global revenues in 2022 were \$7.43 billion from Trulicity, \$2.06 billion from Humalog, \$1.01 billion from Humulin, \$482 million from Mounjaro, and \$760 million from Basaglar.

54. Eli Lilly transacts business in Delaware, targeting Delaware for its products, including the at-issue diabetes medications.

55. Eli Lilly employs sales representatives throughout Delaware to promote and sell Humulin N, Humulin R, Humalog, Mounjaro, Trulicity and Basaglar.

56. Eli Lilly also directs advertising and informational materials to Delaware physicians, payors, pharmacies, and diabetics for the specific purpose of selling more of the at-issue drugs in Delaware and profiting from the Insulin Pricing Scheme.

57. At all times relevant hereto, in furtherance of the Insulin Pricing Scheme, Eli Lilly caused its artificially inflated list prices for the at-issue diabetes medications to be published throughout Delaware with the express knowledge that payment and reimbursement by Delaware diabetics and payors would be based on these prices.

58. During the relevant time period, diabetics and payors in Delaware spent millions of dollars per year out of pocket on Eli Lilly's at-issue drugs based on Eli Lilly's artificially inflated list prices.

59. Delaware diabetics and payors paid for all of the Eli Lilly diabetes medications in Delaware based on the specific inflated list prices Eli Lilly caused to be published in Delaware in furtherance of the Insulin Pricing Scheme.

60. **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.

61. Sanofi is registered to do business in Delaware and may be served through its registered agent: Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808.

62. Sanofi promotes and distributes pharmaceutical drugs in Delaware, including several at-issue diabetes medications: Lantus, Toujeo, Soliqua, Adlyxin, and Apidra.

63. Sanofi’s global revenues in 2023 were \$1.67 billion from Lantus and \$1.32 billion from Toujeo, and \$256 million from Soliqua. Apidra global revenues in 2020 were \$391 million.

64. Sanofi’s global revenues in 2022 were \$2.66 billion from Lantus, \$1.31 billion from Toujeo, and \$253 million from Soliqua. Apidra global revenues in 2019 were \$405 million.

65. Sanofi transacts business in Delaware and targets Delaware for its products, including the at-issue diabetes medications.

66. Sanofi employs sales representatives throughout Delaware to promote and sell Lantus, Toujeo, Soliqua, Adlyxin, and Apidra.

67. Sanofi also directs advertising and informational materials to Delaware physicians, payors, pharmacies, and diabetics for the specific purpose of selling more of the at-issue drugs in Delaware and profiting from the Insulin Pricing Scheme.

68. At all times relevant hereto, in furtherance of the Insulin Pricing Scheme, Sanofi caused its artificially inflated list prices for the at-issue diabetes medications to be published throughout Delaware with the express knowledge that payment and reimbursement by Delaware diabetics and payors would be based on these prices.

69. During the relevant time period, diabetics and payors in Delaware spent millions of dollars per year out of pocket on Sanofi's at-issue drugs based on Sanofi's artificially inflated list prices.

70. Delaware diabetics and payors paid for all of the Sanofi diabetes medications in Delaware based on the specific inflated prices Sanofi caused to be published in Delaware in furtherance of the Insulin Pricing Scheme.

71. **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.

72. Novo Nordisk is registered to do business in Delaware and may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

73. Novo Nordisk promotes and distributes pharmaceutical drugs in Delaware, including at-issue diabetic medications: Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, Xultophy, Rybelsus, and Ozempic.

74. Novo Nordisk's global revenues in 2023 were \$3.13 billion from Novolog, \$629 million from Levemir, \$1.24 billion from Tresiba, \$1.38 billion from Victoza, \$515 million from Xultophy, \$3 billion from Rybelsus, and \$15.31 billion from Ozempic.

75. Novo Nordisk's global revenues in 2022 were \$3.7 billion from Novolog, \$732 million from Levemir, \$1.49 billion from Tresiba, \$1.97 billion from Victoza, \$449 million from Xultophy, \$1.8 billion from Rybelsus, and \$9.56 billion from Ozempic.

76. Novo Nordisk transacts business in Delaware, targeting Delaware for its products, including the at-issue diabetes medications.

77. Novo Nordisk employs sales representatives throughout Delaware to promote and sell Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, Xultophy, Rybelsus, and Ozempic.

78. Novo Nordisk also directs advertising and informational materials to Delaware physicians, payors, pharmacies, and diabetics for the specific purpose of selling more of the at-issue drugs in Delaware and profiting from the Insulin Pricing Scheme.

79. At all times relevant hereto, in furtherance of the Insulin Pricing Scheme, Novo Nordisk caused its artificially inflated list prices for the at-issue diabetes medications to be published throughout Delaware with the express

knowledge that payment and reimbursement by Delaware diabetics and payors would be based on these prices.

80. During the relevant time period, diabetics and payors in Delaware spent millions of dollars per year out of pocket on Novo Nordisk's at-issue drugs based on Novo Nordisk's artificially inflated list prices.

81. Delaware diabetics and payors paid for all of the Novo Nordisk diabetes medications in Delaware based on the specific inflated prices Sanofi caused to be published in Delaware in furtherance of the Insulin Pricing Scheme.

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

C. PBM Defendants

83. **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 Delaware.

84. CVS Health is registered to do business in Delaware and may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

85. CVS Health, through its executives and employees, including its CEO, Chief Medical Officer, Executive Vice Presidents, Senior Executives in Trade Finance, and Chief Communication Officers, is directly involved in the PBM services and formulary construction related to the Insulin Pricing Scheme that give rise to the State's claims.

86. Throughout the relevant time, CVS Health and its predecessor⁶ have repeatedly, continuously, and explicitly stated that *CVS Health*:

- a. “design[s] pharmacy benefit plans that minimize the costs to the client while prioritizing the welfare and safety of the clients’ members and helping improve health outcomes;”
- b. “negotiate[s] 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;”
- c. “utilize[s] 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 [CVS Health’s] drug lists.”

87. CVS Health publicly represents that CVS Health 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 Delaware, 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).

88. In 2017, CVS Health stated that “*CVS Health* pharmacy benefit management (PBM) strategies reduced trend for commercial clients to 1.9 percent per

⁶ Until 2014, CVS Health was known as “CVS Caremark.” In September 2014, “CVS Caremark Corporation announced that it is changing its corporate name to CVS Health to reflect its broader health care commitment and its expertise in driving the innovations needed to shape the future of health.”

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.”

89. Throughout the relevant time period, the Manufacturer Defendants directly engaged with CVS Health executives in furtherance of the Insulin Pricing Scheme. Each Manufacturer Defendant has an entire team of executives dedicated exclusively to interacting with CVS Health.

90. Manufacturer Defendants have explicitly recognized that effectuating the Insulin Pricing Scheme requires intimacy and connection between the Manufacturer Defendants’ leaders and CVS Health’s leaders in order to align on strategic formulary management initiatives to ensure profitable access.

91. On a regular basis throughout the relevant period, the Manufacturer Defendants’ executive teams—which at times included their CEOs—met with CVS Health executives to discuss their coordinated efforts related to the at-issue drugs.

92. **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.

93. CVS Pharmacy owns and operates pharmacies throughout Delaware that are directly involved in and profit from the Insulin Pricing Scheme.

94. CVS Pharmacy is registered to do business in Delaware and may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

95. In its capacity as a retail pharmacy, CVS Pharmacy, working in conjunction with its corporate affiliate entities, knowingly assisted the CVS Health family in profiting from 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 received from payors (which amounts were based on the artificially inflated list prices and, in many cases, were set by CVS Caremark in its capacity as a PBM).

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

97. During the relevant time period, CVS Pharmacy provided retail pharmacy services in Delaware that gave rise to the Insulin Pricing Scheme, which damaged Delaware diabetics and payors.

98. **Defendant Caremark Rx, LLC** is a Delaware limited liability company, and its principal place of business is at the same location as CVS Pharmacy and CVS Health.

99. Caremark Rx, LLC is a wholly owned subsidiary of Defendant CVS Pharmacy.

100. Caremark Rx, LLC is registered to do business in Delaware and may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

101. During the relevant time period, Caremark Rx, LLC provided PBM and mail order pharmacy services in Delaware that gave rise to the Insulin Pricing Scheme and damaged diabetics and payors in Delaware.

102. **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.

103. Caremark, LLC is registered to do business in Delaware and may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

104. During the relevant time period, Caremark, LLC provided PBM and mail order pharmacy services in Delaware that gave rise to the Insulin Pricing Scheme, which damaged diabetics in Delaware.

105. **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.

106. CaremarkPCS Health, LLC provides pharmacy benefit management services.

107. CaremarkPCS Health, LLC is registered to do business in Delaware and may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

108. During the relevant time period, CaremarkPCS Health, LLC provided PBM services in Delaware, which gave rise to the Insulin Pricing Scheme and damaged diabetics and payors in Delaware.

109. 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 CaremarkPCS Health, LLC, Zinc Health, 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 diabetics in Delaware.

110. 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."

111. CVS Caremark is named as a Defendant in its capacities as a PBM and retail and mail order pharmacy.

112. In its capacity as a PBM, CVS Caremark coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the artificially inflated list prices for the at-issue diabetes medications, the placement of these firms' diabetes medications on CVS Caremark's formularies, and the exclusion of lower priced diabetes medications.

113. 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 over \$150 billion in total revenues last year. CVS Health's revenue increased to over \$350 billion in 2023.

114. At all times relevant hereto, CVS Caremark offered pharmacy benefit services to Delaware payors and diabetics, and derived substantial revenue therefrom, and, in doing so, made the at-issue misrepresentations (discussed below) and utilized the artificially inflated prices generated by the Insulin Pricing Scheme to profit off Delaware diabetics and payors.

115. At all times relevant hereto, CVS Caremark constructed standard formularies that are used nationwide, including by CVS Caremark's payor clients in Delaware and that are relied on by residents in Delaware with diabetes and payors as promoting diabetic health, increasing access to affordable diabetes medications, and lowering the price of the at-issue drugs. During the relevant time period, these standard formularies included drugs produced by the Manufacturer Defendants, including the at-issue diabetes medications.

116. At all times relevant hereto, and contrary to all its express representations, CVS Caremark has insisted that its payor clients, including in Delaware, use the artificially inflated list prices produced by the Insulin Pricing Scheme as the basis for payment and reimbursement for the at-issue drugs.

117. At all times relevant hereto, CVS Caremark has concealed its critical role in the generation of those artificially inflated list prices.

118. In its capacity as a mail order and retail pharmacy, CVS Caremark dispensed the at-issue drugs to Delaware diabetics and received payments from Delaware diabetics and payors based on the artificially inflated prices produced by the Insulin Pricing Scheme and, as a result, damaged Delaware diabetics and payors.

119. In its capacity as a retail pharmacy, CVS Caremark further profited from the artificially-inflated 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 they received from payors (which amounts were based on the artificially-inflated list prices and, in many cases, were set by CVS Caremark in its capacity as a PBM).

120. CVS Caremark purchases drugs produced by the Manufacturer Defendants, including the at-issue diabetes medications, for dispensing through its mail order and retail pharmacies including those located in Delaware.

121. At all times relevant hereto, CVS Caremark had express agreements with Defendants Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid to CVS Caremark and placement on CVS Caremark's standard formularies, as well as agreements related to the Manufacturers' at-issue drugs sold through CVS Caremark's mail order and retail pharmacies, including those located in Delaware.

122. **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.

123. Evernorth is registered to do business in Delaware and may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

124. Evernorth, through its executives and employees 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. For example, during the relevant time period Evernorth's CEO Tim Wentworth was involved in communications with the Manufacturer Defendants related to the at-issue drugs and at-issue Manufacturer Payments.

125. Evernorth's conduct has had a direct effect in Delaware and damaged diabetics in Delaware.

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

127. Throughout the relevant time period, the Manufacturer Defendants directly engaged with Evernorth executives in furtherance of the Insulin Pricing Scheme. Each Manufacturer Defendant has an entire team of executives dedicated exclusively to interacting with Evernorth.

128. Manufacturers recognize that effectuating the Insulin Pricing Scheme requires relationships with the executives between the Manufacturers and Evernorth.

129. On a regular basis throughout the relevant time period, these Manufacturer executive teams—which at times include the CEOs from these companies—met with Evernorth to discuss their coordinated efforts related to the at-issue drugs.

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

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

- a. “[Evernorth] is one of the largest PBMs in North America . . . [and Evernorth] help[s] health benefit providers address access and affordability concerns resulting from rising drug costs while helping to improve healthcare outcomes.”
- b. “[Evernorth] manage[s] the cost of the drug benefit by . . . assist in controlling costs; evaluat[es] drugs for efficacy, value and price to assist[ing] 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] leveraging purchasing volume to deliver discounts to health benefit providers.”
- c. “[Evernorth] 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.”

132. **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 at the same location as Evernorth.

133. Express Scripts, Inc. is registered to do business in Delaware and may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

134. Express Scripts, Inc. is the immediate or indirect parent of pharmacy and PBM subsidiaries that operate throughout Delaware that engaged in the conduct, which gives rise to this Complaint.

135. During the relevant time period, Express Scripts, Inc. was directly involved in the PBM and mail order pharmacy services, which gave rise to the Insulin Pricing Scheme and damaged diabetics and payors in Delaware.

136. **Defendant Express Scripts Administrators, 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.

137. Express Scripts Administrators, LLC is registered to do business in Delaware and may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

138. During the relevant time period, Express Scripts Administrators, LLC provided the PBM services in Delaware discussed in this Complaint that gave rise to the Insulin Pricing Scheme that damaged diabetics and payors in Delaware.

139. **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.

140. Medco is registered to do business in Delaware and may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

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

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

143. Prior to the merger, Medco provided the at-issue PBM and mail-order pharmacy services in Delaware, which gave rise to the Insulin Pricing Scheme and damaged diabetics and payors in Delaware.

144. 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.

145. At the time of the merger, on December 6, 2011, in his testimony before the Senate Judiciary Committee, then CEO of Medco, David B Snow, 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."

146. 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.”

147. **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 at the same location as Evernorth.

148. ESI Mail Pharmacy Service, Inc is registered to do business in Delaware and may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

149. During the relevant time period, ESI Mail Pharmacy Service, Inc. provided the mail order pharmacy services in Delaware discussed in this Complaint, which gave rise to the Insulin Pricing Scheme and damaged diabetics in Delaware.

150. **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.

151. Express Scripts Pharmacy, Inc. is registered to do business in Delaware and may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

152. During the relevant time period, Express Scripts Pharmacy, Inc. provided the mail order pharmacy services in Delaware discussed in this Complaint, which gave rise to the Insulin Pricing Scheme and damaged diabetics and payors in Delaware.

153. Collectively, ESI Mail Pharmacy Service, Inc. and Express Scripts Pharmacy, Inc. are referred to herein as “Express Scripts Pharmacy.”

154. As a result of numerous interlocking directorships and shared executives, Evernorth and Express Scripts, Inc. are directly involved in the conduct of and control Express Scripts Administrators, LLC, Ascent Health, Medco Health Solutions, Inc., ESI Mail Pharmacy Service, Inc., and Express Scripts Pharmacy, Inc.’s operations, management and business decisions related to the at-issue formulary construction, Manufacturer Payments, and mail order pharmacy services to the ultimate detriment of Delaware diabetics.

155. 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.”

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

157. In its capacity as a PBM, Express Scripts coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the artificially inflated list prices for the at-issue diabetes medications, the placement of these firms’ diabetes medications on Express Scripts’ formularies, and the exclusion of lower priced diabetes medications.

158. During the relevant period of this Complaint, Express Scripts controlled 30% of the PBM market in the United States.

159. Express Scripts has only grown larger since the Cigna merger.

160. Express Scripts' annual revenue is over \$100 billion.

161. Express Scripts has approximately 65,000 retail pharmacies in its pharmacy networks, representing over 98% of all retail pharmacies in the nation.

162. At all times relevant hereto, Express Scripts offered pharmacy benefit services, and derived substantial revenue therefrom, in Delaware and provided the at-issue PBM services to numerous payors and diabetics in Delaware.

163. At all times relevant hereto, and contrary to all of their express representations, Express Scripts has insisted that its payor clients, including those in Delaware, use the artificially inflated list prices produced by the Insulin Pricing Scheme as the basis for reimbursement of the at-issue drugs.

164. At all times relevant hereto, Express Scripts has concealed its critical role in the generation of those artificially inflated list prices.

165. At all times relevant hereto, Express Scripts constructed standard formularies that are used nationwide, including by Express Scripts' payor clients in Delaware, and that are relied on by Delaware diabetics and payors as promoting diabetic health, increasing access to affordable diabetes medications, and lowering the price of the at-issue drugs. During the relevant time period, these standard formularies included the at-issue diabetes medications and excluded lower-priced drugs.

166. During certain years when some of the largest at-issue price increases occurred, including in 2013 and 2014, Express Scripts worked directly with OptumRx to obtain Manufacturer Payments on behalf of OptumRx and its clients in exchange

for preferred formulary placement. 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.

167. In its capacity as a mail order pharmacy, Express Scripts dispensed the at-issue drugs to Delaware diabetics and received payments from Delaware diabetics based on the artificially inflated prices produced by the Insulin Pricing Scheme and, as a result, damaged Delaware diabetics.

168. At all times relevant hereto, Express Scripts derived substantial revenue providing mail order pharmacy services in Delaware.

169. Express Scripts purchases drugs produced by the Manufacturer Defendants, including the at-issue diabetes medications, for dispensing through its mail order pharmacies, including in Delaware.

170. At all times relevant hereto, Express Scripts had express agreements with Defendants Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer Payments paid to Express Scripts and placement on Express Scripts’ standard formularies, as well as agreements related to the Manufacturers’ at-issue drugs sold through Express Scripts’ mail order pharmacies, including those located in Delaware.

171. In addition, starting in 2019, Express Scripts contracted with another large PBM, Prime Therapeutics, to (among other things) negotiate Manufacturer

Payments and to provide mail order and specialty pharmacy services for Prime Therapeutics' covered lives.

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

173. UnitedHealth Group, Inc. is registered to do business in Delaware and may be served through its registered agent: United Agent Group Inc., 1521 Concord Pike, Suite 201, Wilmington, Delaware 19803.

174. UnitedHealth Group, Inc. is a diversified managed healthcare company. UnitedHealth Group's revenue was in excess of \$370 billion in 2023, and the company is currently ranked fifth on the Fortune 500 list. UnitedHealth Group, Inc. offers a spectrum of products and services including pharmacy services and pharmacy benefits through its wholly owned subsidiaries.

175. More than one-third of the overall revenues of UnitedHealth Group come from OptumRx and OptumInsight.

176. 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, executives of UnitedHealth Group structure, analyze, and direct the company's overarching, enterprise-wide policies, including PBM and mail-order services, as a means of maximizing profits across the corporate family.

177. 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."

178. On a regular basis throughout the relevant time period, executive teams from each Manufacturer Defendant—including at times their CEOs—met with executives from UnitedHealth Group to discuss their coordinated efforts in furtherance of the Insulin Pricing Scheme.

179. In 2011, UnitedHealth Group aligned its formularies across all their segments (Medicare, commercial and managed care) and moved to one Pharmacy & Therapeutics Committee in 2012. This effort also included tasking OptumRx with negotiating Manufacturer Payments and Manufacturer contracts for all UnitedHealth Group enterprise-wide formularies.

180. UnitedHealth Group's conduct had a direct effect in Delaware and damaged diabetics in Delaware.

181. **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.⁷

182. Optum, Inc. is registered to do business in Delaware and may be served through its registered agent: United Agent Group Inc., 1521 Concord Pike, Suite 201, Wilmington, Delaware 19803.

183. 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 Delaware and damaged diabetics and payors in Delaware.

184. 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." In this role, Optum, Inc. is directly responsible for the "business units – OptumInsight, OptumHealth and OptumRx" 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.

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

⁷ UnitedHealth Group, Annual Report (Form 10-K, Exhibit 21) (Dec. 31, 2018).

186. OptumInsight, Inc. is registered to do business in Delaware and may be served through its registered agent: United Agent Group Inc., 1521 Concord Pike, Suite 201, Wilmington, Delaware 19803.

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

188. OptumInsight Life Sciences, Inc. may be served through its registered agent: United Agent Group, Inc., 1521 Concord Pike Suite 201, Wilmington, Delaware 19803.

189. OptumInsight Life Sciences, Inc. and OptumInsight, Inc are referred to herein as “OptumInsight.”

190. During the relevant time period, due to name changes and mergers, a number of different entities make up what is now known as OptumInsight, including Ingenix, Innovus, i3, QualityMetric, Htanalytics, ChinaGate, CanReg, and the Lewin Group. For the purposes of this Complaint, “OptumInsight” refers to and includes each of these entities.

191. OptumInsight is an integral part of the Insulin Pricing Scheme. During the relevant time period, OptumInsight coordinated with the Manufacturer Defendants in furtherance of the Scheme. OptumInsight compiled and analyzed data and other information from the PBM and Manufacturer Defendants to advise Defendants related to the Insulin Pricing Scheme.

192. Each Manufacturer Defendant has dedicated executives assigned to OptumInsight for the purpose of collaborating with key executives and coordinating with OptumInsight for data acquisition and utilization.

193. The Manufacturers utilize their relationships with OptumInsight to deepen their ties to the overall UnitedHealth Group corporate family. During the relevant time period, OptumInsight provided data and analytics to the Manufacturer Defendants related to the at-issue drugs, including the identity of particular pharmacies selling the most at-issue drugs. The Manufacturers used this data to increase sales in furtherance of the Insulin Pricing Scheme.

194. Manufacturer Defendants also contracted with OptumInsight during the relevant time period.

195. During the relevant time period, OptumInsight partnered with OptumRx to provide the at-issue pharmacy benefit and data and cost analytic services to clients.

196. During the relevant time period, OptumInsight's data collection and analysis included prescription claims data related to Delaware diabetics' and payors' utilization of the at-issue drugs, for use in its data and cost analytics efforts in furtherance of the Insulin Pricing Scheme.

197. **Defendant OptumRx, Inc. (“OptumRx”)** is a California corporation with its principal place of business at 2300 Main St., Irvine, California 92614.

198. OptumRx is registered to do business in Delaware and may be served through its registered agent: United Agent Group Inc., 1521 Concord Pike, Suite 201, Wilmington, Delaware 19803.

199. During the relevant time period, OptumRx, Inc. provided the PBM and mail-order pharmacy services in Delaware that gave rise to the Insulin Pricing Scheme, which damaged diabetics and payors in Delaware.

200. As a result of numerous interlocking directorships and shared executives, UnitedHealth Group is directly involved in the conduct and control of OptumInsight's, Emisar's, and OptumRx's operations, management, and business decisions related to the at-issue formulary construction, negotiations, and mail-order pharmacy services to the ultimate detriment of Delaware diabetics.

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

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

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

204. In its capacity as a PBM, OptumRx coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the artificially inflated list prices for the at-issue diabetes

medications, the placement of these firms' diabetes medications on OptumRx's formularies, and the exclusion of lower priced diabetes medications.

205. OptumRx provides PBM services to more than 65 million people in the nation through a network of more than 67,000 retail pharmacies and multiple delivery facilities.

206. OptumRx and OptumInsight generate over \$200 billion in annual revenue.

207. Prior to 2011, OptumRx was known as Prescription Solutions. In addition, OptumRx rose to power through numerous mergers with other PBMs. For example, in 2012, a large PBM, SXC Health Solutions Corp. bought one of its largest rivals, Catalyst Health Solutions Inc. in a roughly \$4.14 billion deal. Shortly thereafter, SXC Health Solutions Corp. renamed the company Catamaran Corp. Thereafter, OptumRx's parent company, UnitedHealth Group, bought Catamaran Corp. in a deal worth \$12.8 billion and combined Catamaran with OptumRx.

208. Prior to merging with OptumRx (or being renamed), Prescription Solutions, Catalyst Health Solutions, Inc., and Catamaran Corp., were conducting business in Delaware and engaged in the at-issue PBM and mail order activities in Delaware.

209. At all times relevant hereto, OptumRx derived substantial revenue providing pharmacy benefits in Delaware.

210. At all times relevant hereto, and contrary to all their express representations, OptumRx has insisted that its payor clients, including its payor

clients in Delaware, use the artificially inflated list prices produced by the Insulin Pricing Scheme as the basis for reimbursement of the at-issue drugs.

211. At all times relevant hereto, OptumRx has concealed its critical role in the generation of those artificially inflated list prices.

212. At all times relevant hereto, OptumRx offered pharmacy benefit management services nationwide and constructed standard formularies that are used throughout Delaware by payors and diabetics, and that are relied on by Delaware diabetics and payors as promoting diabetic health, increasing access to affordable diabetes medications, and lowering the price of the at-issue drugs. During the relevant time period, these standard formularies included the at-issue diabetes medications and excluded lower priced drugs.

213. In its capacity as a mail order pharmacy, OptumRx dispensed the at-issue drugs to Delaware diabetics and received payments from Delaware diabetics and payors based on the artificially inflated prices produced by the Insulin Pricing Scheme and, as a result, damaged Delaware diabetics.

214. At all times relevant hereto, OptumRx purchased drugs produced by the Manufacturer Defendants, including the at-issue diabetes medications, and dispensed the at-issue medications to diabetics in Delaware through its mail order pharmacies.

215. 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.

216. Collectively, CVS Caremark, OptumRx, and Express Scripts are referred to as “PBM Defendants” or “PBMs.”

217. Collectively, the “PBM Defendants” and the “Manufacturer Defendants” are referred to as “Defendants.”

III. JURISDICTION AND VENUE

218. Jurisdiction of this Court is proper under Article IV, Section 10 of the Delaware Constitution, Section 341 of Title 10 of the Delaware Code, and Section 3104 of Title 10 of the Delaware Code.

219. This Court has personal jurisdiction over Defendants because each Defendant is, or was during the relevant time, incorporated in Delaware and/or registered to do business in Delaware; is transacting or has transacted business in Delaware; is contracting or has contracted to supply services or things in Delaware; has or does derive substantial revenue from Delaware or engages in a persistent course of conduct in Delaware; and/or caused tortious injury in Delaware and has intentionally engaged in conduct aimed at Delaware, which has caused harm they knew was likely to be incurred in Delaware. Each Defendant has sufficient contacts with Delaware to give rise to the current action, has continuous and systematic contacts with Delaware, or has consented either explicitly or implicitly to the jurisdiction of this Court. The Insulin Pricing Scheme has been directed at, and has had the foreseeable and intended effect of, causing injury to consumers residing in, located in, or doing business in Delaware.

220. All of the at-issue transactions occurred in Delaware, involved Delaware diabetics, payors, and consumers, or both.

221. Venue is proper in this Court because, at all times relevant to this Verified Complaint, Defendants have engaged in acts, practices, methods, uses, solicitation and conduct described below that violate the CFA and the DTPA in the State of Delaware and purposefully availed itself of this forum.

IV. FACTUAL ALLEGATIONS

A. Diabetes and Insulin Therapy

1. Diabetes: A growing epidemic

222. Diabetes is a disease that occurs when a person's blood glucose, also called blood sugar, is too high. In a non-diabetic person, the pancreas secretes the hormone insulin, which controls the rate at which food is converted to glucose, or sugar, in the blood. When there is not enough insulin or cells stop responding to insulin, too much blood sugar stays in the bloodstream. Over time, that can cause serious health problems, such as heart disease, vision loss, and kidney disease.

223. There are two basic types of diabetes. Roughly 90-95% of diabetics developed the disease because they do not produce enough insulin or have become resistant to the insulin their bodies do produce. Known as Type 2, this form of diabetes is often developed later in life. While Type 2 patients can initially be treated with tablets and other medications, in the long term most patients have to switch to insulin injections.

224. Type 1 diabetes occurs when a patient completely ceases insulin production. In contrast to Type 2 patients, people with Type 1 diabetes do not produce any insulin and, without regular injections of insulin, they will die.

225. Insulin and other diabetic treatments are a necessary part of life for those who have diabetes, and interruptions to a diabetic's medication regimen can have severe consequences. Missed or inadequate therapy can trigger hyperglycemia and then diabetic ketoacidosis. Left untreated, diabetic ketoacidosis can lead to loss of consciousness and death within days.

226. The number of Americans with diabetes has exploded in the last half century. In 1958, only 1.6 million people in the United States had diabetes. By the turn of the century, that number had grown to over 10 million. Fourteen years later, the count tripled again. Now nearly 40 million people—10% of the country—live with the disease.

227. Likewise, the prevalence of diabetes in Delaware has been steadily increasing. Approximately 112,000 residents of Delaware are now living with diabetes, and an additional 130,000 Delaware residents have prediabetes.

228. The burden of diabetes is not equally distributed. Diabetes is significantly more prevalent in impoverished regions; nearly 1 in 4 individuals who earn less than \$25,000 a year have diabetes.

2. Insulin: A century old drug

229. Despite its potentially deadly impact, diabetes is a highly treatable illness. For patients who are able to follow a prescribed treatment plan consistently, the health complications associated with the disease are avoidable.

230. Unlike many high-burden diseases, treatment for diabetes has been available for almost a century.

231. 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 to \$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.”

232. 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.

233. Although early iterations of insulin were immediately perceived as lifesaving, there have been numerous incremental improvements since its discovery. The earliest insulin was derived from animals and, until the 1980s, was the only treatment for diabetes.

234. 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.

235. Over a decade later, Defendant Eli Lilly developed the first analog insulin, Humalog, in 1996.

236. 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.

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

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

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

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

241. Even though insulin was first extracted nearly one hundred (100) years ago, only Defendants Eli Lilly, Novo Nordisk, and Sanofi manufacture insulin in the United States.

242. Many of the at-issue diabetes medications are now off patent. However, due in large part to their ability to stifle all competition, Manufacturer Defendants make 99% of the insulins in the market today.

3. Current diabetes medication landscape

243. While insulin today is generally safer and more convenient to use than when originally developed in 1922, there remain questions as to whether the overall efficacy of insulin has significantly improved over the last twenty (20) years.

244. 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.

245. A recent study published in the Journal of American Medical Association suggests that older human insulins may work just as well as newer analog insulins for patients with Type 2 diabetes.

246. When discussing the latest iterations of insulins, Harvard Medical School professor David Nathan recently stated:

I don't think it takes a cynic such as myself to see most of these [insulins] are being developed to preserve patent protection. The truth is they are marginally different, and the clinical benefits of them over the older drugs have been zero.

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

248. Dr. Kasia Lipska, a Yale researcher and author of a 2018 study in the Journal of the American Medical Association on the cost of insulin, explained:

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.

249. Nor have the production or research and development costs increased. In fact, in the last 10 years, the production costs of insulin have decreased as manufacturers simplified and optimized processes. A September 2018 study published in *BMJ Global Health* calculated that, based on production costs, a reasonable price for a year's supply of human insulin is \$48 to \$71 per person and between \$78 and \$133 for analog insulins—which includes delivering a profit to manufacturers.

250. Another recent study noted anecdotal evidence that the Manufacturers could be *comfortably profitable charging under \$2 a vial.*

251. These figures stand in stark contrast to the \$5,705 that a diabetic spent, on average, for insulin in 2016. Indeed, Americans must sometimes travel to different countries entirely to acquire affordable insulin.

252. Further, while research and development costs often make up a large percentage of the price of a drug, in the case of insulin the initial basic research—original drug discovery and patient trials—was performed 100 years ago.

253. Even the more recent costs, such as developing the recombinant DNA fermentation process and the creation of insulin analogs, were incurred by the Manufacturers decades ago.

254. Today, Manufacturer Defendants only spend a fraction of the billions of dollars in revenue they generate from the at-issue drugs on research and development.

255. Despite this decrease in production costs and no new research and development, the reported price of the at-issue drugs has risen astronomically over the last 15 years.

4. Insulin adjuncts: Type 2 medications

256. Over the past fifteen years, Manufacturer Defendants have also released a number of non-insulin medications that have become critically important for millions of diabetics in their efforts to manage their disease.

257. In 2010, Novo Nordisk released Victoza as an adjunct to insulin to improve glycemic control. In 2014, Eli Lilly released a similar drug, Trulicity. Sanofi did the same with Soliqua in 2016, and, in 2017, Novo Nordisk did the same with Ozempic. Eli Lilly released Mounjaro in 2022.

258. Victoza, Trulicity, Ozempic, and Mounjaro are all medications known as glucagon-like peptide-1 receptor agonists (“GLP-1”) and are similar to the GLP-1 hormone that is already 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.

259. Like insulins, the list prices that the Manufacturers set for their GLP-1 drugs are completely untethered from the extremely low costs to manufacture these drugs. For example, in March 2024 a study conducted by a team of researchers from Yale University, King’s College Hospital in London, and Boston-based Harvard Medical School found that GLP-1s and other Type 2 diabetes medications, including those at-issue in this Complaint, could be manufactured for between 89 cents and

\$4.73 per month. Notably, these “cost-based” estimates both for GLP-1s and insulins are based on manufacturing costs plus a profit margin with an allowance for tax.

260. Despite the fact that the Manufacturers could profitably price their GLP-1 drugs at under \$5 a month, they nonetheless charge nearly \$1000 (or more) a month for these drugs.

261. Today, Manufacturer Defendants have a dominant position in the market for all diabetes medications. The following is a list of diabetes medications at issue in this lawsuit:

Table 1: Diabetes medications at issue in this case

Insulin Type	Action	Name	Company	FDA Approval
Human	Rapid-Acting	Humulin R	Eli Lilly	1982
		Humulin R 500	Eli Lilly	1994
		Novolin R	Novo Nordisk	1991
	Intermediate	Humulin N	Eli Lilly	1982
		Humulin 70/30	Eli Lilly	1989
		Novolin N	Novo Nordisk	1991
		Novolin 70/30	Novo Nordisk	1991
Analog	Rapid-Acting	Humalog	Eli Lilly	1996
		Novolog	Novo Nordisk	2000
		Apidra	Sanofi	2004
	Long-Acting	Lantus	Sanofi	2000
		Levemir	Novo Nordisk	2005
		Basaglar	Eli Lilly	2016
		Toujeo	Sanofi	2015
		Tresiba	Novo Nordisk	2015
Type 2 Medications	GLP-1s	Trulicity	Eli Lilly	2014
		Mounjaro	Eli Lilly	2022
		Victoza	Novo Nordisk	2010
		Ozempic	Novo Nordisk	2017
		Xultophy	Novo Nordisk	2016
		Rybelsus	Novo Nordisk	2019
		Soliqua	Sanofi	2016
		Adlyxin	Sanofi	2016

B. The Dramatic Rise in the Price of Diabetes Medications

1. Diabetes medication price increases

262. In 2003, PBMs began their rise to power (which will be discussed in greater detail in the next section).

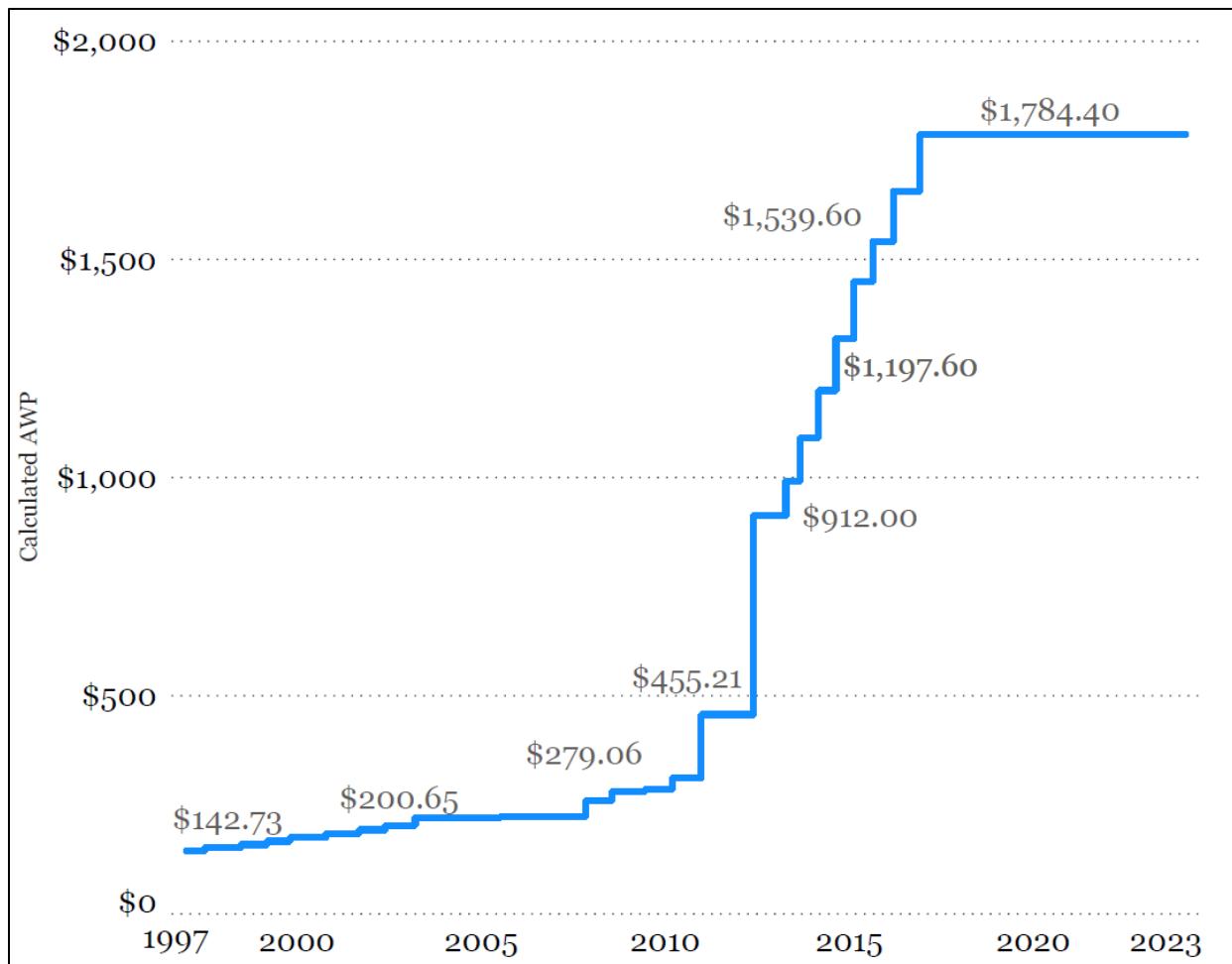
263. That same year, the price of diabetic treatments began its dramatic rise to its current exorbitant level.

264. Since 2003, the list price of certain insulins has increased in some cases by more than 1000%.

265. By 2016, the average price per month of the four most popular types of insulin rose to \$450 — and costs continue to rise, so much so that now one in four diabetics are skimping on or skipping lifesaving doses. This behavior is dangerous to a diabetic's health and can lead to a variety of complications and even death.

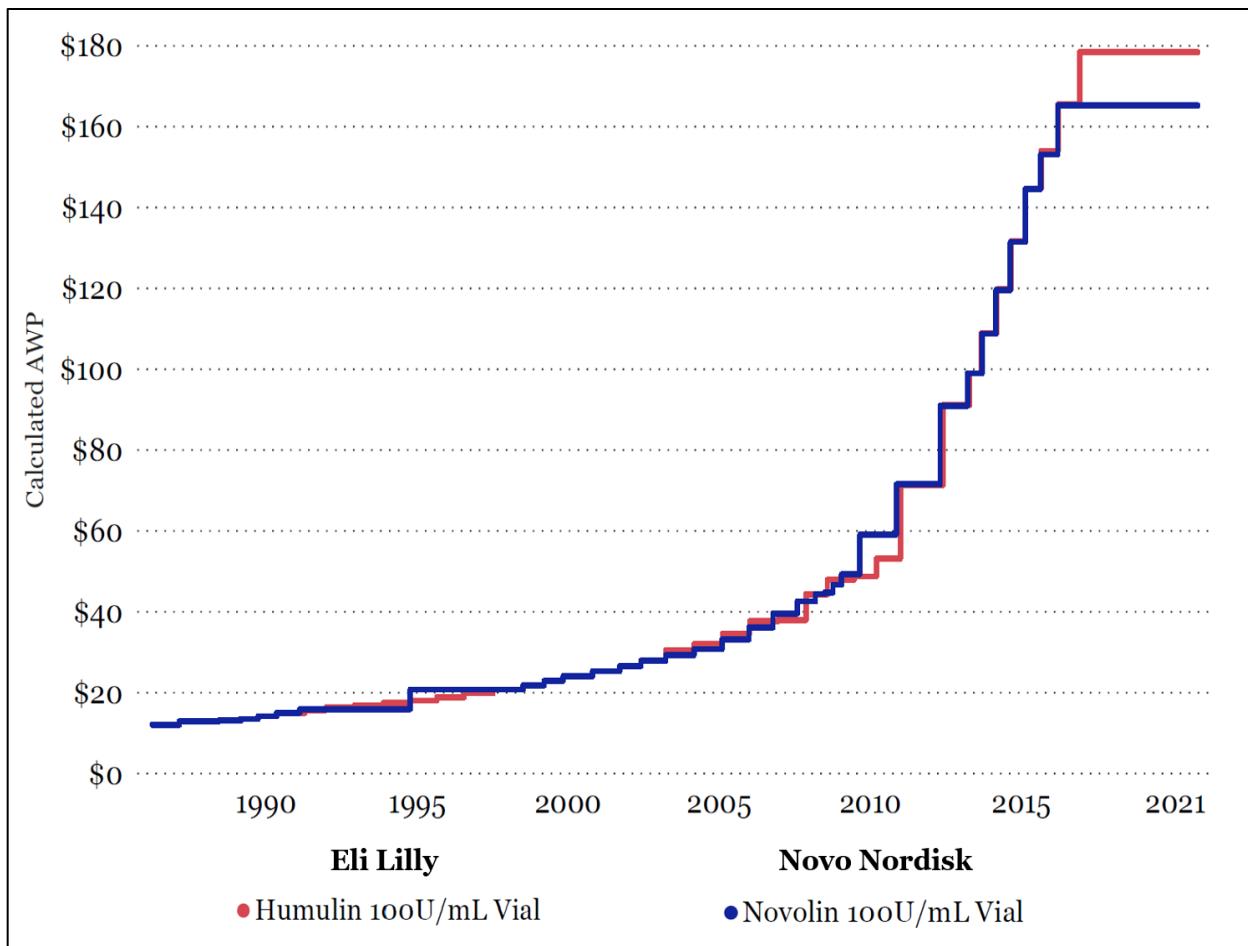
266. Since 1997, Defendant Eli Lilly has artificially inflated the list price of a vial of Humulin R (500U/ML) from \$165 to \$1784 (*See Figure 1*).

**Figure 1: Rising list prices of Humulin R (500U/mL) Vial
1997 –2023**



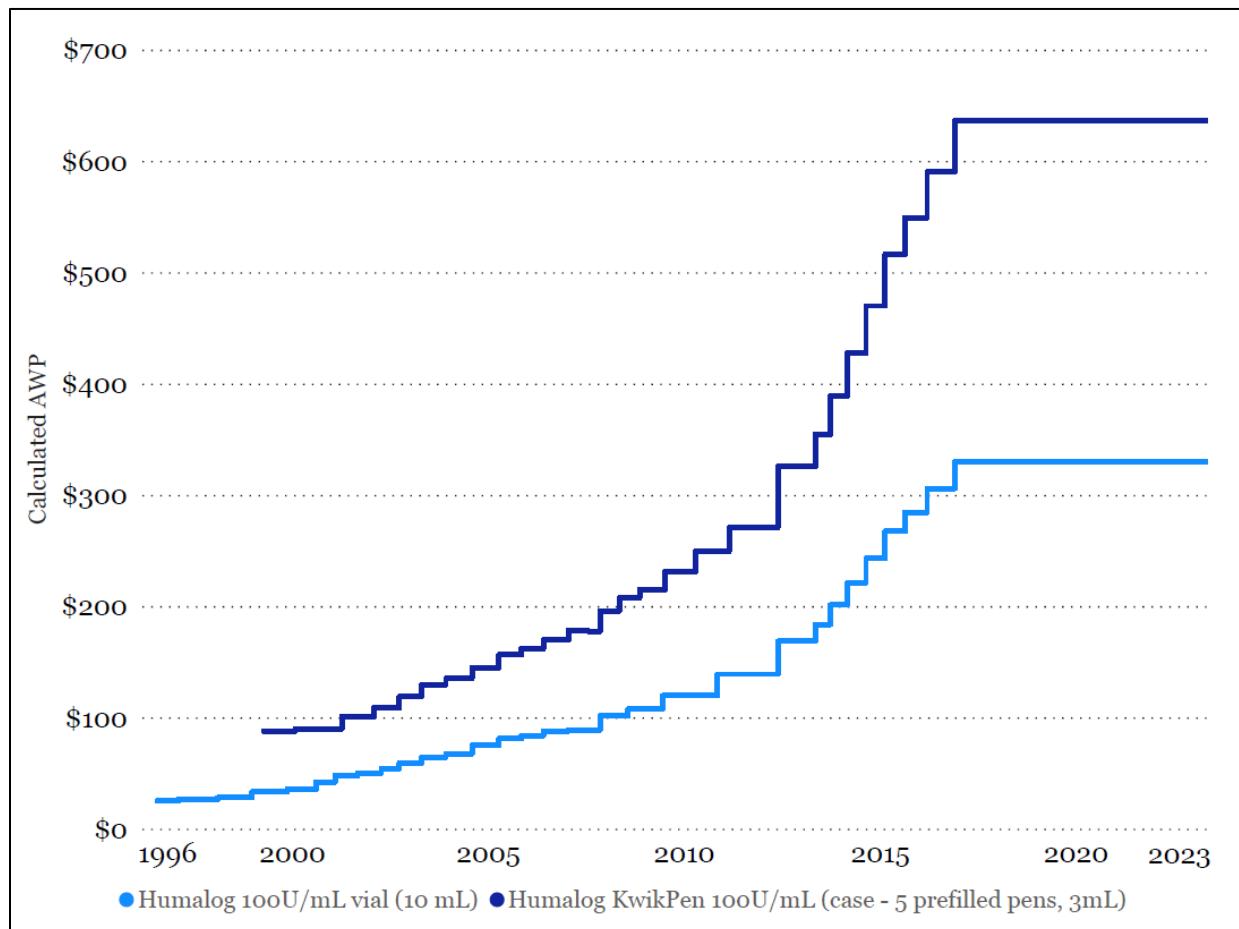
267. Since the early 2000s, both Eli Lilly and Novo Nordisk have substantially increased the prices for their human insulins, Humulin and Novolin.

Figure 2: Rising list price increases for human insulins



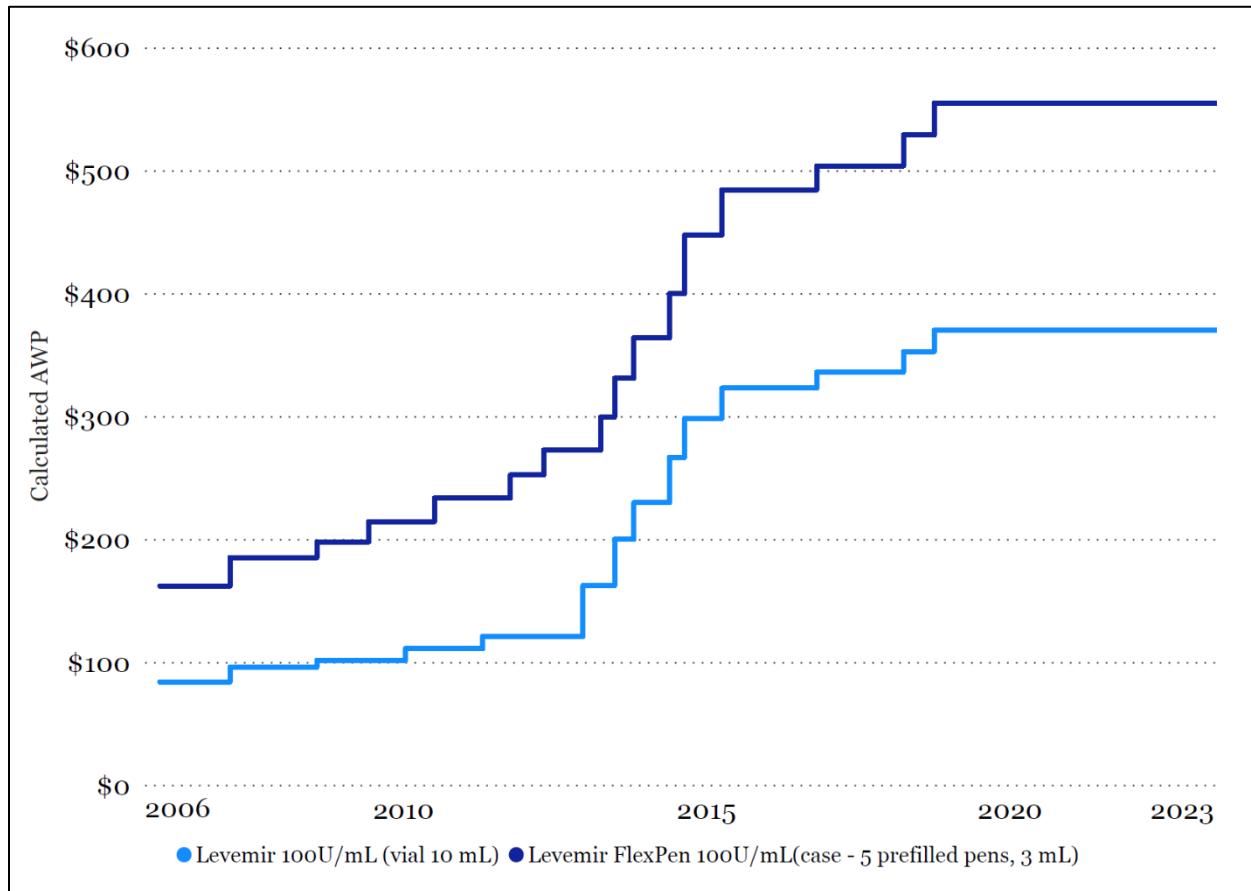
268. Since 1996, Defendant Eli Lilly has artificially inflated the list price for a package of pens of Humalog from less than \$100 to \$663 and from less than \$50 for a vial to \$342 (See Figure 3).

**Figure 3: Rising list prices of Humalog vials and pens
1996 –2023**



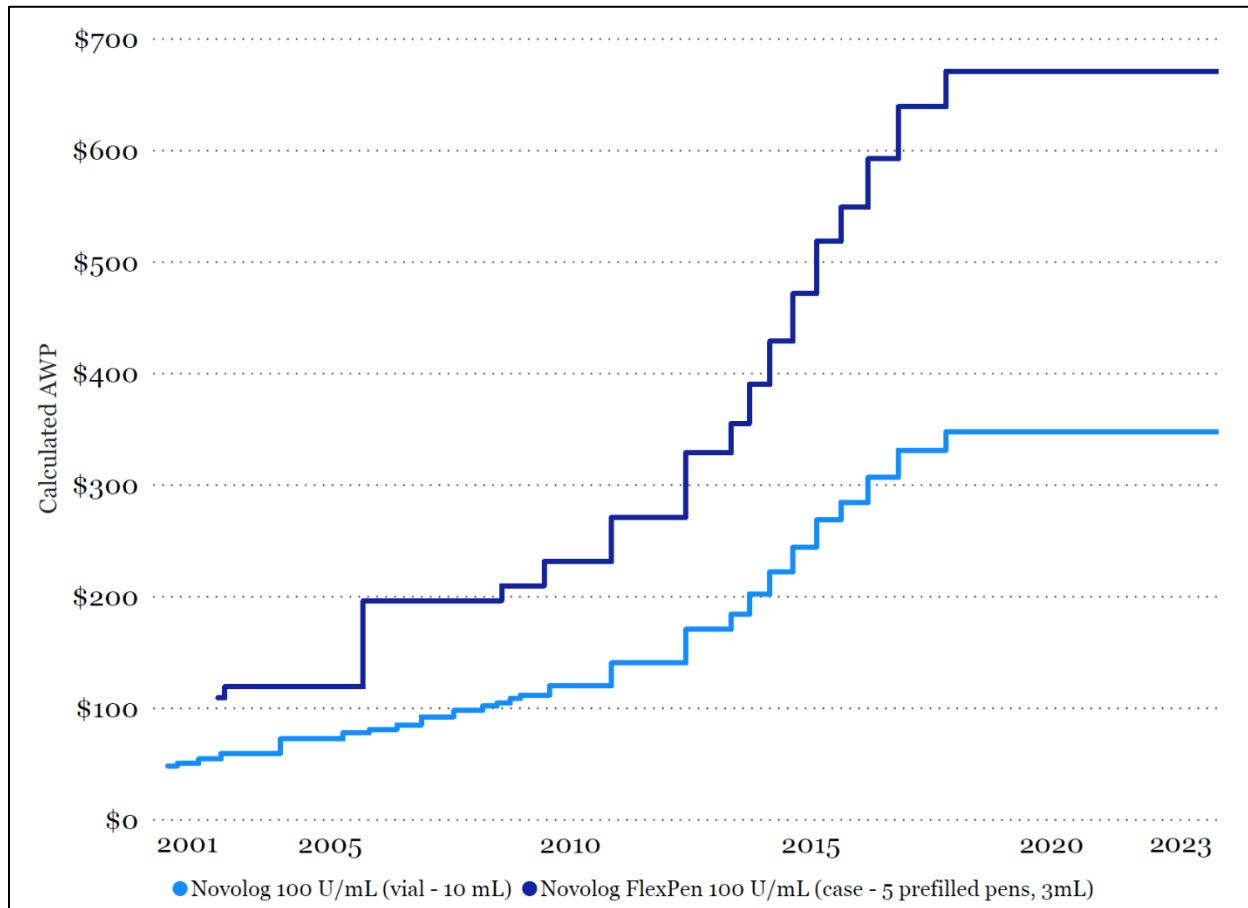
269. Novo Nordisk has also artificially inflated list prices. Since 2006, Levemir rose from \$162 to \$555 for pens and from under \$100 to \$370 per vial (See Figure 4).

**Figure 4: Rising list prices of Levemir
2006 –2023**



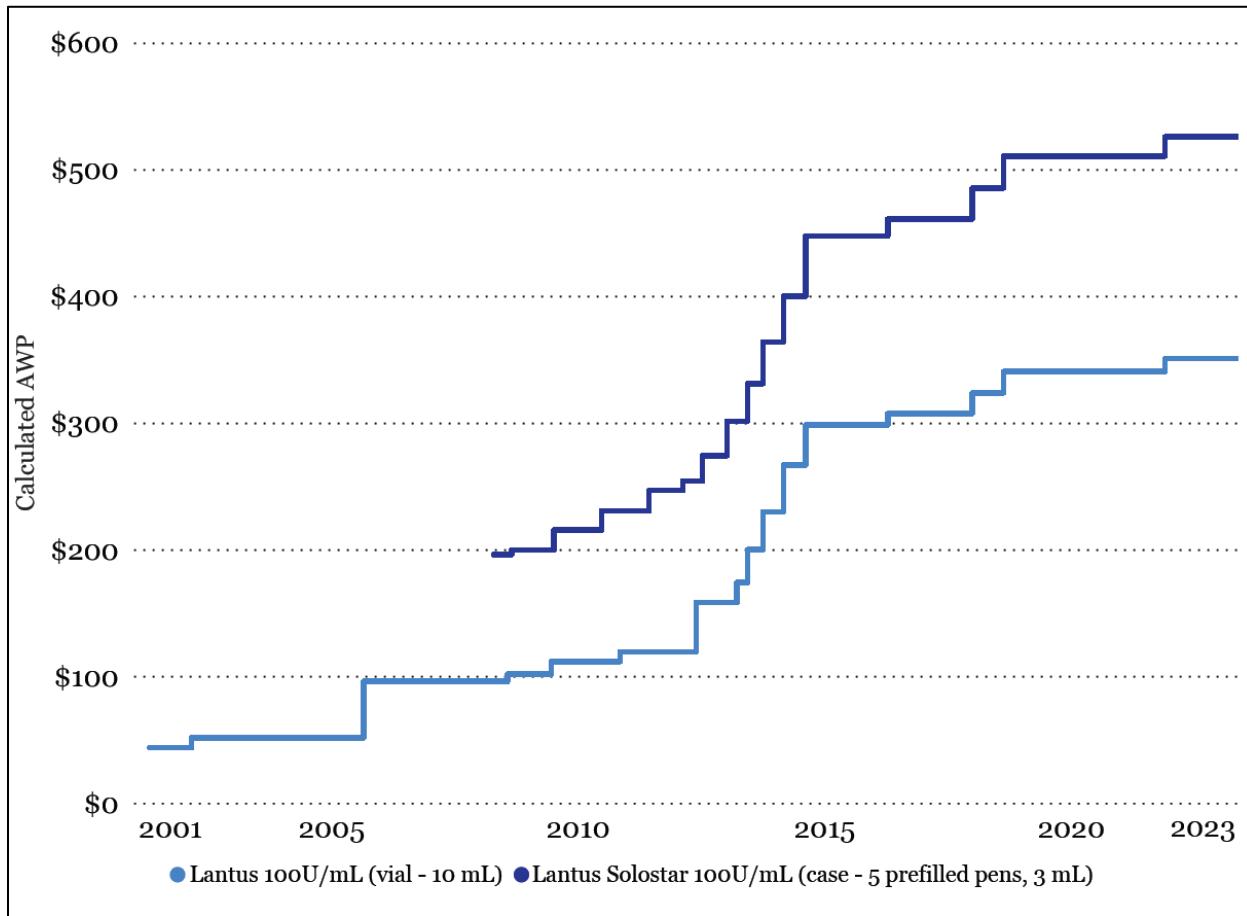
270. From 2002 to 2023, Novo Nordisk has artificially inflated the list price of Novolog from \$108 to \$671 for a package of pens and from less than \$50 to \$347 for a vial (See Figure 5).

**Figure 5: Rising list prices of Novolog vials and pens
2001 –2023**



271. Defendant Sanofi has kept pace as well, artificially inflating the list price for Lantus, the top-selling analog insulin, from less than \$200 in 2006, to over \$500 in 2023 for a package of pens and from less than \$50 to \$340 for a vial (See Figure 6).

**Figure 6: Rising list prices of Lantus vials and pens
2001 –2023**



272. The timing of the list price increases reveal that each Manufacturer Defendant has not only dramatically increased prices for the at-issue diabetes treatments, but they have also done so in perfect lockstep.

273. In thirteen (13) instances since 2009, competitors Sanofi and Novo Nordisk raised the list prices of their insulins, Lantus and Levemir, in tandem, taking the same price increase down to the decimal point within a few days of each other.

274. This practice of increasing drug prices in lockstep with competitors is known as “shadow pricing” and, as healthcare expert Richard Evans from SSR Health recently stated, “is pretty much a clear signal that your competitor does not intend to price-compete with you.”

275. In 2016, Novo Nordisk and Sanofi’s lockstep increases for the at-issue drugs were responsible for the highest drug price increases in the entire pharmaceutical industry.

276. Eli Lilly and Novo Nordisk have engaged in the same lockstep behavior with respect to their rapid-acting analog insulins, Humalog and Novolog. Figure 7 demonstrates these price increases with respect to Lantus and Levemir. Figure 8 demonstrates this behavior with respect to Novolog and Humalog.

Figure 7:
Rising list prices of long-acting insulins
from 2006-2021

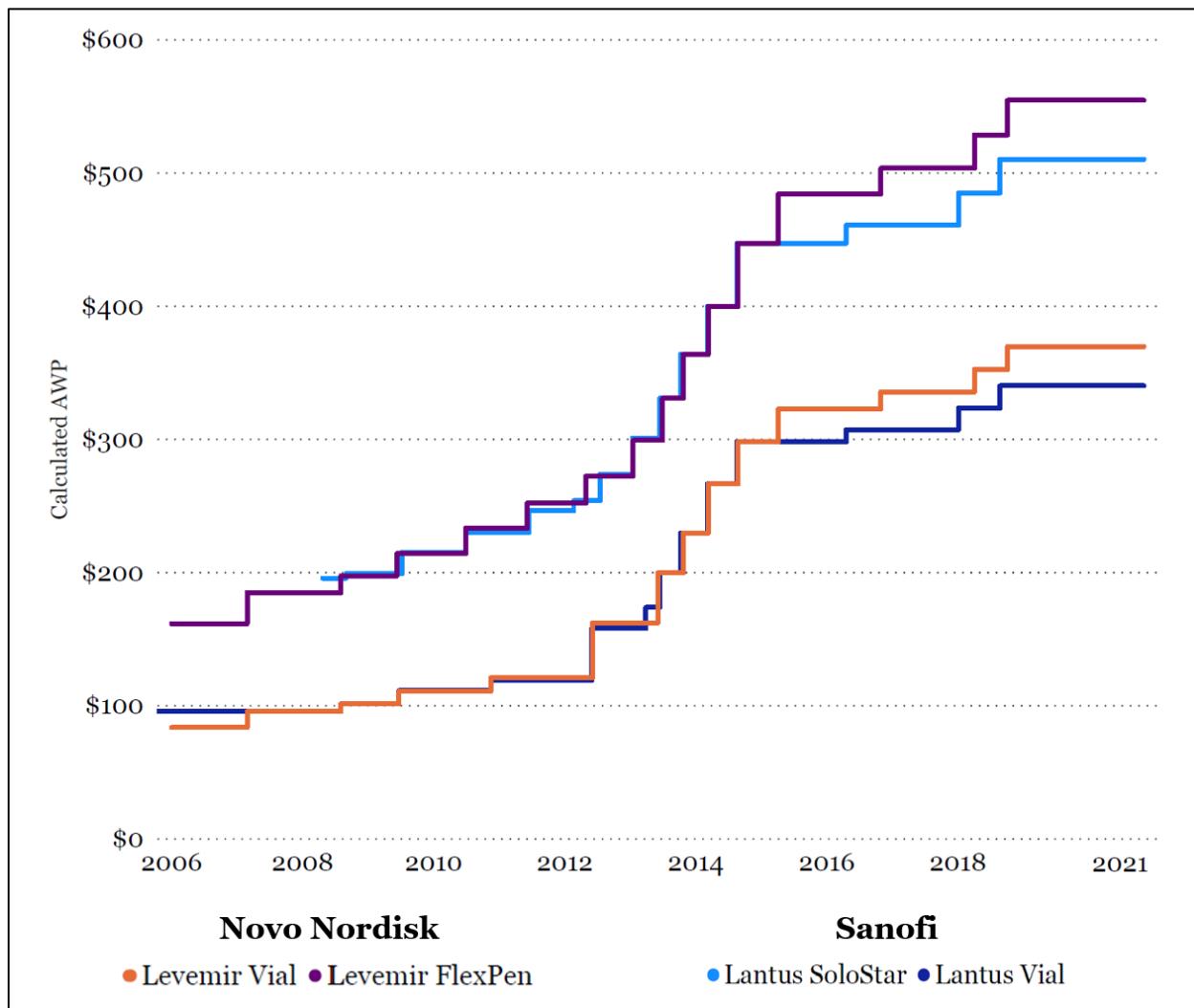
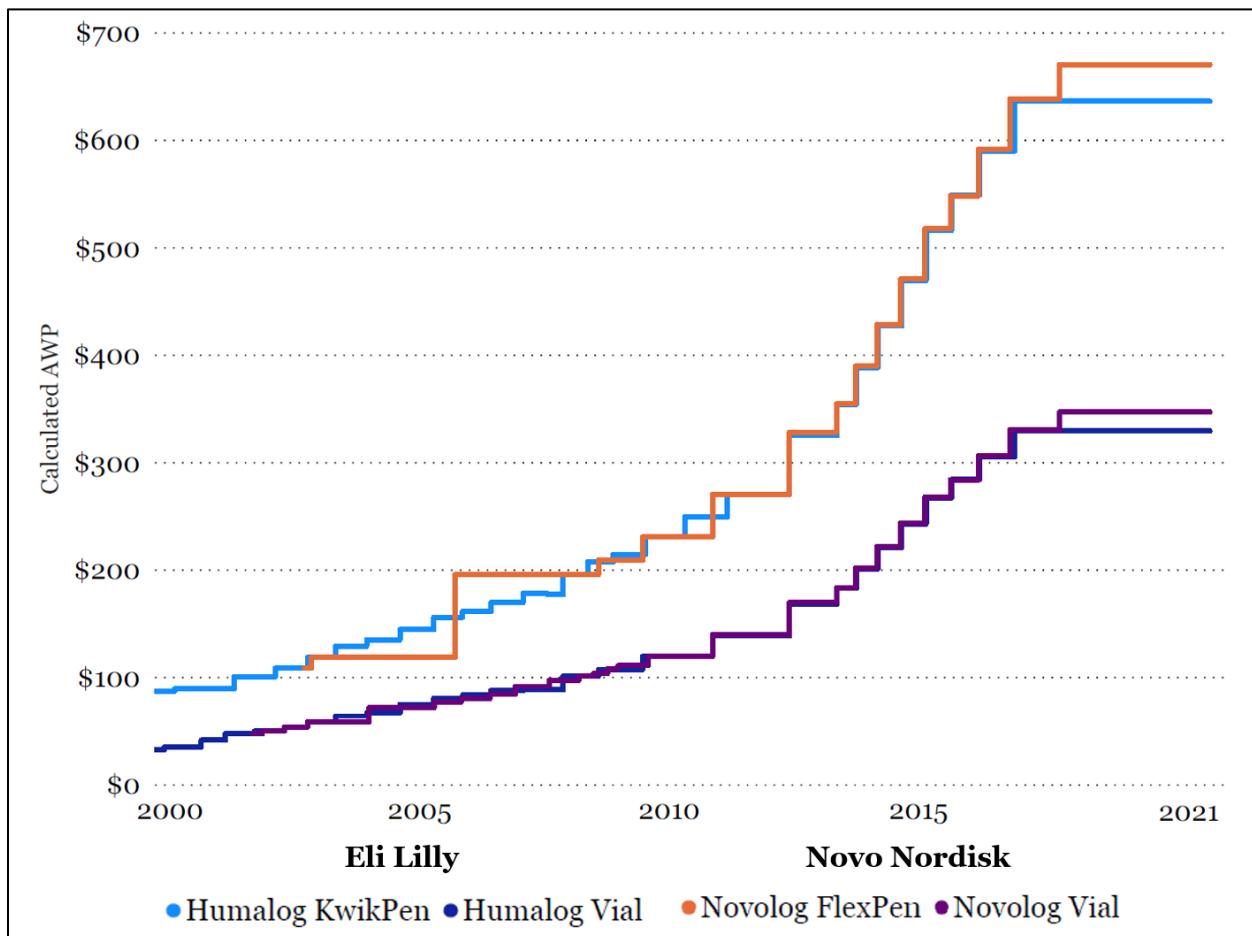
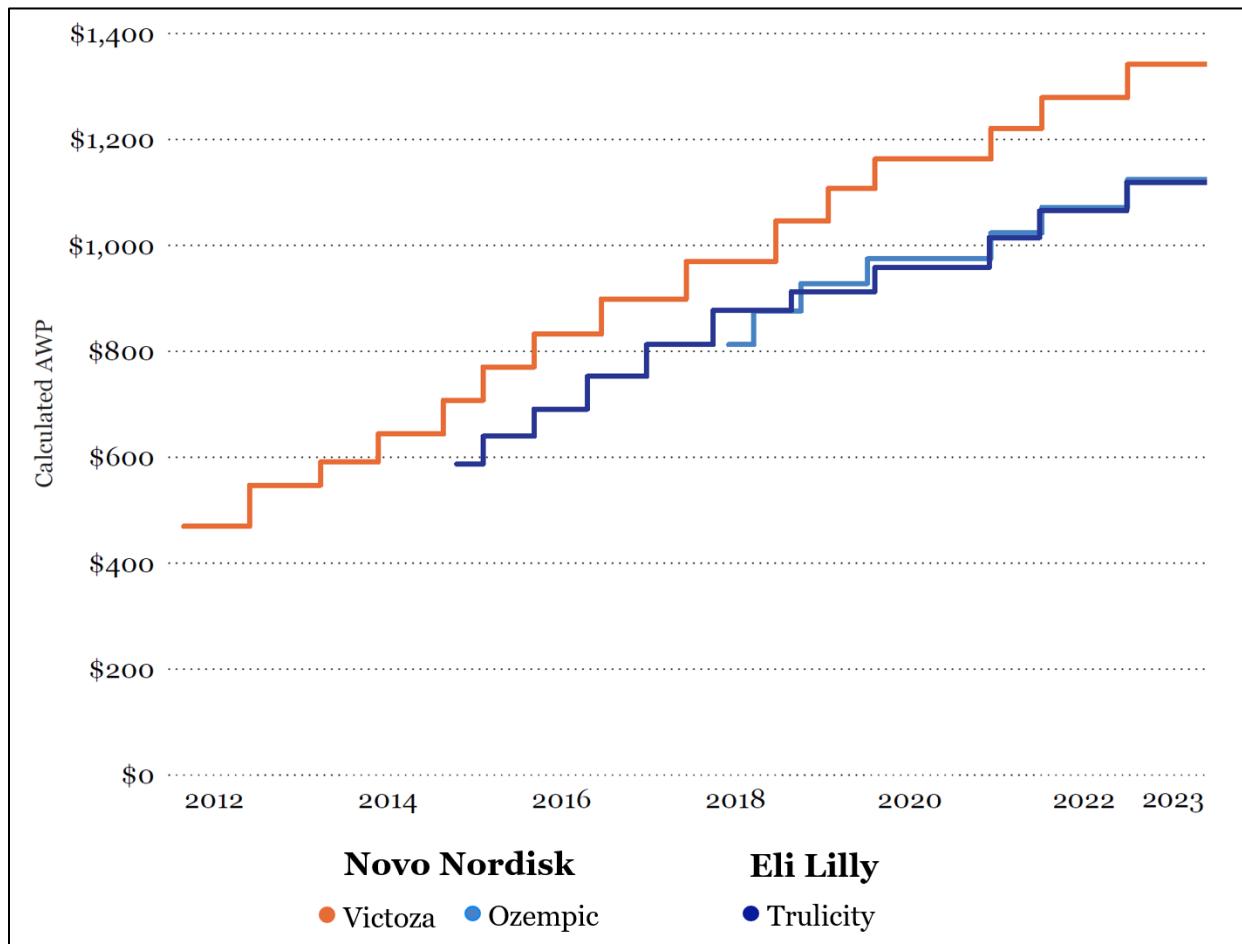


Figure 8:
Rising list prices of rapid-acting insulins
from 2000-2021



277. Manufacturer Defendants' non-insulin diabetes medications have experienced similar and exorbitant price increases. For example, since the release of their GLP-1 drugs, Eli Lilly and Novo Nordisk have more than tripled the prices of Victoza, Ozempic, and Trulicity.

Figure 9: Rising list prices of Type 2 drugs



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

C. Pharmaceutical Payment and Supply Chain

279. The prescription drug industry consists 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, pharmacy benefit managers, and patients.

280. Generally speaking, branded prescription drugs, such as the at-issue diabetes medications, are distributed in one of two ways: (1) from manufacturer to wholesaler, wholesaler to pharmacy and pharmacy to patient; or (2) from manufacturer to mail order pharmacy to patient.

281. 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: different actors pay different prices set by different entities for the same drugs. The unifying factor is that the price that almost every entity in the pharmaceutical chain pays for a drug is directly tied to manufacturer's list price.

282. The PBMs ensure there is no transparency in this pricing system and that all of their clients' and patients' payments are tied to the "list prices," typically wholesale acquisition cost ("WAC"), or average wholesale price ("AWP").

283. Manufacturers set the WAC price. Even though the WAC name implies that it is the price that wholesalers pay for drugs, that is not true in practice. After chargebacks and other discounts, wholesalers pay substantially less than the WAC price.

284. Drug manufacturers self-report list prices to publishing compendiums such as First DataBank, Redbook and others who then publish the prices.

285. AWP prices are either set by the manufacturer and then reported to publishing compendiums or are calculated by the publishing compendium based on the WAC price and then published. AWPs are set at generally 20% greater than WAC.

286. PBMs use AWP prices to set the amount that their payor clients pay for prescription drugs.

287. Notwithstanding their knowledge that list prices are disconnected from actual transaction costs, the PBM Defendants insist that their clients make payments for the at-issue drugs based on list prices. Even while PBM Defendants have more accurate pricing available, they persist in requiring AWP to be used by payors and patients.

288. As a direct result of Defendants' conduct, their misleading, unfair, and deceptive list prices persist as the most commonly and continuously used prices in reimbursement and payment calculations and negotiations for all payors.

289. Notably, the Manufacturer Defendants are not required to report or publish only WAC and/or AWP list prices. Nothing prevents them from publishing their net prices, but they choose not to in furtherance of the Scheme.

290. Moreover, the PBM Defendants are not required to use list prices to set the prices paid by their clients and diabetics.

291. Rather, the PBM Defendants continue to perpetuate the use of list prices as the backbone of their contracts with their clients and pharmacies because it opens the door to unchecked profitability—through Manufacturer Payments and pharmacy spread pricing (discussed in detail below).

1. Drug Costs for Diabetics

292. Whether insured or not, all Delaware diabetics pay a substantial part of their diabetic drug costs based on the misleading and deceptive list prices generated by the Insulin Pricing Scheme.

293. Uninsured diabetics must pay the full, point-of-sale prices (based on the artificial prices generated by the Insulin Pricing Scheme) every time they fill their prescriptions. In Delaware, approximately 65,000 Delaware residents are uninsured. Approximately 18% of uninsured people are diabetic. As a direct result of the Insulin Pricing Scheme, the prices uninsured Delaware residents with diabetes pay for the at-issue life-sustaining drugs has skyrocketed over the last fifteen years.

294. The uninsured are not the only patients saddled with high costs. Insured diabetics also often pay a significant portion of a drug's price out-of-pocket including in deductibles, coinsurance requirements, and/or copayment requirements based on the artificially inflated list prices generated by the Insulin Pricing Scheme.

295. Thus, nearly all Delaware diabetics have been damaged by having to pay for diabetes medications out-of-pocket based upon the specific artificially inflated prices generated by the Insulin Pricing Scheme.

296. In addition, these exorbitant indefensible out-of-pocket costs created by the Insulin Pricing Scheme make it more difficult for patients to adhere to their medications, resulting in avoidable complications and higher overall healthcare costs. An American Diabetes Association 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."

297. As executives from the PBM Defendants have explicitly recognized, lack of adherence drives up costs for Delaware diabetics, payors, and the healthcare system.

298. On May 10, 2023, the Senate Health, Education, Labor, and Pensions (HELP) Committee held a hearing entitled “The Need to Make Insulin Affordable for All Americans” (“2023 Senate Hearing”) (discussed in greater detail below).

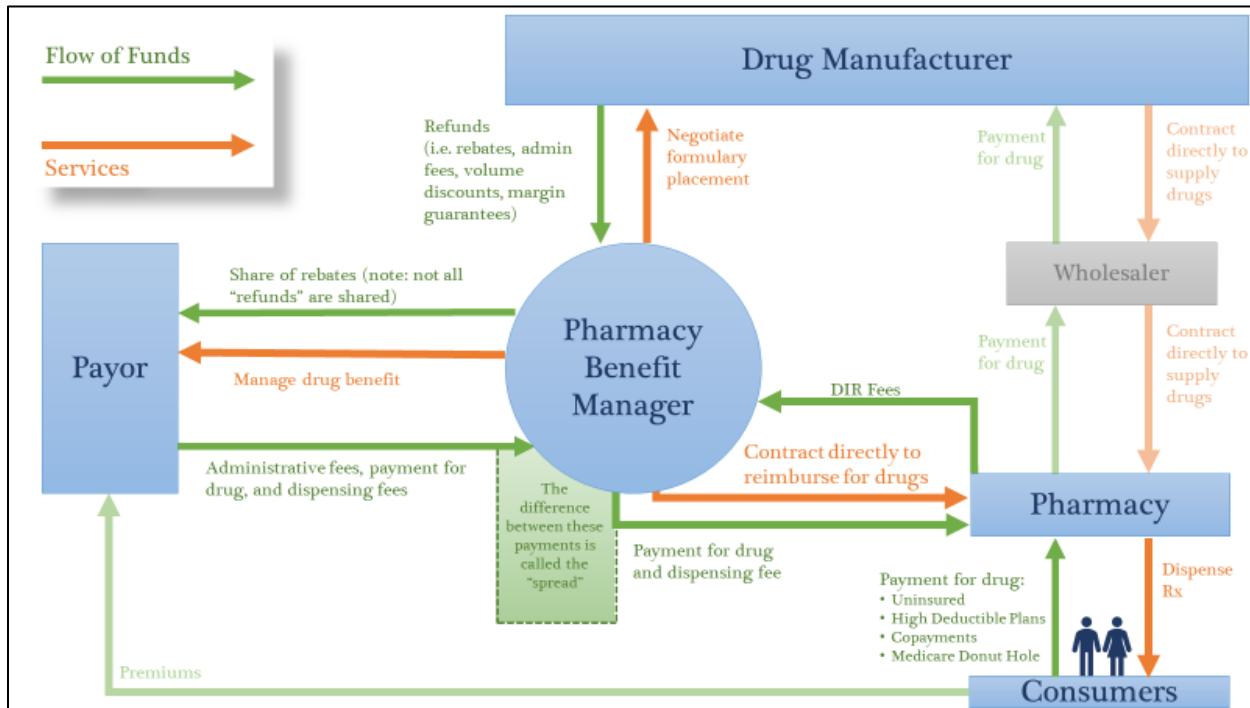
299. President of CVS Caremark, David Joyner stated in his opening statement at the 2023 Senate Hearing, “When people can afford their medications, like insulin, they are more likely to adhere to prescribed therapies. Adherence means better outcomes; better outcomes mean the health care system will spend far less on complications and hospitalizations.”

300. The overall economic impact from the loss of productivity and increased healthcare costs that result from diabetics underdosing their medications has been deeply damaging to the State.

2. PBMs' role in the pharmaceutical payment chain

301. PBMs are at the center of the convoluted pharmaceutical payment chain, as illustrated in Figure 10:

Figure 10: Diabetes drug distribution and payment chain



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

303. The PBM Defendants provide services to both payors and consumers by administering prescription drug benefits. As CVS Caremark explains to consumers through its welcome kit: "We manage your prescription drug benefits just like your health insurance company manages your medical benefits."

304. The PBM Defendants have consumer-facing websites representing that they "serve" consumers and that consumers are their "members."

305. The PBM Defendants further represent that giving consumers access to necessary prescription drugs at an affordable price is a top priority.

306. PBMs also contract with a network of retail pharmacies, including those pharmacies that are affiliated with the PBM Defendants. Pharmacies agree to dispense drugs to patients and pay fees back to the PBMs. PBMs reimburse pharmacies for the drugs dispensed.

307. PBM Defendants also own mail-order, retail and specialty pharmacies, which purchase and take possession of prescription drugs, including those at-issue here, and directly supply those drugs to patients.

308. Often times—including for the at-issue drugs—the PBM Defendants purchase drugs from the Manufacturers and dispense them to the patients.

309. Even where PBM Defendant's pharmacies purchase drugs from wholesalers, their costs are set by direct contracts with the Manufacturers.

310. In addition, and of particular significance here, PBM Defendants contract with pharmaceutical manufacturers, including Manufacturer Defendants.

311. These relationships allow PBMs to exert tremendous influence over what drugs are available throughout Delaware and at what prices.

312. Thus, PBMs are at the center of the flow of money in the pharmaceutical supply chain. In sum:

- a. PBMs negotiate the price that payors pay for prescription drugs (for the at-issue drugs based on artificially inflated prices generated by the Insulin Pricing Scheme);
- b. they separately negotiate a different (and often lower) price that pharmacies in their networks receive for that same drug;
- c. they set the amount in fees that the pharmacy pays back to the PBM for each drug sold (for the at-issue drugs based on artificially inflated prices generated by the Insulin Pricing Scheme);

- d. they set the amount of out-of-pocket payments paid by diabetics (often based on artificially inflated prices generated by the Insulin Pricing Scheme);
- e. they set the price paid for each drug sold through their mail order pharmacies (for the at-issue drugs based on artificially inflated prices generated by the Insulin Pricing Scheme); and
- f. they determine the amount of Manufacturer Payments that the Manufacturers pay back to the PBM for each drug sold (for the at-issue drugs based on artificially inflated prices generated by the Insulin Pricing Scheme).

313. For the majority of these transactions, only the PBMs are privy to the amount that any other entity in this pricing chain is paying or receiving for the exact same drugs.

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

3. The rise of the PBMs in the pharmaceutical supply chain

315. When they first came into existence in the 1960s, PBMs functioned largely as claims processors. Over time, however, they have taken on a larger and larger role in the pharmaceutical industry. Today, PBMs wield significant control over the drug pricing system.

316. One of the roles PBMs took on was negotiating with drug manufacturers ostensibly on behalf of payors and patients.

317. In the early 2000s, PBMs started buying pharmacies.

318. When a PBM combines with a pharmacy, it has increased incentive to collude with Manufacturers to keep certain prices high.

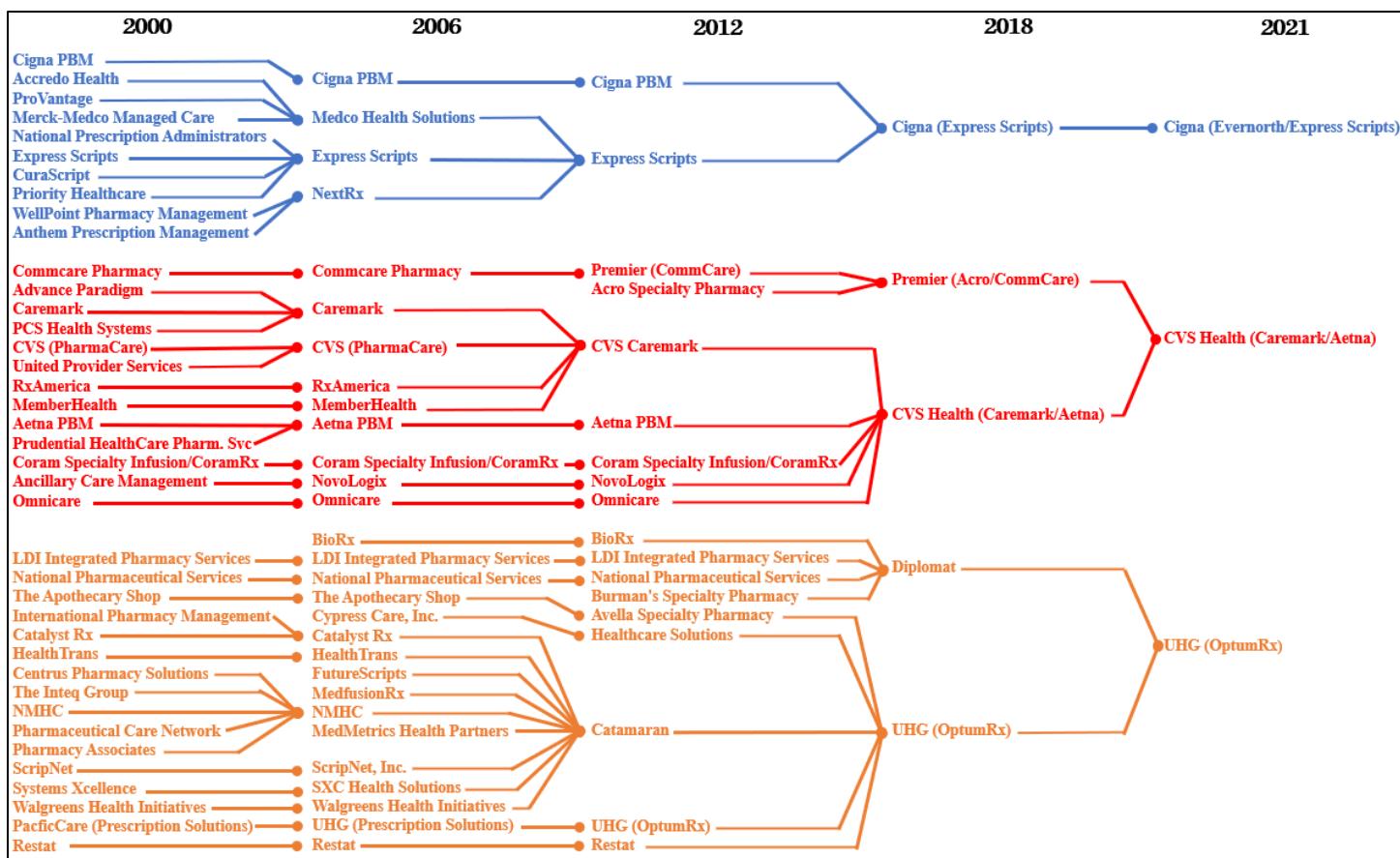
319. These perverse incentives still exist today with respect to both retail and mail order pharmacies housed within the PBMs' corporate families.

320. More recently, further consolidation in the industry has afforded PBMs a disproportionate amount of market power.

321. In total, nearly 40 different PBM entities have merged or otherwise been absorbed into what are now the PBM Defendants.

322. Figure 11 depicts this consolidation within the PBM market.

Figure 11: PBM consolidation



323. After merging or acquiring all their competitors and now backed by multi-billion-dollar corporations, PBM Defendants have taken over the market in the

past decade—controlling over 80% of the market and managing pharmacy benefits for over 270 million Americans.

324. Importantly, PBM Defendants have near *complete* control over the Manufacturer Payment market, given that in addition to their own clients' members (which represent 80% of the market), most smaller pharmacy benefit managers—including the largest pharmacy benefit manager in the United States outside the PBM Defendants, Prime Therapeutics—contract with the PBM Defendants (or their controlled affiliate rebate aggregator companies also referred to as group purchasing organizations) to negotiate Manufacturer Payments on behalf of their members as well.

325. Business is booming for PBM Defendants. Together, they report more than \$300 billion in annual revenue.

326. PBMs are able to use the consolidation in the market as leverage when negotiating with other entities in the pharmaceutical pricing chain. Last year, industry expert Lindsay Bealor Greenleaf from the Advice and Vision for the Healthcare Ecosystem (ADVI) consulting firm described this imbalance in power, “it’s really difficult to engage in any type of fair negotiations when one of the parties has that kind of monopoly power . . . I think that is something that is going to continue getting attention, especially as we see more of these payors and PBMs continue to try to further consolidate.”

4. Insular nature of the pharmaceutical industry

327. The insular nature of the PBM and pharmaceutical industry has provided PBM Defendants with ample opportunity for contact and communication

amongst themselves, as well as with Manufacturer Defendants, in order to devise and agree to the Insulin Pricing Scheme.

328. Each Manufacturer Defendant is a member of the Pharmaceutical Research and Manufacturers of America (“PhRMA”) and has routinely communicated through PhRMA’s meetings and platforms in furtherance of the Insulin Pricing Scheme.

329. David Ricks, CEO of Eli Lilly, Paul Hudson, CEO of Sanofi, and Douglas Langa, Executive Vice President of Novo Nordisk, are all members of the PhRMA board of directors and/or PhRMA executive leadership team.

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

331. Each year during the relevant time period, the main PBM trade association, the Pharmaceutical Care Management Association (“PCMA”), held several yearly conferences, including its Annual Meeting and its Business Forum conferences.

332. The board of the PCMA has included executives from all Defendants, including: David Joyner (chairman), Executive Vice President and President, Pharmacy Services, at CVS Health Corp.; Dr. Patrick Conway, CEO of OptumRx; Adam Kautzner, President of Express Scripts; Heather Cianfrocco, CEO of OptumRx; John Prince, President and COO of Optum, Inc. and former CEO of OptumRx; Jon Roberts, Executive Vice President and COO of CVS Health Corp.; Amy Bricker, Chief

Product Officer of CVS Health Corp. (and former President of Express Scripts); Alan Lotvin, Executive Vice President of CVS Health Corp. and President of CVS Caremark; and Tim Wentworth, CEO of Evernorth and Express Scripts.

333. All PBM Defendants are members of and, because of their leadership positions, control the PCMA. Each Manufacturer Defendant is an affiliate member of this organization.

334. The PCMA annual conferences appear to be at the center of the Insulin Pricing Scheme.

335. Every year, high-level representatives and corporate officers from both PBM and Manufacturer Defendants attend these conferences to meet in person to discuss their shared business opportunities within the pharmaceutical industry. Defendants also have used these conferences to engage in private meetings in furtherance of the Insulin Pricing Scheme.

336. In fact, for at least the last six years, all of the Manufacturer Defendants have been “Presidential Sponsors” of these PBM conferences.

337. 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.”

338. Representatives from each Manufacturer Defendant regularly meet privately with representatives from each PBM Defendant during both the Annual Meetings and Business Forum conferences that the PCMA holds each year.

339. Prior to these meetings, dedicated teams of executives from each Defendant spend weeks preparing PCMA “pre-reads” and reports in preparation for these meetings. These reports not only demonstrate the deep involvement of each Defendant in the Insulin Pricing Scheme, but they also reflect the tangled web that gave rise to the Scheme.

340. In addition, all PCMA members, affiliates and registered attendees of these conferences are invited to join PCMA-Connect, “an invitation-only LinkedIn Group and online networking community.” PCMA-Connect provides PBM and Manufacturer Defendants with a year-round, non-public online forum to engage in private discussions in furtherance of the Insulin Pricing Scheme.

341. Notably, key price increases occurred shortly after the Defendants met at PCMA meetings. For example, on September 26 and 27, 2017 the PCMA held its annual meeting where each of the Manufacturer Defendants and PBM Defendants engaged in meetings. Several days after the conference, on October 1, 2017, Sanofi increased Lantus’s list price by 3% and Toujeo’s list price by 5.4%. A few weeks later Novo Nordisk recommended that the company make a 4% list price increase on January 1, 2018, to match the Sanofi increase, which was approved Nov 3, 2017.

342. Likewise, on May 30, 2014, Novo Nordisk raised the list price of Levemir several hours after Sanofi increased its list price on Lantus, and this occurred only a

few weeks after a PCMA spring conference in Washington, D.C. attended by representatives from all the PBM Defendants.

343. Further, the PBMs control the PCMA and have weaponized it to further their interests and to conceal the Insulin Pricing Scheme. The PCMA has brought numerous lawsuits and lobbying campaigns aimed at blocking PBM and drug pricing transparency efforts. including 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.

D. The Insulin Pricing Scheme

344. The market for the at-issue diabetes medications is unique in that it is highly concentrated with, until recently, little to no generic/biosimilar options and the drugs have similar efficacy and risk profiles. In fact, PBMs treat the at-issue drugs as commodity products in constructing their formularies.

345. In such a market, where manufacturing costs have significantly decreased, PBMs should have great leverage in negotiating with the Manufacturer Defendants to drive prices down in exchange for formulary placement.

346. But the PBMs do not want the prices for diabetes medications to go down because they make more money on higher prices. So do the Manufacturers.

347. As a result, Defendants have found a way to game the system for their mutual benefit—the Insulin Pricing Scheme.

348. PBM Defendants’ formularies are at the center of the Insulin Pricing Scheme. Given the asymmetry of information and disparity in market power between payors and patients and PBM Defendants and the costs associated with making

formulary changes, most payors and patients accept the standard formularies offered by the PBMs.

349. Manufacturer Defendants recognize that because PBM Defendants have such a dominant market share, if they chose to exclude a particular diabetes medication from their standard formularies, or give it a non-preferred position, it could mean billions of dollars in profit loss for Manufacturer Defendants.

350. For example, Olivier Brandicourt, Sanofi's Chief Executive Officer, in a recent interview stressed the importance of the PBMs' standard formularies: "if you look at the way [CVS Caremark] is organized in the U.S . . . 15 million [lives] are part of [CVS Caremark's standard] formulary and that's very strict, all right. So, [if we were not included in CVS Caremark's standard formulary] we wouldn't have access to those 15 million lives."

351. Manufacturer Defendants also recognize that the PBM Defendants' profits are directly tied to the Manufacturers' list prices. For example, the January 2021 Senate Insulin Report noted this in summarizing the 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 . . . In other words, the drug makers were aware that higher list prices meant higher revenue for PBMs.

352. The documents released by the Senate contemporaneously with the January 2021 Senate Insulin Report further corroborate the degree to which the Manufacturers' pricing strategy is focused 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.

353. Because the Manufacturer Defendants know that—contrary to their public representations—PBM Defendants make more money from *higher* prices, over the course of the last fifteen years and working in coordination with the PBMs, the Manufacturers have artificially inflated their list prices for the at-issue drugs exponentially, while maintaining their net prices, by paying larger and larger amounts of Manufacturer Payments back to the PBMs.

354. Starting in 2011, the PBMs began constructing and implementing exclusionary formularies which accelerated the insulin price increases.

355. As a result, during the last fifteen years the amount of Manufacturer Payments paid to the PBMs has increased substantially. For example, the January 2021 Senate Insulin Report found that:

In July 2013, Sanofi offered rebates between 2% and 4% for preferred placement on CVS Caremark's commercial formulary. Five years later, in 2018, Sanofi rebates were as high as 56% for preferred formulary placement. 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% for Lantus for preferred formulary placement on their client's commercial formulary, compared to just 42% in 2015. Similarly, Novo Nordisk

offered Express Scripts rebates up to 47% for Levemir for preferred formulary placement on their client’s commercial formulary, compared to 25% in 2014.

356. Beyond increased rebate demands, the PBMs have also requested and received larger and larger administrative fee payments from the Manufacturers during the relevant time period. 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.

357. The value of these rebates and administrative fees to the PBMs was highlighted during a May 10, 2023 Congressional Hearing before the Senate Health, Education, Labor, and Pensions (HELP) Committee, where Defendants testified entitled “The Need to Make Insulin Affordable for All Americans” (“2023 Senate Hearing”).

358. During the 2023 Senate Hearing the executives from the Manufacturer Defendants testified that \$0.75 to \$0.84 of every dollar spent on the list price of insulin goes directly to PBMs and their affiliated rebate aggregators—despite the rising out-of-pocket costs to diabetics.

359. In exchange for the Manufacturer Defendants inflating these prices and paying the PBMs substantial amounts in Manufacturer Payments, PBM Defendants grant Manufacturer Defendants’ diabetes medications with the most elevated price and that are the most profitable to the PBMs preferred status on their standard formularies.

360. At all times relevant hereto the PBM Defendants have known that the list prices for the at-issue drugs are grossly inflated. Indeed, the Manufacturers' list prices have become so untethered from the Manufacturers' net prices⁸ as to constitute unlawful prices.

361. Despite this knowledge, PBMs include the artificially inflated list price—often the AWP price—in their contracts as a basis to set the rate that payors and patients pay for the at-issue drugs and pharmacies are reimbursed for the at-issue drugs.

362. Moreover, the PBMs also use the artificially inflated list 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.” Likewise, in April 2019, CVS Caremark President and Executive Vice President of CVS Health Corp. 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.”

363. The PBM Defendants also misrepresent the amount of “savings” they can generate for their prospective payor clients.

⁸ “Net Price” refers to the Manufacturers’ list price minus all Manufacturer Payments paid to the PBMs.

364. In making these misrepresentations, the PBMs fail to disclose that the amount of “savings” they have generated is calculated based on the artificially inflated list prices, which are not paid by any entity in the pharmaceutical pricing chain and which the PBMs are directly responsible for inflating.

365. The PBM Defendants are not only favoring higher list price/higher Manufacturer-Payment drugs on their formularies, they also are excluding (or disadvantaging) lower priced diabetes drugs from their formularies. And because the PBM Defendants control 80% of the market, that means the PBM Defendants are cutting off or restricting access to affordable diabetic treatments for 80% of the diabetics and payors in Delaware.

366. One example of this was discussed at the 2023 Senate Hearing, involving the insulin drug Semglee. In July 2021, the FDA designated Semglee as interchangeable with Lantus, meaning that Semglee could be substituted for Lantus at the pharmacy without the doctor writing a new prescription. In the 2023 Senate Hearings, Senator Susan Collins detailed how the drug manufacturer Viatris released Semglee at a 65% lower list price to Lantus but was nonetheless excluded from the PBM Defendants’ formularies. Several years later, Viatris rereleased the exact same product, this time at a much higher list price (only 5% lower than Lantus); this time, the PBM Defendants allowed Semglee onto many of their formularies.

367. In addition, the global strategic consulting company, Xcenda, put out a report in May 2022 titled “Skyrocketing growth in PBM formulary exclusions continues to raise concerns about patient access” that found:

Exclusions, potentially driven in part by misaligned [PBM Defendant] incentives, have had an extensive impact on patients' access to insulin over the study period. Lower list-priced insulins have been available since 2016—including follow-on insulins, “authorized generic” insulins, and, more recently, biosimilar insulins. However, [the PBM Defendants] often exclude these insulins from their formularies in favor of products with higher list prices and larger rebates. For example, 2 of the 3 [PBM Defendants] have excluded the 2 insulin authorized generics from their formulary exclusion lists since 2020, instead favoring the higher list-priced equivalents. Remarkably, this was true even though the list prices for these authorized generic insulins can be half the list price of the brand. In addition to the exclusions of authorized generic insulins, lower list-priced biosimilar insulins have also faced formulary exclusions. The first biosimilar insulin was launched in 2021. Due to prevailing market dynamics, 2 identical versions of the product were simultaneously introduced—one with a higher list price and large rebates and one with a lower list price and limited rebates—giving payers the option of which to cover. All 3 PBMs excluded the lower-list priced version in 2022, instead choosing to include the identical product with a higher list price.

368. Further, in July 2024 the Federal Trade Commission released its Interim Staff Report related to its investigation of the PBM Defendants titled, “Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies” (“FTC Interim PBM Report”). In the Report, the FTC shared “evidence that [the PBM Defendants] and brand pharmaceutical manufacturers sometimes enter agreements to exclude generic drugs and biosimilars from certain formularies in exchange for higher rebates from the manufacturers.”

369. Two months later, on September 20, 2024, the FTC brought action against PBM Defendants and their affiliated rebate aggregators (Ascent, Emisar, Zinc) for engaging in “unfair rebating practices that have artificially inflated the list price of insulin drugs, impaired patients' access to lower list price products, and

shifted the cost of high insulin list prices to vulnerable patients (referred to herein as the Insulin Pricing Scheme)."

370. Importantly, the non-public internal materials produced by Defendants and relied upon by the FTC, reveal that the Insulin Pricing Scheme is a coordinated effort between the Manufacturer and PBM Defendants, that each agreed to and participated in and that created enormous profits for all Defendants. For example:

- a. Manufacturers and PBMs are in constant communication and regularly meet and exchange information to construct and refine the PBM formularies that 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 determining the same for competing products;
- b. Manufacturers and 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 pharmacy claims (retail and mail-order), internal medical efficacy studies and financial data. Defendants then use this information in coordination to set the misleading and deceptive prices for the at-issue medications and 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
- c. Manufacturers and PBMs engage in coordinated outreach programs directly to patients, pharmacies and prescribing physicians to convince them to switch to the at-issue 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 January 2021 Senate Insulin Report 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.⁹ 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."

371. Far from using their prodigious bargaining power to lower drug prices as they claim, Defendants use their dominant positions to work together to generate billions of dollars of profit at the expense of Delaware diabetics.

E. Defendants' Congressional Testimony

372. On April 10, 2019, the United States House of Representatives Committee on Energy and Commerce held a hearing on Defendants' Insulin Pricing Scheme titled, "Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin."

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

374. Representatives from each Defendant explicitly admitted that the price that diabetics have to pay out-of-pocket for insulin is too high. For example:

- a. Dr. Sumit Dutta, Chief Medical Officer of OptumRx 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."

⁹ "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.

- b. 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.”
- c. 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 . . .”
- d. 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 . . .”
- e. 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.”

375. Notably, none of the testifying Defendants claimed that the significant increase in the price of insulin was related to competitive factors such as increased costs or improved clinical benefit.

376. None of the Defendants pointed to any other participant in the pharmaceutical pricing chain as responsible for the exorbitant price increases for these diabetes medications—nor could they—for these Defendants collectively are solely responsible for the price of almost every single vial of insulin sold in the United States.

377. At the April 2019 Congressional hearing, Novo Nordisk's President, Doug Langa, explained Novo Nordisk's and PBM Defendants' role in perpetuating the "perverse incentives" of the Insulin Pricing Scheme:

[T]here is this perverse incentive and misaligned incentives (in the insulin pricing system) 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 spend almost \$18 billion in rebates in 2018 . . . [I]f we eliminate all the rebates . . . we would be in jeopardy of losing [our formulary] positions. (Emphasis added).

378. Eli Lilly, too, has 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 to secure [formulary position] . . . \$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 [formulary position].

379. Sanofi has also conceded its participation in the Insulin Pricing Scheme. When testifying at the April 2019 Congressional hearing, Kathleen Tregoning, Executive Vice President for External Affairs of Sanofi, testified:

The rebates are 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.

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

381. Amy Bricker, then President of Express Scripts, 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 [payments] for exclusive [formulary] position . . .”

382. While all Defendants acknowledged their participation in the Insulin Pricing Scheme before Congress, in an effort to avoid culpability each Defendant group pointed the finger at the other as the responsible party.

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

384. This statement is objectively false. The Manufacturers’ price increases are a direct reflection of the PBMs’ coordinated requests for larger Manufacturer Payments. A February 2020 study by the Leonard D. Schaeffer Center for Health Policy & Economics at the University of South California titled “The Association Between Drug Rebates and List Prices,” found that an increase in the amount that the Manufacturers pay back to the PBMs is directly correlated to an increase in prices—on average, a \$1 increase in Manufacturer Payments is associated with a \$1.17 increase in price—and that reducing or eliminating Manufacturer Payments could result in lower prices and reduced out-of-pocket expenditures.

385. In addition, in a report the National Community Pharmacists Association estimated that Manufacturer Payments add nearly 30 cents per dollar to the price consumers pay for prescriptions.

386. Further, in large part because of the increased list prices, and related Manufacturer Payments, PBMs profit per prescription has grown exponentially over the same time period that prices for the at-issue drugs have been increasing. By way of example, since 2003 Defendant Express Scripts has seen its profit increase over 500 percent per adjusted prescription.

387. The Manufacturers, on the other hand, argued before Congress that the PBMs were to blame for high drug prices because of their demands for higher Manufacturer Payments in exchange for formulary placement.

388. However, that also is not true. For example, a 2020 study from the Institute of New Economic Thinking titled, “Profits, Innovation and Financialization in the Insulin Industry,” demonstrates that Manufacturer Defendants are still making substantial profits from the sale of diabetes products regardless of any Manufacturer Payments they are sending back to the PBMs. During the same time period when diabetes medication price increases were at their steepest, distributions to Manufacturers’ shareholders in the form of cash dividends and share repurchases totaled *\$122 billion*. In fact, during this time period the Manufacturers spent a significantly lower proportion of profits on research and development compared to shareholder payouts.

389. Indeed, over the past 3 years, each Manufacturer has conducted billions of dollars in stock buybacks. For example, in 2021 Eli Lilly was authorized to conduct \$5 billion in stock buybacks over the course of 2 years.

390. The January 2021 Senate Insulin Report concluded, *inter alia*:

- a. Manufacturer Defendants are retaining 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;
- b. Manufacturer Defendants have aggressively raised the list price of their insulin products absent significant advances in the efficacy of the drugs; and
- c. 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. From 2016 to 2020, Novo Nordisk spent approximately \$29 billion on stock buybacks and shareholder dividend payouts while only spending approximately \$12 billion on R&D costs.

391. As discussed above, on May 10, 2023, at the 2023 Senate Hearing, Defendants again testified before Congress and each Defendant group once again blamed the other.

392. For example, Paul Hudson, CEO of Sanofi, said during the hearing: “Today, there are just three payors in the system that cover 80% of American lives . . . These consolidated entities encompass PBMs, health insurance, specialty pharmacies and group purchasing organizations. This vertical integration gives these corporations near total control over the products patients can access and the price they have to pay.”

393. Adam Kautzner, president of Express Scripts, had this to say during the hearing: “Drug manufacturers seek the highest price point possible and exploit the patent system and marketing practices to maintain monopoly status for their brands,”

and “For employers sponsoring high-deductible health plans, restrictions prevent lowering costs for patients before meeting their deductible.”

394. The PBM Defendants also continued to misrepresent that their conduct lowers diabetic drug prices. For example, Adam Kautzner testified, “Without the ability to use [rebates] to achieve lower drug costs, health care spending would be much higher.”

395. The truth is—despite their finger pointing in front of Congress—Manufacturers and PBMs are both responsible for their concerted efforts in creating the Insulin Pricing Scheme. This reality was echoed in the statement from the Senate Insulin Report, summarizing Congress’s findings of their two-year probe into the Insulin Pricing Scheme:

[M]anufacturers and [PBMs] have created a vicious cycle of price increases that have sent costs for patients and taxpayers through the roof . . . This industry is anything but a free market when PBMs spur drug makers to hike list prices in order to secure prime formulary placement and greater rebates and fees.

F. Defendants Profit Off the Insulin Pricing Scheme

1. Manufacturers Profit Off Insulin Pricing Scheme

396. For Manufacturer Defendants, the Insulin Pricing Scheme affords them the ability to increase their revenues while paying the PBM Defendants significant, yet undisclosed, Manufacturer Payments in exchange for formulary placement. During the relevant time period, PBM Defendants granted preferred formulary position to each at-issue drug in exchange for large Manufacturer Payments and inflated prices.

397. In addition, coordinating with the PBM Defendants to exclude lower priced diabetes medications from the PBMs' formularies results in increased sales and utilization of higher priced diabetes medications which are more profitable for the Manufacturers.

398. 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.

2. PBMs Profit Off Insulin Pricing Scheme

399. Because of the Insulin Pricing Scheme, PBMs' profit per prescription has grown exponentially during the relevant time period. A recent study published in the Journal of the American Medical Association titled, "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" concluded that the amount of money that goes to the PBM Defendants for each insulin prescription increased over 150% from 2014 to 2018. In fact, for transactions where the PBM Defendants control the insurer, the PBM, and the pharmacy (i.e. Aetna-CVS Health/Caremark-CVS Pharmacy) these Defendants now capture an astonishing 50% of the money spent on each insulin prescription (up from only 25% in 2014), despite the fact that they do not contribute to the development, manufacture, innovation or production of the product.

400. PBM Defendants profit off the Insulin Pricing Scheme in myriad ways, including: (1) retaining a significant—yet undisclosed—percentage of the Manufacturers Payments; (2) using the inflated price to generate profits from

pharmacies in their networks; and (3) utilizing their captive mail order and retail pharmacies in furtherance of the Insulin Pricing Scheme.

a) PBM_s profit off Manufacturer Payments

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

402. The amount that the Manufacturers pay back to the PBMs has accelerated to represent a large percentage of the list price of diabetes medications.

403. Historically, when PBMs contracted with payors, the contract allowed the PBM to keep all or at least some of the Manufacturer Payments they received, rather than pass them along to the payor and/or patient.

404. Over time, payors have secured contract provisions guaranteeing them all or some portion of the “rebates” paid by the Manufacturers to the PBMs. But critically, “rebates” are only a portion of the total secret Manufacturer Payments.

405. In this regard, PBM and Manufacturer Defendants have created a “hide-the-ball” system where the consideration exchanged between them (and not shared with payors and diabetics) is labeled and relabeled. As more payors moved to contracts that require PBMs to pass a majority of the manufacturer “rebates” through to the payor, PBMs have begun renaming the Manufacturer Payments in order to keep a larger portion of this money. Payments once known as “rebates” are now called administrative fees, volume discounts, service fees, data fees, inflation fees or other industry jargon terms designed to obfuscate and distract from the substantial sums being secretly exchanged and retained.

406. And these renamed Manufacturer Payments are indeed substantial. A heavily redacted complaint filed by Defendant Express Scripts revealed that *Express Scripts now retains up to 13 times more in “administrative fees” than it passes through to payors and/or patients in formulary rebates.*

407. In addition, the PBMs have come up with numerous ingenious methods to hide these renamed Manufacturer Payments in order keep them for themselves.

408. 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 and/or patients.

409. 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 around 6% to 8%—if the Manufacturer Defendants raise their prices by more than 6% (or 8%) during a specified time period they pay the PBM Defendants an additional “inflation fee” (based on a percentage of the artificially inflated prices).

410. 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 revert a portion of that amount back to these clients.

411. The PBMs set these “price protection guarantees” at a higher rate than the thresholds that trigger the Manufacturers’ “inflation fees,” usually around 12%-15%.

412. If the Manufacturers increase their list prices more than the 6%-8% inflation fee rate but less than the 10%-15% client price protection guarantee rate, then the PBMs keep 100% of the “inflation fee” payments. This is a win-win for the Manufacturers and PBMs—both retain and share all of the benefit of the price increases while costs for diabetics continue to rise.

413. Another method that the PBMs have devised to conceal and retain Manufacturer Payments is through the use of “rebate aggregators.” Rebate aggregators, sometimes referred to as rebate group purchasing organizations (“GPOs”), are entities that negotiate for and collect Manufacturer Payments from drug manufacturers, including the Manufacturers, on behalf of a large group of pharmacy benefit managers (including the PBM Defendants) and different entities that contract for pharmaceutical drugs.

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

415. With respect to Ascent Health, the PBM Prime Therapeutics is a minority owner along with Express Scripts. Ascent negotiates Manufacturer Payments for the majority (if not all) of Prime Therapeutics’ covered lives.

416. 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.

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

418. These rebate aggregator entities generate additional and new Manufacturer Payments for the PBM Defendants from new administrative fees, prescription data services, data portals, enterprise fees, and other sources—all based on a percentage of drug list prices. These are revenues earned in addition to the PBM Defendants' typical administrative service fees. The PBM Defendants use Zinc Health, Emisar Pharma, and Ascent Health to retain these new Manufacturer Payments which have become a substantial source of enterprise-wide profits and are yet another driver of higher drug prices.

419. The *New York Times* recently published an investigation titled, “The Opaque Industry Secretly Inflating Prices for Prescription Drugs: Pharmacy benefit managers are driving up drug costs for millions of people, employers and the government” (“NYT PBM Investigation”). The NYT PBM Investigation found that “in 2022, PBMs and their [rebate aggregator affiliates] pocketed \$7.6 billion in fees, double what they were bringing in four years earlier.”

420. The NYT PBM Investigation included a quote from an OptumRx executive who admitted the true purpose behind the creation of these rebate aggregator entities:

“The intention of the [rebate aggregator entities] is to create a fee structure that can be retained and not passed on to a client,” said Kent Rodgers, a former OptumRx executive who helped set up Emisar, “A PBM has to keep some level of income for them to grow and satisfy stockholders.”

421. Moreover, during the relevant time period the PBM Defendants have used their controlled rebate aggregator entities in furtherance of the Insulin Pricing Scheme. For example, a 2017 audit conducted by a local governmental entity on Defendant OptumRx related to its PBM activities from January 1, 2013 until December 31, 2015 concluded that the auditor was unable to verify the percentage of rebates OptumRx passed through 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.

422. 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.”

423. In other words, according to this audit report, OptumRx contracts with its own affiliate rebate 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 between itself, its affiliate, and its co-conspirator to obscure the amount of Manufacturer Payments that are being generated from its client's utilization.

424. The January 2021 Senate Insulin Report contained the following observation on these rebate aggregators:

[I]t 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. 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.

425. On April 19, 2024, the Inspector General of the US Office of Personnel Management (OPM) published its final audit report of Express Scripts' management of the pharmacy benefit of the America Postal Workers Union Health Plan (the "Carrier") from 2016 to 2021. The audit found that Express Scripts overcharged the Carrier nearly \$44.9 million by not passing through all Manufacturer Payments required under the contract, which included Ascent Health withholding approximately \$15.8 million in Manufacturer Payments that should have been passed through to the Carrier.

426. Further, in July 2024, CVS Caremark agreed to pay the State of Illinois \$45 million for Manufacturer Payments collected by Zinc Health that should have been passed through to the State of Illinois's health plan.

427. The NYT PBM Investigation also discussed the role of the PBM Defendants' rebate aggregator entities in the Insulin Pricing Scheme:

A former executive of a major drug company, whose responsibilities included negotiating with [PBM Defendants' rebate aggregators], said that he had a set pool of money to cover fees to [PBM Defendants' rebate aggregators] and rebates to employers. When he paid more in fees, he offered less in rebates. Employers are none the wiser. They receive rebates. But they can't see the billions of dollars in fees that the [PBM Defendants' rebate aggregators] take for themselves.

428. Because the PBMs are able to hide (and retain) a majority of the secret Manufacturer Payments that they receive, they continue to make significant profits on the Insulin Pricing Scheme.

429. Even in the rare cases where certain payor clients receive a portion of the Manufacturer Payments from their particular pharmacy benefit manager (whether it is a PBM Defendant or not), patients in those plans are still significantly overcharged as a direct result of the Insulin Pricing Scheme given the extent to which Defendants have inflated the prices of the at-issue drugs.

b) *PBMs profit off pharmacies*

430. A second way that PBM Defendants profit off the Insulin Pricing Scheme is by using the artificially inflated price generated by the scheme to profit off the pharmacies with which they contract, including those in Delaware.

431. PBM Defendants decide which pharmacies are included in the PBM's network and how much they will reimburse these pharmacies for each drug dispensed.

432. PBMs pocket the spread between the amount that the PBMs get paid by their clients for the at-issue drugs (which is based on the artificially inflated prices generated by the Insulin Pricing Scheme) and the amount the PBM reimburses the pharmacy (which is often less).

433. PBMs do not disclose to their clients or network pharmacies how much the PBM is receiving from or paying to the other.

434. This spread pricing, like the secret Manufacturer Payment negotiation, happens behind closed doors. There is no transparency, no commitment from PBM Defendants to take into account 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. The higher the Manufacturers inflate their prices, the more money the PBMs make off this spread.

435. PBMs also use the Insulin Pricing Scheme to generate additional profits from pharmacies by charging the pharmacies post-purchase fees, including DIR fees¹⁰, based on the artificially inflated prices generated by the Scheme—and again, the

¹⁰ “DIR” fees are post-purchase concessions pharmacies pay back to the PBMs.

higher the list price for each diabetes medication sold, the more the PBMs generate in these pharmacy fees.

c) PBM Defendants' captive mail order and retail pharmacies are integral to the Insulin Pricing Scheme

436. A third way PBMs profit off the Insulin Pricing Scheme is through the PBM Defendants' own mail order and retail pharmacies.

437. As explained above, the PBM Defendants are vertically integrated corporate families that include both PBM entities and mail order/specialty/retail pharmacies (among other entities). Express Scripts (PBM) is affiliated with Accredo (specialty pharmacy) and mail order pharmacies (including Defendant Express Scripts Pharmacy); CVS Caremark (PBM) is affiliated with CVS Specialty Pharmacy (specialty pharmacy), mail order pharmacies, and Defendant CVS Pharmacy (retail), and OptumRx is affiliated with mail order and specialty pharmacies.

438. By owning pharmacies, the PBM Defendants are able to steer their clients' prescription-drug plans to those pharmacies, including by requiring and/or incentivizing their covered lives to utilize their own mail order and retail pharmacies, including CVS Pharmacy, Express Scripts Pharmacy, and Optum's mail order pharmacies. As stated in the NYT PBM Investigation: the PBM Defendants "push, and sometimes force, patients to use their pharmacies, whether mail-order or, in [CVS Pharmacy's] case, the physical drugstores."

439. In June 2024, the House Committee on Oversight and Accountability released a report titled "The Role of Pharmacy Benefit Managers in Prescription Drug Markets" ("2024 House Committee PBM Report") which found that the PBM

Defendants steer patients to their own pharmacies, including CVS Pharmacy and Express Scripts Pharmacy:

The three largest PBMs [including the PBM Defendants] each own retail, mail-order, and specialty pharmacies that are “preferred” in-network under the pharmacy benefit. PBMs steer patients to pharmacies they own by various means, including: (1) preventing patients from receiving 90-day prescriptions at competing pharmacies; (2) abusing data received by the PBM to target patients with highly profitable medications; (3) only covering specialty medications if they are dispensed from a particular pharmacy; and (4) charging patients higher copays at competing pharmacies to incentivize patients to use the PBM owned pharmacy. [Such practices] harms patients and independent community pharmacies, increasing drug prices for patients, employers, and government payers.

440. In addition, the State of Minnesota recently levied a large fine against CVS Caremark for steering patients to its captured pharmacies, including by “[f]orcing a family to drive more than 100 miles or use a mail-order service to refill an insulin prescription.”

441. Once the PBM Defendants steer patients to their affiliated pharmacies, they are overcharging them for the at-issue drugs.

442. The higher the price that PBM Defendants are able to get their customers, such as Delaware diabetics and payors, to pay for diabetes medications, the higher the profits PBM Defendants realize through their mail order and retail pharmacies.

443. Because the PBMs base the price they charge for the at-issue diabetes medications on the list price, the more the Manufacturers inflate these prices, the more money the PBMs make at their captive pharmacies, including CVS Pharmacy, Express Scripts Pharmacy and Optum mail order pharmacies.

444. A June 2024 study by Three Axis Advisors, a PBM research and investigation firm, found that the PBM Defendants are charging significantly higher prices at their captive pharmacies (which would include CVS Pharmacy, Express Scripts Pharmacy and the Optum mail order pharmacies) for branded drugs, such as the at-issue diabetes medications, than for those prescriptions filled by independent pharmacies. For example, the PBM Defendants are charging their clients a significantly higher markups on brand drugs through their captive mail order pharmacies as demonstrated by the Figure 12:

Figure 12: Average Markups for Medicines Dispensed through Mail Order versus other channels



445. PBMs also collect and retain Manufacturer Payments that are paid based on the drugs dispensed by their captive pharmacies, including CVS Pharmacy and the PBMs' mail order pharmacies. These Manufacturer Payments include pharmacy supplemental discount fees, indirect purchase and fees and rebates. The PBM Defendants do not pass these pharmacy Manufacturer Payments through to their clients. And again, these pharmacy Manufacturer Payments are based on the list price, thus the higher the price, the more profits the PBM Defendants make.

446. Another way the PBMs generate pharmacy profits from the inflated prices generated by the Insulin Pricing Scheme is by way of an arbitrage purchase scheme. Because of their coordinated efforts with the Manufacturers in furtherance of the Insulin Pricing Scheme, the PBMs often know when the Manufacturers are going to raise their prices. The PBMs use this knowledge to purchase large quantities of the at-issue drugs prior to the price increases at a lower price. The PBMs then charge diabetics and payors the higher price after the increase and conceal and retain the difference.

447. In sum, the PBM Defendants' captive pharmacies, including CVS Pharmacy and the PBMs' mail order pharmacies, are directly involved in and create substantial profits from the Insulin Pricing Scheme.

448. Every way that the PBMs make money on diabetes medications is directly tied to the artificially inflated list prices generated by the Insulin Pricing Scheme. PBMs are not lowering the price of diabetes medications as they publicly

represent—rather they are making billions of dollars by fueling these skyrocketing prices.

G. Defendants Deceived Delaware Diabetics and Payors

1. Manufacturer Defendants deceived Delaware diabetics and payors

449. At all times during the relevant time period, Manufacturer and PBM Defendants knew that Delaware diabetics and payors relied on the artificially inflated list prices generated by the Insulin Pricing Scheme to pay for the at-issue drugs. That is, they relied on the artificially inflated list prices by purchasing diabetic medications at such prices.

450. Manufacturer and PBM Defendants further knew that Delaware diabetics and payors expected and desired to pay the lowest fair-market price possible for the at-issue drugs. In fact, as discussed in greater detail below, the PBM Defendants repeatedly represented that they were using their market power to ensure that Delaware diabetics paid the lowest price possible.

451. Manufacturer and PBM Defendants knew that the artificially inflated list prices generated by the Insulin Pricing Scheme were deceptive and completely untethered from the net prices that the Manufacturer Defendants actually received for the drugs.

452. As the list prices for the at-issue drugs detached completely from the Manufacturers' net prices, the list prices became misrepresentative and unlawful.

453. Despite this knowledge, Manufacturer Defendants caused the artificially inflated list prices generated by the Insulin Pricing Scheme to be published

throughout Delaware through publishing compendia and in various promotional and marketing materials distributed by entities downstream in the drug supply chain.

454. Manufacturer Defendants also published these prices to the PBMs and pharmacies in their networks, including their own captive pharmacies such as CVS Pharmacy and the PBMs' mail order pharmacies, who then use the misleading and deceptive prices to set the amount diabetics and payors pay for the at-issue drugs.

455. By publishing their artificially inflated prices throughout Delaware, the Manufacturers held these prices out as a reasonable price by which to base the prices diabetics and payors pay for the at-issue drugs.

456. These representations are misleading and deceptive. Manufacturer Defendants knew that their artificially inflated list prices are not remotely related to the net prices they receive for the at-issue drugs and are not based on transparent or market-based factors such as competition, cost of production, or research and development.

457. The Manufacturer Defendants could have reported and published prices that accurately reflected the actual net prices of the at-issue diabetes medications. However, in furtherance of and in order to conceal the Insulin Pricing Scheme, the Manufacturer Defendants deliberately published only the artificially inflated prices.

458. Notably, during the relevant time period, the Manufacturers published prices in Delaware of \$300-\$400 for the same at-issue drugs that were sold in other countries for less than \$5.

459. Manufacturer Defendants have also 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 and research. For example, briefing materials prepared for Chief Executive Officer (CEO) Dave Ricks 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 time period, executives from Sanofi and Novo Nordisk also represented that research and development costs were key factors driving the at-issue price increases.

460. These statements are also false. Between 2005 and 2018, Eli Lilly only 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 time period. Additionally, data reported in the 2021 Senate Report demonstrates that Eli Lilly’s R&D spending for its entire “diabetes franchise”, including both insulins and GLP-1s, was “just one-third of its sales, goods and administrative expenses” for 2017-2018.

461. Novo Nordisk has spent triple the amount it spends on R&D on stock buyouts and shareholder dividend payouts in recent years.

462. As for Sanofi, the 2021 Senate Report concluded that its R&D spending on Lantus, Soliqua, Toujeo, Apidra, and one other diabetes medication accounted for a “fraction of the company’s reported revenue from its diabetes franchise” between 2014-2018.

463. The Manufacturers' list prices were artificially inflated in furtherance of the Insulin Pricing Scheme to generate profits for the Manufacturer and PBM Defendants.

464. Manufacturer Defendants affirmatively withheld the truth from Delaware diabetics and payors and specifically made these misrepresentations in furtherance of the Insulin Pricing Scheme and to induce reliance in diabetics and payors to purchase their at-issue drugs.

465. PBM Defendants ensured that the Manufacturers' artificially inflated list prices harmed diabetics by requiring that their contracts with both pharmacies and with payors included them as the basis for payment.

466. PBMs 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 concealment and lack of transparency affords Defendants the opportunity to construct and perpetuate the Insulin Pricing Scheme, and to profit therefrom.

2. PBM Defendants deceived Delaware diabetics and payors

467. PBM Defendants have deceived diabetics and payors in Delaware.

468. Throughout the relevant time period, PBM Defendants have consistently and repeatedly represented that: (a) their interests are aligned with diabetics and payors; (b) they work to lower the price of the at-issue drugs and, in doing so, they achieve substantial savings for diabetics and payors; and (c) that the PBMs construct formularies designed to improve the health of diabetics.

469. PBMs understand that diabetics rely on the PBMs to achieve the lowest prices for the at-issue drugs and to construct formularies designed to improve their health and lower costs.

470. At no time have the PBM Defendants disclosed their knowledge and perpetuation of the artificially inflated list prices for the at-issue drugs; to the contrary, the PBMs ensured that diabetics and payors pay based on those artificially inflated list prices.

471. In addition to the general PBM misrepresentations discussed above in the Parties section, throughout the relevant time period and continuing to this day, PBM Defendants have purposefully, consistently, and routinely made misrepresentations specifically about the at-issue Manufacturer Payments, formulary construction, and the PBMs' role in the diabetic pricing system. Examples include:

- a. In a public statement issued on May 11, 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."
- b. On June 22, 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."
- c. 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."
- d. On August 31, 2016, Glen Stettin, Senior Vice President and Chief Innovation Officer at Express Scripts released a statement that stated "[d]iabetes is wreaking havoc on patients, and it is also a runaway driver of costs for payors . . . [Express Scripts] helps our clients and diabetes patients prevail over cost and care challenges created by this terrible disease."

- i. Mr. Stettin continued on to represent 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.”
 - e. In January 2017, Tim Wentworth, CEO of Express Scripts represented that “without PBMs, and specifically without Express Scripts, our clients would pay [many times] more for [insulin].”
 - i. Mr. Wentworth continued on to state Express Scripts is dedicated to controlling insulin prices because “we stand up for payers and patients.”
 - f. On June 1, 2018, Mark Merritt, President of the PCMA, in response to a question about PBMs’ role in the insulin pricing system stated, “[Through their formulary construction], PBMs are putting pressure on drug companies to reduce insulin prices.”
 - g. On April 4, 2019, Steve Miller, Express Scripts’ chief medical officer, stated that Express Scripts “give[s] people who rely on insulin greater affordability and cost predictability so they can focus on what matters most: their well-being.” Dr. Miller continued on to describe Express Scripts’ work on behalf of diabetics as, “[b]etter care and better outcomes are rooted in greater choice, affordability, and access, and we can bring all of these to people with the greatest needs.”
 - h. CVS Health’s Chief Policy and External Affairs Officer testified during 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.”
 - i. 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.”
- The PCMA website contains the following misrepresentations: “the insulin market is consolidated, hindering competition and limiting alternatives, leading to higher list prices on new and existing brand insulins. PBMs work hard to drive down costs using formulary management and rebates.”

j. In August 2022, Heather Cianfrocco, CEO of OptumRx, stated that “[t]he need for affordable insulin is urgent, especially for uninsured populations” and represented that OptumRx can improve access and lower costs for those who need an affordable insulin solution. OptumRx also reiterated that it leverages its core clinical and pharmacy benefit capabilities to negotiate lower prices and discounts.

472. PBM Defendants also misrepresent that they negotiate with Manufacturer Defendants to lower the price of the at-issue diabetes medications for diabetic patients. Examples include:

- a. Express Scripts' publicly available code of conduct states, “[a]t 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.” (Emphasis added).
- b. Amy Bricker, then President at Express Scripts 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.” (Emphasis added).
- c. Amy Bricker of Express Scripts also testified at the Congressional hearing that “Express Scripts remains committed to . . . *patients* with diabetes and creating affordable access to their medications.” (Emphasis added).
- d. OptumRx's website has stated “[t]he services we provide help *improve health outcomes for patients* while making prescription drugs more affordable for plan sponsors and *individuals*, and more sustainable for the country . . . the reason is simple: drug manufacturers are responsible for the high cost of prescription drugs . . . OptumRx negotiates better prices with drug manufacturers for our customers and *consumers* . . . At OptumRx, *our mission is helping people live healthier lives and to help make the health system work better for everyone.*” (Emphasis added).
- e. 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).

- f. The PCMA website states, “PBMs have kept average out-of-pocket (OOP) payments flat for beneficiaries with commercial insurance.”
- g. On March 12, 2019, OptumRx represented, “OptumRx is uniquely able to deploy the broadest range of tools to rein in high drug prices, [which] demonstrates our commitment to delivering better prices for consumers.”

473. In 2024, Travis Tate, VP of Formulary and Trend Solutions for CVS Caremark represented on CVS Health’s website that CVS Caremark’s “formulary design continues to deliver savings while optimizing plan member experience.” Mr. Tate further represented that CVS Caremark’s managed formularies deliver \$4.8 billion in client savings and \$138 in savings per patient. Mr. Tate also represented that “[CVS Caremark is] dedicated to keeping member costs low so they can afford their medications while limiting member disruption.”

474. In April 2024, David Joyner, the Executive Vice President of CVS Caremark, made the following representations in a Fortune article:

- a. “[CVS Caremark] exist[s] to make prescription drugs more affordable.”
- b. “As we work to bring down costs, you’ll hear from others who want to raise [drug prices], specifically pharmaceutical companies who are directly responsible for how drugs are priced in our country.”
- c. “At CVS Caremark, we are creating a more transparent environment for drug pricing in this country . . . for every drug from every manufacturer for every condition and every patient.”
- d. “[CVS Caremark’s] size and scale allow us to go toe-to-toe with drug companies, driving competition and negotiating discounts that make the difference between someone affording their medication or going without.”

- e. “[CVS Caremark] take[s] on every challenge, manage every drug, and deliver savings and safety.”

475. CVS Caremark’s website represents it is “[w]orking to keep prescription drug costs down for members and clients.” CVS Caremark further claims it is “[i]mproving health through affordability” because “people are more likely to take their prescribed medications when they know they can afford them – and that can lead to better health outcomes.”

476. CVS Caremark also represents to diabetics on the CVS Health website:

- a. “Pharmaceutical manufacturers insist that increasing drug prices are a result of them having to pay rebates. This is simply not true.”
- b. “Pharmaceutical manufacturers also argue that PBMs retain the rebates they negotiate, and that higher prices mean more rebates and greater profits for PBMs. This is entirely false. Rebate retention also has no correlation to higher drug prices.”
- c. “At CVS Health, we are committed to using every tool possible and continuing to drive innovation to bring down the cost of drugs. We remain focused on providing the right drug to the right patient at the right time at the lowest possible cost.”

477. Express Scripts claimed in a 2019 article titled “What’s a Pharmacy Benefit Manager” that Express Scripts “work[s] with plan sponsors to provide a benefit that delivers the best clinical outcome and the lowest possible cost.” Express Scripts also publicly represented in this article:

- a. “By delivering smarter solutions to patients and clients, PBMs provide better care and lower cost with every prescription, every time.”
- b. “Rebates do not raise drug prices, drug makers raise drug prices, and they alone can lower them. Consider the cost of Humalog® (insulin lispro): over the past seven years, the list price for this medication has increased dramatically, yet the net cost has

remained relatively constant. Without PBMs, and specifically without Express Scripts, plan sponsors would have paid exponentially more for their prescription drugs.”

- c. “We . . . negotiate with drug manufacturers so no one pays more than they need to.”
- d. “FACT: Public disclosure of negotiated rebates will not lower prescription drug costs. PBMs Express Scripts negotiates with drug manufacturers to increase competition and lower costs for patients.”

478. Not only have PBM Defendants intentionally misrepresented that they use their market power to save diabetics and payors money, they also falsely disavowed that their conduct drives the artificially inflated list prices higher.

Examples include:

- a. On an Express Scripts’ earnings call in February 2017, CEO Tim Wentworth stated, “Drugmakers set prices, and we exist to bring those prices down.”
- b. 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.”
- c. In 2017, Express Scripts’ Wentworth went on CBS News to again argue that PBMs play no role in rising drug prices, stating that PBMs work to “negotiate with drug companies to get the prices down.”
- d. 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 answered, “we can’t see a correlation that rebates raise list prices.”
- e. In 2019, when testifying under oath before Congress on the rising price of insulins, then Senior Vice President Amy Bricker of Express Scripts testified, “I have no idea why the prices [for insulin] are so high, none of it is the fault of rebates.”
- f. In 2023 when testifying before Congress about insulin prices, Heather Cianfrocco stated, “[OptumRx] has been at the forefront of efforts to make insulin more affordable.” Ms. Cianfrocco continued, “we support and encourage lower list prices across the board.”

479. Throughout the relevant time period, PBM Defendants have also misrepresented that they are transparent about the Manufacturer Payments that they receive and that they pass along (or do not pass along) to payors. As stated above, PBM Defendants retain many times more in total Manufacturer Payments than the traditional formulary “rebates” they may pass through—in whole or part—to payors.

480. Despite this, in 2011, OptumRx’s President stated: “We want our clients to fully understand our pricing structure . . . [e]veryday 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.”

481. In a 2017 CBS News interview, Express Scripts’ CEO, represented, among other things, that Express Scripts was “absolutely transparent” about the Manufacturer Payments it receives and that payors, “know exactly how the dollars flow” with respect to these Manufacturer Payments.

482. When testifying before Congress in April 2019, Amy Bricker, then President of Express Scripts, had the following exchange with Representative John Sarbanes of Maryland regarding the transparency (and lack thereof) of the Manufacturer Payments:

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. . . [However] 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. What about if we made it completely transparent? Who would be for that?

Ms. Bricker. Absolutely not . . . it will hurt the consumer.

Mr. Sarbanes. I don't buy it.

Ms. Bricker – prices will be held high.

Mr. Sarbanes. I am not buying it. I think a system has been built that allows for gaming to go on and you have all got your talking points. Ms. Tregoning [of Sanofi], you have said you want to guarantee patient access and affordability at least ten times, which is great, but there is a collaboration going on here . . . the system is working for both of you at the expense of the patient. Now I reserve most of my frustration for the moment in this setting for the PBMs, because I think the lack of transparency is allowing for a lot of manipulation. I think the rebate system is totally screwed up, that without transparency there is opportunity for a lot of hocus-pocus to go on with the rebates. Because the list price ends up being unreal in certain ways except to the extent that it leaves certain patients holding the bag, then the rebate is negotiated, but we don't know exactly what happens when the rebate is exchanged in terms of who ultimately benefits from that. And I think we need more transparency, and I do not buy the argument that the patient is going to be worse off, the consumer is going to be worse off if we have absolute transparency . . . *I know when you started out, I understand what the mission was originally with the PBMs . . . But now things have gotten out of control. You are too big and the lack of transparency allows you to manipulate the system at the expense of the patients.* So I don't buy the argument that the patient and consumer is going to get hurt if we have absolute transparency. (Emphasis added)

483. Throughout the relevant time period, the PBMs have made similar misrepresentations—that they lower prices, promote diabetic health, and work in the interests of patients—to Delaware diabetics through member communications, formulary change notifications, and through extensive direct-to-consumer pull through efforts engaged in with the Manufacturers.

484. PBM Defendants also make these same representations directly to their Delaware payor clients—that their interests are aligned with their payor clients, that

they lower the price of the at-issue drugs, and that their formulary construction is for the benefit of diabetics.

485. The above-stated PBM Defendants' representations are misleading and deceptive, and the Defendants knew they were deceptive when they made these representations.

486. Contrary to their representations that they lower the price of the at-issue drugs for diabetics, PBMs' formulary construction and the Manufacturer Payments they receive in exchange for formulary placement have caused the price paid by diabetics and payors to significantly increase.

487. For example, diabetics in Europe and Canada pay significantly less for their diabetes medications than diabetics in the United States who are affected by the Insulin Pricing Scheme.

488. In addition, diabetics that 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 that found that federal health care programs that negotiate directly with the Manufacturers (such as the Department of Veterans Affairs), and thus are 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 thus are victims of the PBMs' concerted efforts to drive up the list prices).

489. Another example is the price paid by the Veterans Affairs (“VA”) for the at-issue drugs through their national contracts with the Manufacturers. Notably, the VA prices involve the same Manufacturers, the same drugs, the same packaging, the same distributors, the same time period, the same cost of goods sold, the same distribution fees, the same consequential volumes, the same therapeutic category, the same therapeutic interchangeability within the therapeutic category, and the same exclusivity as the commercial market. Indeed, the only difference between the VA and commercial worlds relevant to the price disparity is that the VA prices resulted from actual price competition between the Manufacturers, whereas the artificially inflated list prices resulted from the Insulin Pricing Scheme. Figures 13 and 14 show the price of Novolog and Novolin paid by the VA through its national contract versus the WAC prices of those drugs.

Figure 13: Novolog VA Prices (Pink Dotted Line) vs. Novolog WAC Prices (Blue Line)

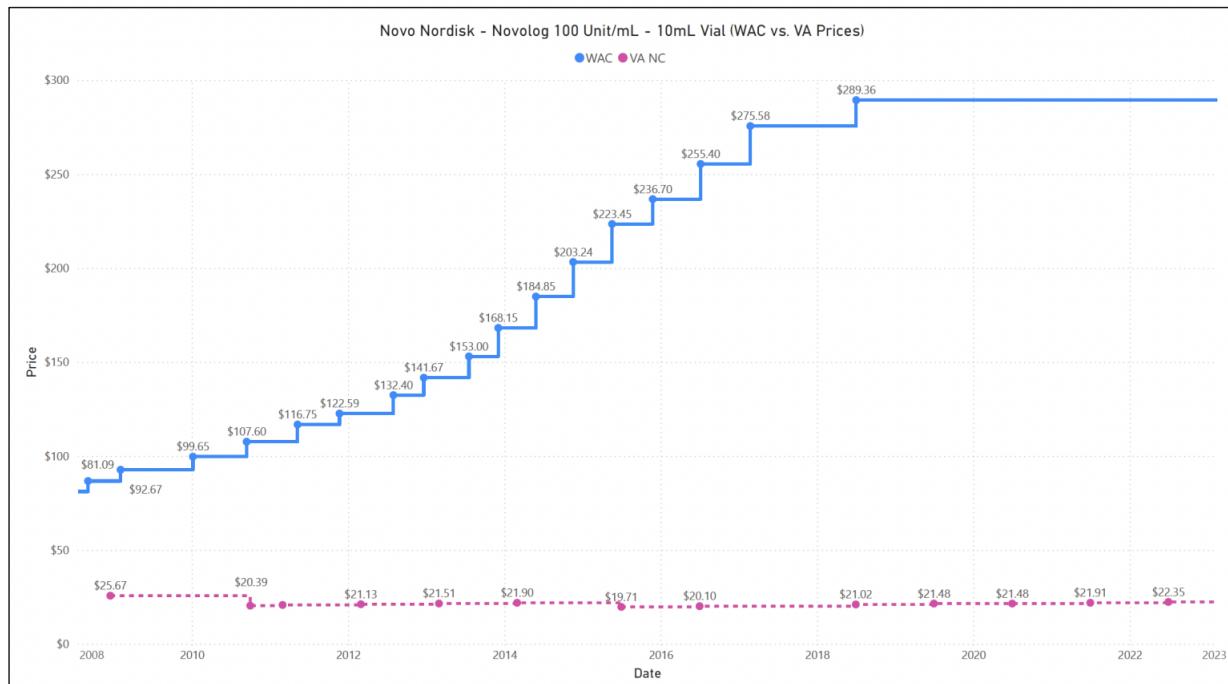
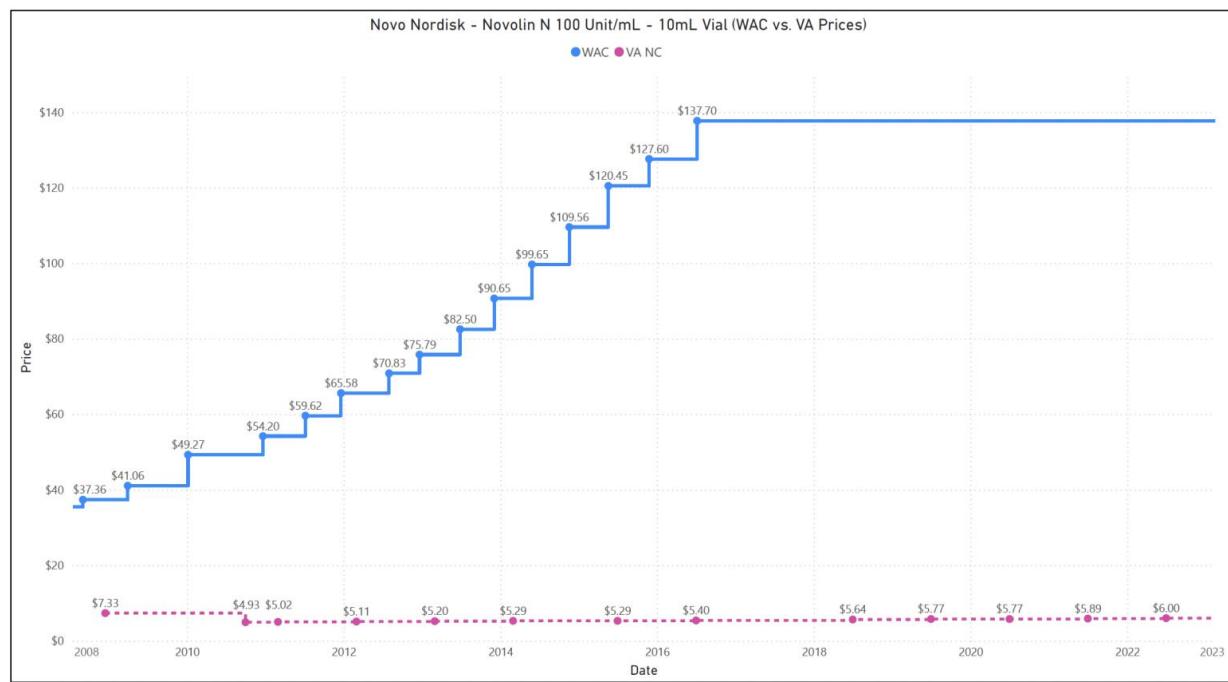


Figure 14: Novolin VA Prices (Pink Dotted Line) vs. Novolin WAC Prices (Blue Line)



490. The NYT PBM Investigation found:

The job of the PBMs is to reduce drug costs. Instead, they frequently do the opposite. They steer patients toward pricier drugs, charge steep markups on what would otherwise be inexpensive medicines and extract billions of dollars in hidden fees.

491. The NYT PBM Investigation further “found that the largest PBMs often act in their own financial interest, at the expense of their clients and patients.” Among the findings of the NYT PBM Investigation:

- a. PBMs sometimes push patients toward drugs with higher out-of-pocket costs, shunning cheaper alternatives.
- b. They often charge employers . . . multiple times the wholesale price of a drug, keeping most of the difference for themselves. That overcharging goes far beyond the markups that pharmacies, like other retailers, typically tack on when they sell products.
- c. The largest PBMs recently established subsidiaries that harvest billions of dollars in fees from drug companies, money that flows straight to their bottom line and does nothing to reduce health care costs.

492. Contrary to their representations that they work to promote the health of diabetics, as a result of the Insulin Pricing Scheme many diabetics have been priced out of these life-sustaining medications. As a result, many of these diabetics are forced to either ration their insulin or to skip doses. This behavior is dangerous to a diabetic’s health and can lead to a variety of complications and even death.

493. Both PBM and Manufacturer Defendants knew that these representations were misleading and deceptive when they made them and affirmatively withheld the truth regarding the artificially inflated list prices, formulary construction, and Manufacturer Payments from Delaware diabetics,

payors, and the State. Both PBM Defendants and Manufacturer Defendants intended for Delaware residents with diabetes and payors to rely on their misrepresentations.

494. Defendants concealed the falsity of these representations by closely guarding their pricing structures, agreements, and sales figures.

495. Manufacturer Defendants do not disclose to diabetics the actual prices they receive for the at-issue drugs or the amount in Manufacturer Payments they pay to the PBM Defendants.

496. PBM Defendants do not disclose to diabetics, payors, or the public the details of their agreements with Manufacturer Defendants or the Manufacturer Payments they receive from them—nor do they disclose the details related to their agreements with payors and pharmacies.

497. Each Defendant conceals this information and its unfair and deceptive conduct by signing confidentiality agreements with any entity in the supply chain with which it contracts.

498. PBM Defendants have gone as far as suing governmental entities to block the release of details on their pricing agreements with Manufacturers and pharmacies.

499. Even when audited, PBM Defendants often still refuse to disclose their agreements with Manufacturers and pharmacies, relying on overly broad confidential agreements, claims of trade secrets, and other unnecessary restrictions.

500. Each Defendant's effort to conceal its pricing structures for the at-issue drugs is evidence that each Defendant knows its conduct is unfair and deceptive.

501. To make matters worse, Delaware diabetics have no choice but to pay based on Defendants' artificially inflated list prices because they need these medications to survive, the Manufacturer Defendants make virtually all of the diabetes medications available in Delaware, and the PBM Defendants completely dominate the pharmacy benefit services market and control nearly every Manufacturer Payment paid in the market.

502. In sum, the entire diabetes drug pricing structure created by the Defendants—from the deceptive prices, to the Manufacturers' misrepresentations related to the reason behind the price, to the inclusion of the deceptive prices in payor contracts, to the non-transparent Manufacturer Payments, to the misuse of formularies, to the PBMs' representations that they work to lower prices and promote the health of diabetics—is unfair and deceptive.

503. Delaware diabetics and payors pay for the at-issue diabetes medications at the artificially inflated prices generated by the Insulin Pricing Scheme, because they relied on these prices as reasonable bases for their life-sustaining medications.

504. Delaware diabetics and payors utilize the PBM Defendants' pharmacy benefit services, mail order and retail pharmacy services, and formularies because the PBM Defendants represent that they lower prices and promote health.

505. Delaware diabetics and payors did not know, because the Defendants affirmatively concealed, that contrary to their representations: (i) the Defendants' conduct was driving up prices; (ii) the list prices were manipulated to satisfy Defendants' profit demands; (iii) the list prices bore no relationship to the net prices

received by the Manufacturers for the at-issue drugs; and (iv) the entire diabetic drug pricing structure was created and perpetuated by Defendants' deceptive and unfair conduct.

H. The Insulin Pricing Scheme Has Damaged Diabetics and Payors

1. Defendants' misconduct has caused increased healthcare costs

506. As discussed below, the PBM Defendants' formulary exclusions and the rising prices for the at-issue drugs has had a devastating effect on the health of diabetics. It has also caused a staggering increase in healthcare costs.

507. As a direct result of the Insulin Pricing Scheme, 1 in 4 diabetics can no longer afford their diabetes medication and are forced to ration and skip doses. This forced lack of adherence to their diabetes medications leads to substantial additional healthcare costs.

2. The Insulin Pricing Scheme has damaged Delaware diabetics and payors

508. Delaware payors pay for the at-issue drugs based on the inflated prices generated by the Insulin Pricing Scheme and have been overcharged by millions of dollars a year for the relevant time period.

509. Delaware diabetics, whether insured or not, pay a substantial part of their diabetic drug costs based on Defendants' artificially inflated list prices generated by the Insulin Pricing Scheme and thus have been directly damaged as well.

510. The Manufacturer Defendants' list price increases have resulted in high costs for both insured patients and uninsured. In 2019, the Department of Health and Human Services found that for patients using diabetes medications with commercial

insurance, 19% of insulin prescriptions required out-of-pocket costs exceeding \$70. For uninsured patients, 27% of insulin prescriptions involved costs greater than \$70.

511. The Insulin Pricing Scheme has caused the prices that Delaware diabetics must pay for insulin and other diabetic drugs to skyrocket over the last fifteen years.

512. In addition to financial losses, for many diabetics in Delaware, the Insulin Pricing Scheme has cost them their health and emotional well-being. As a result of increased prices and the fact that the PBM Defendants have been excluding more affordable diabetes medications from their formularies, many Delaware diabetics have been priced out of these life sustaining medications.

513. Unable to afford Defendants' price increases, many diabetics in Delaware have begun to engage in risky behaviors with respect to their disease, such as rationing their medications, skipping their refills, injecting expired insulin, reusing needles, and avoiding doctors' visits. To compensate for their lack of treatment, some patients starve themselves, foregoing one or even two meals a day. These practices—which ineffectively control blood sugar levels—can lead to serious complications such as kidney disease and failure, heart disease and heart attacks, infection, amputation, and blindness, which harm not only the individual persons affected, but also harm the Delaware healthcare system as a whole, by burdening its resources, and the Delaware economy, by requiring millions of dollars of additional revenues to be spent.

514. A recent study by Yale researchers found that 14% of diabetics face “catastrophic” spending on insulin (defined as 40% of their income beyond what they spend on food and housing) and nearly half of diabetics reported rationing their insulin supply because of its cost.

515. In addition to insulin, recent articles have described GLP-1s as an absolute gamechanger for people living with diabetes, however GLP-1s have been priced out of the reach of tens of millions of people because of the Insulin Pricing Scheme.

516. A recent article by the Kaiser Family Foundation explained how the inflated prices for GLP-1 drugs caused by the Insulin Pricing Scheme is harming diabetics:

[O]ver half of adults who had taken a GLP-1 drug, including those with insurance, said the cost was “difficult” to afford. But it is patients with the lowest disposable incomes who are being hit the hardest. These are people with few resources who struggle to see doctors and buy healthy foods. In the United States, Novo Nordisk charges about \$1,000 for a month’s supply of Ozempic, and Eli Lilly charges a similar amount for Mounjaro. The high prices also mean that not everyone who needs the drugs can get them. “They’re kind of disadvantaged in multiple ways already and this is just one more way,” said Wedad Rahman, an endocrinologist with Piedmont Healthcare in Conyers, Georgia . . . By the time many of Rahman’s patients see her, their diabetes has gone unmanaged for years [because they cannot afford their medicines] and they’re suffering from severe complications like foot wounds or blindness. “And that’s the end of the road,” Rahman said. “I have to pick something else that’s more affordable and isn’t as good for them.”

517. Earlier this year CBS News reported in an article titled “High Price of Ozempic, other diabetes drugs deprive low-income people more effective treatment”:

The “outrageously high” price has “the potential to bankrupt Medicare, Medicaid, and our entire health care system,” Sen. Bernie Sanders, an

independent from Vermont, who chairs the U.S. Senate Committee on Health, Education, Labor and Pensions, wrote in a letter to Novo Nordisk in April.

518. Even when diabetics can still afford their diabetic medications, as a direct result of PBM Defendants shifting which diabetes medications are favored on their formularies (“non-medical switching”), diabetics are often forced to switch medications every few years or go through a lengthy appeal process (or try the favored drug first) before receiving the patient’s preferred medication.

519. Non-medical switching for biologic drugs, such as the at-issue drugs, causes increased health problems for diabetics and increased healthcare costs.

520. The Insulin Pricing Scheme has pushed, and will continue to push, access to these lifesaving drugs out of reach for many diabetes patients in Delaware.

521. Because Delaware diabetics and payors continue to pay for the at-issue drugs based on the artificially inflated prices generated by the Insulin Pricing Scheme, the harm is ongoing.

I. Defendants’ Recent Efforts in Response to Rising Insulin Prices

522. In reaction to the mounting political and public pressure, Defendants recently have taken action in the insulin marketplace.

523. Defendants have recently begun introducing programs ostensibly aimed at lowering the cost of insulins.

524. These affordability measures fail to address the structural issues that have given rise to the price hikes. Rather, these steps are merely public relations stunts that do not solve the problem.

525. 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.”

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

527. Following this, a Congressional staff report was issued 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 was widely unavailable in pharmacies across the country, and that the company has not taken meaningful steps to increase insulin accessibility and affordability.

528. The conclusion of the report was that: “Eli Lilly has failed to deliver on its promise to put a more-affordable insulin product on the shelves. Instead of giving patients access to its generic alternative, this pharmaceutical behemoth is still charging astronomical prices for a drug people require daily and cannot live without.”

529. In addition, in 2023 the Manufacturer Defendants significantly lowered the list prices of certain insulins (in some cases by as much as 70%). While the Manufacturer Defendants each made public statements that the price reductions were designed to help diabetics by making insulin affordable, those statements obscure the true motivations behind these price cuts.

530. First, the Manufacturer Defendants could have taken these steps years ago. Taking this action now only confirms how grossly and artificially inflated their prices have been for years.

531. Second, even with the price cuts, the Manufacturer Defendants are still making sizeable profits, and the price is still significantly inflated compared to other countries. As reported in a 2023 Los Angeles Times article:

Moreover, the price rollback still doesn't bring Lilly insulin back to where it should be on an inflation-adjusted basis compared with the price of its key product, Humalog, upon its launch in 1996. Back then, Humalog cost \$21 per vial, which would be about \$40 in today's money; the rollback will reduce the price of a vial from \$274.70 to \$66.40, according to calculations by the Washington consulting firm Veda Partners. So it's still higher by two-thirds than it should be, accounting for inflation . . .

"Lilly is going to bank a lot of goodwill for this, without taking necessarily a big hit to their bottom line," says Andrew Mulcahy, senior researcher at Rand Corp. and lead author of a 2020 Rand comparison of insulin prices in the U.S. and other countries. That analysis showed that U.S. insulin prices were way out of line with the rest of the world: For example, a benchmark unit cost (in U.S. dollars) \$6.94 in Australia, \$12 in Canada and \$7.52 in Britain — but nearly \$100 in the U.S. Even if Lilly's price cuts are followed by its competitors, "U.S. prices are still higher than prices in the other countries," Mulcahy told me, though by two to three times rather than by 10 times.

532. Third, despite years of growing recognition of harm to patients from high diabetic drug pricing, the Manufacturer Defendants did not actually lower their prices of certain insulins until regulatory change forced the price cuts. As explained in the FTC Complaint:

The American Rescue Plan of 2021 repealed the Average Manufacturer Price (AMP) Cap. Under Medicaid regulations, manufacturers must pay Medicaid rebates equal to the difference between the current average price of the drug paid by retail pharmacies and wholesalers and the inflation-adjusted list price of the drug (sometimes referred to as the

Medicaid inflation penalty). If a drug's list price has increased faster than inflation, the manufacturer has to rebate the difference to Medicaid. The AMP Cap, in place since 2010, had capped the Medicaid rebate at 100% of the drug's average price, even if manufacturers continued to raise list prices. The repeal of the AMP Cap, however, took away this 100% rebate maximum. Thus, beginning in 2024, insulin manufacturers who had dramatically increased list prices (exceeding the inflation rate) would be required to pay a Medicaid rebate in excess of 100% of the drug's price on every unit dispensed in Medicaid.

Humalog, Novolog, and Lantus, which had experienced up to sevenfold list price increases, were among [the drugs affected by the change in the law]. The insulin manufacturers projected incurring hundreds of millions of dollars in Medicaid liability due to the AMP Cap repeal. Because of the relationship between the AMP Cap and list price, however, manufacturers could mitigate the effect of the AMP Cap repeal by lowering list price.

533. Indeed, as a result of the new Medicaid regulations, each of the Manufacturer Defendants faced huge penalties due to their steep insulin price increases if they did not significantly lower their prices by the end of 2023. For example, one study estimated that Eli Lilly's insulin price cuts would produce approximately \$517 million in gains for the company by avoiding the new Medicaid charges.

534. Finally, the price cuts only affect certain analog insulins, such as Lilly's Humalog and Novo's Novolog, not all diabetes medications. More importantly, the price cuts do not address the fundamental unfair and deceptive conduct driving the Insulin Pricing Scheme.

V. TOLLING OF STATUTE OF LIMITATIONS

535. The State asserts that it diligently pursued and investigated the claims asserted in this Complaint. Through no fault of its own, neither the State, nor any Delaware diabetic and/or payor, received inquiry notice or learned of the factual basis

for its claims in this Complaint and the injuries suffered therefrom until recently. Consequently, the following tolling doctrines apply.

A. Discovery Rule Tolling.

536. The State and Delaware diabetics and payors had no way of knowing about the Insulin Pricing Scheme.

537. As discussed above, PBM Defendants and Manufacturer Defendants refused to disclose the actual prices of diabetes medications realized by Defendants, the details of the Defendants' negotiations and payments between each other or their pricing structures and agreements—labeling them trade secrets and protecting them with confidentiality agreements.

538. Each Defendant group also affirmatively blamed the other for the price increases described herein, both during their congressional testimonies and through the media. Defendants essentially continued to work and conspire together to conceal their misrepresentations in their blame of the other.

539. The State and Delaware diabetics and payors could not have discovered and did not know of facts that would have caused a reasonable person to suspect that Defendants were engaged in the Insulin Pricing Scheme, nor would a reasonable and diligent investigation have disclosed the true facts.

540. Even today, lack of transparency in the pricing of diabetes medications and the arrangements, relationships and agreements between and among Manufacturer Defendants and PBM Defendants that result from the Insulin Pricing Scheme continue to obscure Defendants' unlawful conduct.

541. For these reasons, the discovery rule tolls all applicable statutes of limitations.

B. Fraudulent Concealment Tolling.

542. Defendants' knowing and active fraudulent concealment and denial of the facts alleged herein, as described in detail above, also tolls any applicable statutes of limitation.

C. Estoppel.

543. Defendants intentionally misrepresented the prices and intended for Delaware diabetics and payors to rely upon the misrepresentations. Due to Defendants' misrepresentations, they benefitted from inducing Delaware diabetics and payors with diabetes to rely upon their misrepresentations.

544. Based on the foregoing, Defendants are estopped from relying on any statutes of limitations in defense of this action.

D. Continuing Violations.

545. Any applicable statutes of limitations are also tolled because Defendants' activities have not ceased and still continue to this day and thus any causes of action are not complete and do not accrue until the tortious and anticompetitive acts have ceased.

VI. CLAIMS FOR RELIEF

Count One – Deceptive Practices in Violation of the Delaware Consumer Fraud Act, 6 Del. C. § 2511, et seq

546. The State re-alleges and incorporates herein by reference each of the allegations contained in this Complaint.

547. Defendants are, and at all relevant times were, “persons” engaged in trade or commerce in Delaware as defined in the CFA, 6 *Del. C.* § 2511(7), including by advertising, offering, distributing, and dispensing of the at-issue drugs; advertising and offering of pharmacy benefit services; and advertising and offering pharmacy services.

548. Defendants intentionally and purposefully sold and transacted in merchandise and advertisement within the State of Delaware at all relevant times.

549. By engaging in the Insulin Pricing Scheme, as described herein, in the course of their business Defendants acted, used, and/or employed deception, fraud, false pretense, false promise, misrepresentation, and/or the concealment, suppression, or omission of material fact with intent that others rely upon such concealment, suppression, or omission, in connection with the sale, lease, receipt or advertisement of merchandise.

550. In furtherance of the Insulin Pricing Scheme, at least once a year for each year during the relevant time period, the Manufacturer Defendants reported and published artificially inflated list prices to compendia, pharmacies, PBMs, and distributors. By publishing these prices, the Manufacturers held these prices out to have the characteristic and quality of being reasonably related to the actual net prices realized by the Defendants and to be prices that arose from competitive and transparent market factors.

551. The Manufacturer Defendants’ list prices are so untethered from the actual, net price realized by Defendants, as well as from the cost to manufacture,

market, and sell the at-issue drugs and the statements otherwise made by the Manufacturer Defendants to the marketplace, as to constitute a deceptive price.

552. In reality, the Manufacturer Defendants raised their list prices (and corresponding Manufacturer Payments) solely for the purposes of increasing their and the PBMs' profits at the expense of diabetics and payors.

553. PBM Defendants then granted preferred formulary positions to the at-issue drugs with the highest list price and highest Manufacturer Payments and excluded (or disadvantaged) drugs with lower list price drugs. In doing so, the PBM Defendants ensured that diabetics and payors only had access to higher priced diabetes medications (which were more profitable for each of the Defendants) and foreclosed access to lower priced diabetic treatments.

554. PBM Defendants further ensured that Defendants' misleading and deceptive list prices harmed diabetics and payors by mandating these prices were included in their contracts with payors and pharmacies, thereby ensuring that the Manufacturers' artificially inflated list prices would be used to set the price paid by diabetics and payors.

555. The Manufacturer Defendants could have reported and published prices that reflected their net prices, and the PBMs could have used these prices to determine formulary inclusion and to set the price paid by diabetics and payors. Defendants however failed to do so and concealed this information in furtherance of the Insulin Pricing Scheme.

556. The Manufacturer Defendants further concealed the Insulin Pricing Scheme by misrepresenting that research and development costs were responsible for the at-issue price increases and by concealing the size and purpose behind the millions of dollars in Manufacturer Payments that they paid to the PBMs.

557. Defendants have further violated the CFA by:

- a. Misrepresenting that their formulary construction lowers the cost of prescription drugs and promotes patient health;
- b. Misrepresenting that the Manufacturer Payments they pay and receive lower the cost of prescription drugs;
- c. Misrepresenting that their formulary decisions are evidence- and/or value-based decisions;
- d. Misrepresenting that their relationships with their affiliated pharmacies, including CVS Pharmacy and their captive mail order pharmacies, lowers the cost of prescription drugs and promotes patient health;
- e. Misrepresenting and concealing the reasons behind the price increases for prescription drugs;
- f. Misrepresenting that their formulary preferences and exclusions are lowering prices and promoting patient health;
- g. Misrepresenting the amount of “savings” that they generate for their clients, patients, and the healthcare system;
- h. Failing to disclose and concealing that the Manufacturer Payments that they pay and receive are intended to and do exclude lower priced drugs from formularies and drive up their profits;
- i. Failing to disclose that they are utilizing rebate aggregators, including Ascent Health, Emisar Health, and Zinc Health, to rename, obfuscate, and retain Manufacturer Payments;
- j. Failing to disclose and concealing that they financially benefit from preferring and/or excluding certain prescription drugs on their formularies; and

k. Failing to disclose and concealing that formulary preferences and exclusions are not based on the best interests of their clients and/or diabetics.

558. By engaging in the above-described misconduct, Defendants have misrepresented, omitted or concealed, and are misrepresenting, omitting and concealing material facts about the at-issue drugs, published prices, their formularies, the Manufacturer Payments, and their relationships with the affiliated entities, the disclosure of which would influence the decisions of diabetics and payors to purchase the at-issue drugs, the decisions of diabetics and payors to purchase PBM and pharmacy services, and the prices that diabetics and payors paid for the at-issue drugs.

559. In addition, engaging in the above-described misconduct, Defendants have created a false impression of the value of the at-issue drugs, their formularies, their relationships with their affiliated entities, and the Manufacturer Payments they pay and receive.

560. Each diabetes medication sold at the artificially inflated price caused by the Insulin Pricing Scheme constitutes a violation of the CFA.

561. Defendants have willfully engaged in the acts and practices described in this Complaint in violation of the CFA because they know or should have known that their conduct was a violation of the CFA.

Count Two – Unfair Practices in Violation of the Delaware Consumer Fraud Act, 6 Del. C. § 2511, et seq.

562. The State re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

563. The CFA makes unlawful any person employing any unfair practice in connection with the sale or advertisement of any merchandise in trade or commerce.

564. Defendants are, and at all relevant times were, “persons” engaged in trade or commerce in Delaware as defined in the CFA, 6 Del. C. § 2511(7), including in their advertising, offering, distributing, and dispensing of the at-issue drugs; advertising and offering of pharmacy benefit services; and advertising and offering pharmacy services.

565. By engaging in the Insulin Pricing Scheme, Defendants’ conduct caused substantial injury to consumers which was not reasonably avoidable by consumers and not outweighed by countervailing benefits. In particular:

- a. It is a public policy in Delaware that patients have access to healthcare and life saving medicines that are affordable.¹¹
- b. It is also a Delaware public policy that PBMs not engage in any “advertisement, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading.”¹²
- c. Defendants violated these public policies.
- d. The PBM and Manufacturer Defendants have created a non-transparent and misleading system—the Insulin Pricing Scheme—that is intentionally driving up prices—while simultaneously foreclosing diabetic and payor access to lower priced, life-saving drugs. The Insulin Pricing Scheme has caused substantial harm to Delaware consumers.
- e. Delaware diabetics are unable to avoid the artificially and illegally inflated prices caused by the Insulin Pricing Scheme because (1) the

¹¹ See, e.g. Section 9901, *et seq.*, of Title 16 of the Delaware Code - the Delaware Health Care Commission (DHCC) was created by the Delaware General Assembly to further the public policy of ensuring affordable health care for all Delawareans. Its mission explicitly includes promoting equitable access to high-quality, affordable healthcare; *see also* <https://diabetes.org/newsrooms/delaware-governor-signs-law-capping-insulin-co-pays-at-100-for-people-with-diabetes>.

¹² See 18 Del. C. § 3372A.

PBM and Manufacturer Defendants control the diabetic drug pricing chain in Delaware and (2) Delaware diabetics need the drugs at-issue to sustain a healthy life.

f. There are no conceivable benefits to diabetics in Delaware to being forced to pay egregiously inflated prices for medicines they need to stay alive or being cut off from access to lower priced, clinically equivalent alternatives. In fact, the opposite is true—as a direct result of Defendants’ egregious price increases Delaware diabetics’ health and wellbeing have been severely and detrimentally impacted and they have overpaid millions of dollars for the at-issue drugs.

566. As a direct and proximate result of Defendants’ unfair practices, Delaware diabetics and payors have sustained substantial health and economic damages.

567. Defendants have willfully engaged in the acts and practices described in this Complaint in violation of the CFA because they know or should have known that their conduct was a violation of the CFA.

**Count Three – Violations of the Delaware Deceptive Trade Practices Act, 6
*Del. C. § 2531, et seq.***

568. The State re-alleges and incorporates herein by reference each of the allegations contained in this Complaint.

569. Defendants are, and at all relevant times were, “persons” engaged in business in Delaware as defined in the DTPA, 6 *Del. C. § 2531(5)*, including in their advertising, offering, distributing, and dispensing of the at-issue drugs; advertising and offering of pharmacy benefit services; and advertising and offering pharmacy services. 6 *Del. C. § 2531*.

570. By engaging in the Insulin Pricing Scheme, as described herein, in the course of their business Defendants have engaged in deceptive trade practices in violation of the DTPA. 6 Del. C. § 2532.

571. Defendants misrepresented that their diabetes medications, formularies, and Manufacturer Payments have characteristics and benefits that they do not have in violation of 6 Del. C. § 2532(5), (11), and (12). In particular, Defendants:

- a. Misrepresented that their published prices for their diabetes medications were reasonably related to the actual, net prices they received for those drugs;
- b. Misrepresented that the reasons behind the significant price increases were to fund research and development;
- c. Misrepresented that their formulary construction lowers the cost of prescription drugs and promotes patient health;
- d. Misrepresented that the Manufacturer Payments they pay and receive lower the cost of prescription drugs;
- e. Misrepresented that their formulary decisions are evidence- and/or value-based decisions;
- f. Misrepresented that their relationships with their affiliated pharmacies, including CVS Pharmacy and their captive mail order pharmacies, lowers the cost of prescription drugs and promotes patient health;
- g. Misrepresented and concealed the reasons behind the price increases for prescription drugs;
- h. Misrepresented that their formulary preferences and exclusions are lowering prices and promoting patient health;
- i. Misrepresented the amount of “savings” that they generate for their clients, patients, and the healthcare system;

- j. Failed to disclose and concealed that the Manufacturer Payments that they pay and receive are intended to and do exclude lower priced drugs from formularies and drive up their profits;
- k. Failed to disclose that they are utilizing rebate aggregators, including Ascent Health, Emisar Health, and Zinc Health, to rename, obfuscate, and retain Manufacturer Payments;
- l. Failed to disclose and concealing that they financially benefit from preferring and/or excluding certain prescription drugs on their formularies; and
- m. Failed to disclose and concealing that formulary preferences and exclusions are not based on the best interests of their clients and/or diabetics.

572. Defendants further made false and misleading statements concerning the fact that Manufacturer Payments reduce the price of the at-issue diabetes medications when, in fact, they were an integral part of the Insulin Pricing Scheme that was driving up prices in violation of 6 *Del. C.* § 2532(11).

573. Defendants' conduct in furtherance of the Insulin Pricing Scheme also constitutes conduct which creates a likely of confusion and misunderstanding in violation of 6 *Del. C.* § 2532(12).

574. The Defendants' actions constituted willful violations of the DTPA because they knew or should have known that their conduct was prohibited by the DTPA.

Count Four – Unjust Enrichment

575. The State re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

576. Defendants deceived Delaware diabetics and payors and have received a financial windfall from the Insulin Pricing Scheme at the expense of Delaware diabetics.

577. Defendants wrongfully secured and retained unjust benefits from Delaware diabetics, in the form of: (1) amounts paid for diabetes medications and (2) Manufacturer Payments and pharmacy/other profits collected based on the artificially inflated prices generated by the Insulin Pricing Scheme.

578. There is no justification for the Insulin Pricing Scheme and it is inequitable and unfair for Defendants retain these benefits from the Scheme.

579. Defendants knowingly accepted the unjust benefits of their unfair and deceptive conduct.

580. Defendants have been enriched by profits resulting from the Insulin Pricing Scheme while Delaware diabetics have been impoverished by Defendants' misconduct. Defendants' enrichment and Delaware diabetics' impoverishment are connected.

581. Accordingly, Defendants should not be permitted to retain the proceeds from the benefits conferred upon them by the Insulin Pricing Scheme. The State seeks disgorgement of 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. The State's claims do not arise out of a contract but rather are based on the larger unfair and deceptive Insulin Pricing Scheme that drove up the at-issue artificially inflated list prices for all Delaware diabetics.

583. As a direct and proximate cause of Defendants' unjust enrichment, as referenced above, Delaware diabetics suffered, and continue to suffer, ascertainable losses and damages as specified herein in an amount to be determined at trial.

Count Five – Civil Conspiracy

584. The State re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

585. Each Defendant engaged in a civil conspiracy with other Defendants to violate the CFA and DTPA described above. Each Defendant is therefore jointly liable for the tortious conduct of his or her co-conspirators.

586. There was a meeting of the minds on this course of action to engage in the Insulin Pricing Scheme, and Defendants aided and abetted each other in the violations alleged above. Unlawful overt acts in this conspiracy included the direct agreements between the Manufacturers and PBMs for formulary placement and Manufacturer Payments, as well as the agreements between the PBMs and their affiliated rebate aggregator and pharmacy entities.

587. The State alleges both direct agreements (in the form of Manufacturer Payment agreements and other agreements) and circumstantial evidence demonstrating Defendants' conspiracy. The following circumstantial evidence demonstrates the Defendants' concerted activity:

- a. Defendants coordinated at least twice a year PCMA conferences, which included private exchanges and meetings that appear to be focused on developing and maintaining the Insulin Pricing Scheme, which all Manufacturers and PBM Defendants attended;
- b. Defendants' refusal to disclose the details of their pricing structures, agreements and sales figures in order to maintain the secrecy of their Insulin Pricing Scheme;
- c. Numerous ongoing government investigations, hearings and inquiries have targeted the collusion between Defendants related to the at-issue drugs, including:
 - i. In 2016, the U.S. Attorney's Office for the Southern District of New York issued a CID for information related to the Defendants' conduct involving insulin prices;
 - ii. In 2016, Defendants received civil investigative demands from the State of Washington, in conjunction with the Attorney Generals for California, Florida and Minnesota, related to their role in increasing insulin prices;
 - iii. In 2017, Manufacturers received civil investigation demands from the States of Minnesota, California and Florida related to the pricing of their insulin products and their relationships with the PBMs;
 - iv. In April 2019, U.S Congress held a hearing on the Insulin Pricing Scheme before the Senate Financing Committee in which each Defendant testified;
 - v. The Senate Finance Committee's two-year probe into the Insulin Pricing Scheme that resulted in the January 2021 Senate Insulin Report;
 - vi. A December 10, 2021 Congressional Report prepared by the House Committee on Oversight and Reform Minority Staff titled "A View from Congress: Role of Pharmacy Benefit Managers in Pharmaceutical Markets" that concluded:
 - Manufacturers raise their prices due to PBMs;
 - PBMs' retail and mail order pharmacies create conflicts of interest, hurt competition and distort the market;
 - PBMs' practices impact patient health; and

- PBMs use their market leverage to increase their profits, not reduce costs for consumers;
- vii. In June 2022, the FTC announced it would investigate the PBM Defendants (and later, their affiliated rebate aggregators) including related to the impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients;
- viii. The 2023 Senate Hearing;
- ix. The 2024 House Committee PBM Report;
- x. The NYT PBM Investigation;
- xi. The FTC Interim PBM Report; and
- xii. The FTC Complaint.

588. As a direct result of the overt acts taken in furtherance of Defendants' conspiracy, Delaware diabetics have suffered damages in an amount to be proven at trial. Defendants are all jointly and severally liable for the actions taken in furtherance of their joint conduct.

VII. REQUEST FOR RELIEF

The State requests that the Court:

A. Determine that Defendants have violated, and are violating, the CFA, the DTPA, and the Delaware common law by committing deceptive and/or unfair practices against Delaware consumers, by being unjustly enriched, and by conspiring to commit unlawful acts;

B. Grant comprehensive injunctive relief and permanently enjoin Defendants from engaging in the above-described unfair and deceptive acts and practices under the DTPA;

C. Grant comprehensive injunctive relief and permanently enjoin Defendants from engaging in the above-described unfair and deceptive acts and practices under the CPA;

D. Require Defendants to pay all restitution, disgorgement, and other relief that may be owed to Delaware consumers affected by Defendants' unlawful acts and practices;

E. Award the State civil penalties against Defendants for each separate violation of the DTPA;

F. Award the State civil penalties against Defendants for each separate violation of the CFA;

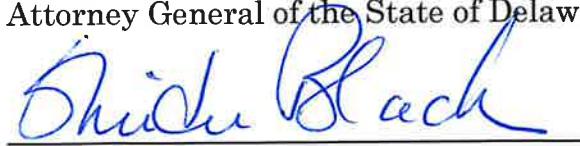
G. Award the Attorney General the costs of investigation, interest on all moneys owed, and attorneys' fees; and

H. Grant such additional relief as the Court deems just and proper.

Date: January 13, 2026

Respectfully submitted,

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