Filed: 3/19/2024 11:14 AM
Clerk
Lake County, Indiana

STATE OF INDIANA

IN THE LAKE COUNTY SUPERIOR COURT

CAUSE NO._____

STATE OF INDIANA,

Plaintiff,

v.

SANOFI-AVENTIS U.S. LLC;

NOVO NORDISK, INC.;

CAREMARKPCS HEALTH, LLC;

CAREMARK, LLC;

EXPRESS SCRIPTS ADMINISTRATORS, LLC d/b/a EXPRESS SCRIPTS;

CVS HEALTH CORP;

OPTUMRX, INC.

Defendants.

COMPLAINT FOR INJUNCTION, RESTITUTION, CIVIL PENALTIES, AND COSTS

JURY DEMAND REQUESTED

I. INTRODUCTION

1. The State of Indiana, by Attorney General Theodore E. Rokita, commences this civil action under the Indiana Deceptive Consumer Sales Act, Indiana Code § 24-5-0.5-1 *et seq.*, the Indiana Antitrust Act, Indiana Code § 24-1-2-1 *et seq.*, and the Indiana Medicaid False Claims Act, Indiana Code § 5-11-5.7-1 *et seq.,* for injunctive relief, restitution, civil penalties, costs, attorneys' fees, and other equitable relief.

2. Diabetes is an epidemic and a public health crisis in Indiana. According to the American Diabetes Association, approximately 640,435 Indiana residents have diagnosed diabetes. This number represents 12.3% of the adult population of Indiana. An additional 146,000 people are estimated to have undiagnosed diabetes in Indiana. Over one-third of the State's residents (over 1.7 million people) have prediabetes; up to 70% of those will eventually become diabetic.[1,2]

3. Diabetes is the leading cause of blindness, kidney failure, and lower limb amputations. It is the seventh leading cause of death in Indiana despite the availability of effective treatment.[3]

4. The economic impact of diabetes is staggering. Every year, the direct medical expenses associated with diabetes care in Indiana are an estimated five billion dollars.

5. Approximately one-third of diabetes patients rely on daily insulin alone or in combination with other medications to control and treat their condition. As a result, hundreds of thousands of Indiana residents are reliant upon the companies that manufacture diabetes medications in order to stay alive.

6. Defendants Novo Nordisk and Sanofi (collectively "Manufacturers")[4] manufacture the vast majority of insulins and other diabetic medications available in Indiana.

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[1] https://diabetes.org/sites/default/files/2022-04/ADV_2022_State_Fact_sheets_all_rev_IN-4-4-22.pdf

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3891203/#:~:text=According%20to%20an%20ADA%20expert,prediabetes%20will%20eventually%20develop%20diabetes.

[3] https://www.cdc.gov/nchs/pressroom/states/indiana/in.htm

[4] A third insulin manufacturer, Eli Lilly, is part of the conduct described herein but (1) is communicating with the State regarding these allegations and (2) has been proactive in reducing the cost of insulin. Thus, it is not made a defendant at this time.

7. By using the complicated drug distribution scheme reliant upon Pharmacy Benefit Managers ("PBMs") to facilitate and hide their scheme, Defendants have conspired to raise prices on insulin medications more than 1000% in the last decade alone. Drugs that were priced at $20 when released in the late 1990's, Defendants now price between $300 and $700. Insulins cost Defendants less than $2 to produce. Raising prices lockstep, Defendants have extracted illegal profits from the State and its citizens.

8. Soaring insulin prices have also left numerous diabetics unable to afford their medication at all. Many diabetics in Indiana are forced to ration or under-dose their insulin, inject expired insulin, reuse needles, and starve themselves to control their blood sugars. These behaviors are extremely dangerous and can lead to serious complications and death.

9. Insulin rationing also compounds the existing health problems diabetics face and creates preventable complications. One national model found that if all people with diabetes adhered to their medication protocol, over $8.3 billion in direct medical costs would be saved annually.

NATURE OF THE ACTION

10. The Attorney General brings this action with respect to purchases of and reimbursements for Defendant's insulin medications and other costs associated with Defendants' behavior, on behalf of the State of Indiana, as a statutory enforcement action for violations of the laws of Indiana as well as in its proprietary and *parens patriae* capacities.

11. As described by the Constitution of the State of Indiana, its government is established to protect the peace, safety, and well-being of its people.[5] The Attorney General shall have charge of and direct the prosecution of all civil actions that are brought in the name of the state of Indiana or any state agency.[6]

12. Additionally, the Attorney General has specific statutory right to enforce the Indiana Deceptive Consumer Sales Act[7] (DCSA), the Indiana Antitrust Act, Indiana Code § 24-1-2-1 *et seq.*, and the Indiana Medicaid False Claims Act, Indiana Code § 5-11-5.7-1 *et seq.* Through DCSA, the Attorney General is authorized to seek injunctive relief, restitution, costs, and civil penalties.

PARTIES

13. Plaintiff is the State of Indiana as authorized by Indiana Code §§ 4-6-3-2(a), 24-5-0.5-1 *et seq.,* 24-1-2-5.1, the Indiana Antitrust Act, Indiana Code § 24-1-2-1 *et seq.*, and the Indiana Medicaid False Claims Act, Indiana Code § 5-11-5.7-1 *et seq.* This action is brought in the public interest to seek injunctive relief, restitution, civil penalties, costs, and other equitable relief against Defendants, and to prohibit them from engaging in conduct, activities or proposed actions in violation of Indiana law.

14. 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. Sanofi is registered to do business in Indiana and can be served through its designated registered agent, Corporation Service Company, 135 Pennsylvania St., Suite 1610, Indianapolis, Indiana 46204. Sanofi manufactures, promotes, and

[5] In. Const., (as amended 2018) Preamble and Article 1, Section 1.
[6] IC § 4-6-3-2(a).
[7] IC § 24-5-0.5-4(c)

distributes the following at-issue diabetes medications in Indiana: Lantus, Toujeo, Apidra and Soliqua.

15. 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. Novo Nordisk is registered to do business in Indiana and can be served through its designated registered agent, CT Corporation System, 334 North Senate Ave., Indianapolis, Indiana 46204. Novo Nordisk promotes and distributes the following at-issue diabetes medications in Indiana: Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza and Ozempic.

16. Defendants Sanofi, and Novo Nordisk are hereinafter sometimes referred to collectively as the "Manufacturer Defendants" or "Manufacturers."[8]

17. Defendant OPTUMRX, INC. ("Optum") is a California corporation with a principal place of business at 2300 Main Street, Irvine, California, 92614. Optum is registered to do business in Indiana and can be served through its designated registered agent, CT Corporation System, 334 North Senate Ave, Indianapolis, Indiana, 46204. Optum is registered as a pharmacy benefit manager and a third party administrator with the Indiana Department of Insurance. Optum enters into rebate contracts with the Manufacturer Defendants related to the purchase of insulin. At all relevant times, Optum transacted and continues to transact business in Indiana.

18. Defendant CAREMARKPCS HEALTH, L.L.C. ("CaremarkPCS") is a Delaware limited liability company with its principal place of business at One CVS Drive, Woonsocket, Rhode Island, 02895. CaremarkPCS is registered to do business in

[8] The term "Manufacturers" is inclusive of insulin product manufacturer Eli Lilly. *See* footnote 4.

Indiana and can be served through its designated registered agent, CT Corporation System, 334 North Senate Ave, Indianapolis, Indiana, 46204. CaremarkPCS is registered as a third party administrator with the Indiana Department of Insurance. CaremarkPCS enters into rebate contracts with the Manufacturer Defendants related to the purchase of insulin.

19. Defendant CAREMARK, L.L.C. ("Caremark") is a limited liability company with its principal place of business at One CVS Drive, Woonsocket, Rhode Island, 02895. Caremark is registered to do business in Indiana and can be served through its designated registered agent, CT Corporation System, 334 North Senate Ave, Indianapolis, Indiana, 46204. Caremark is registered as a pharmacy benefit manager and a third party administrator with the Indiana Department of Insurance. Caremark enters into rebate contracts with the Manufacturer Defendants related to the purchase of insulin.

20. Defendant CVS HEALTH CORP ("CVS") is a Delaware limited liability company with its principal place of business at One CVS Drive, Woonsocket, Rhode Island, 02895. Defendants CaremarkPCS, and Caremark are wholly owned subsidiaries of CVS Health. CVS Health holds itself out as deliberately directing, and is therefore responsible for, CaremarkPCS and Caremark's forum-related activities. Among other things:

a. Prior to 2014, CVS Health bore the name CVS Caremark Corporation. When announcing its name change in 2014, CVS Health stated that its PBM services would continue to be known as "CVS/Caremark."

b. CVS Health continues to use CVS Caremark to refer to its PBM services on its website and in other locations.

c. The website located at www.caremark.com bears the name CVS Caremark.

d. CVS Health states in its filings with the U.S. Securities and Exchange Commission that its "Pharmacy Services segment provides a full range of PBM solutions, including plan design offerings and administration, formulary management, retail pharmacy network management services, and mail order pharmacy."

e. Likewise, CVS Health has stated that as part of its PBM services, CVS Health designs pharmacy benefit plans and negotiates with pharmaceutical companies to obtain discounted acquisition costs for many of the products on CVS Health's drug lists.

21. Defendants CaremarkPCS, Caremark, and CVS Health are referred to as "CVS Caremark." At all relevant times CVS Caremark transacted and continues to transact business in Indiana.

22. Defendant EXPRESS SCRIPTS ADMINISTRATORS, LLC, d/b/a EXPRESS SCRIPTS is a Delaware corporation with a principal place of business at 1 Express Way, St. Louis, Missouri, 63121. Express Scripts is registered to do business in Indiana and can be served through its designated registered agent, CT Corporation System, 334 North Senate Ave, Indianapolis, Indiana, 46204. Express Scripts is registered as a third party administrator with the Indiana Department of Insurance. Express Scripts enters into rebate contracts with the Manufacturer Defendants related to the purchase of insulin. At all relevant times, Express Scripts transacted business in Indiana.

23. CVS Caremark, Express Scripts and Optum are hereinafter sometimes referred to collectively as the "PBM Defendants."

24. The Manufacturer Defendants separately conspired with each PBM Defendant to commit the violations alleged in this Petition. Specifically, Novo Nordisk separately conspired with each PBM Defendant to artificially inflate the list prices of Novo Nordisk's insulin products, while agreeing to provide secret payments to each PBM Defendant in an attempt to obtain preferred positions on the respective PBM Defendant's standard drug formularies. Likewise, Sanofi separately conspired with each PBM Defendant to artificially inflate the list prices of Sanofi's insulin products, while agreeing to provide secret payments to each PBM Defendant in an attempt to obtain preferred positions on the respective PBM Defendant's standard drug formularies. Each Defendant has committed overt acts in furtherance of their respective conspiracies. Defendants' conduct, and each conspiracy, continues to the present. The parties to each conspiracy are jointly and severally liable for the harm resulting from that particular conspiracy.

JURISDICTION AND VENUE

25. IND. CODE § 4-6-3-2 authorizes the Attorney General to bring actions on behalf of the State of Indiana.

26. IND. CODE § 24-5-0.5-4(c) empowers the Indiana Attorney General to "bring an action to enjoin a deceptive act" under Indiana's Deceptive Consumer Sales Act.

27. IND. CODE § 24-5-0.5-4(g) further provides that where the "court finds any person has knowingly violated" the prohibition on deceptive acts, the Attorney General "may

recover from the person on behalf of the state a civil penalty" of up to $5,000 per violation.

28. IND. CODE § 24-5-0.5-8 also authorizes the Attorney General, through a petition brought under this section, to seek a civil penalty against a person who commits an "incurable" deceptive act, of up to $500 for each violation.

29. Accordingly, this Court has jurisdiction to hear this dispute, and is further authorized to "order the supplier to pay to the state the reasonable costs of the attorney general's investigation and prosecution related to the action." IND. CODE § 24-5-0.5-4(c)(4).

30. The State of Indiana is a governmental organization and thus bears no requirement to give security for the payment of costs and damages for any party wrongfully enjoined. Ind. R. Civ. P. 65(C).

31. All Defendants operate and transact business in the State of Indiana and have done so within the applicable statute of limitations. Defendants have availed themselves of the benefit of transacting business in Indiana through their operations. This Court has personal jurisdiction over Defendants under Ind. R. Trial P. 4.4(A).

32. Venue is proper under Ind. R. Trial P. 75.

FACTUAL BACKGROUND

A. Diabetes and Insulin Therapy

Diabetes: A Growing Epidemic

33. 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 when cells stop responding to insulin, too much blood

sugar stays in the bloodstream. Over time, this can cause serious health problems such as heart disease, vision loss and kidney disease.

34. There are two basic types of diabetes. Roughly 90-95% of diabetics develop 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, in the long-term most patients must switch to insulin injections.

35. 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 insulin injections they will die.

36. Insulin treatments are a necessary part of life for those who have diabetes. Interruptions to a diabetic's insulin regimen can have severe consequences. Missed or inadequate doses can trigger hyperglycemia and diabetic ketoacidosis. Left untreated, diabetic ketoacidosis can lead to loss of consciousness and death within days.

37. 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 ten million. Fourteen years later, the count tripled again. Today, over thirty million people (9.4% of the country) live with diabetes.

38. Likewise, the prevalence of diabetes in Indiana has been steadily increasing. Today over 600,000 Indiana adults live with the disease, and another 1.7 million are prediabetic.

Insulin: A Century-Old Drug

39. 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.

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

41. 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 one dollar, explaining that "[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."

42. After purchasing the patent, the University of Toronto contracted with Eli Lilly and Defendant 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.

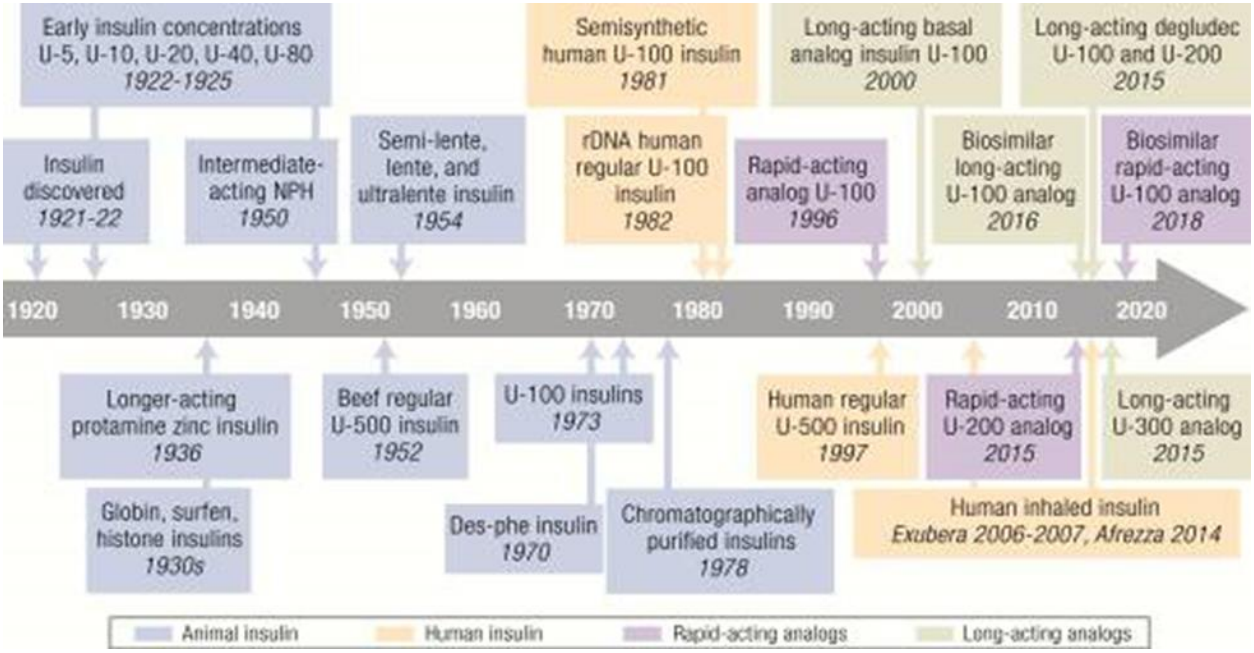
43. Although early iterations of insulin were immediately perceived as lifesaving, there have been numerous incremental improvements since its discovery. The earliest insulin was derived from animals, and until the 1980's was the only treatment available for diabetes.

44. 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 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.

45. Over a decade later, Eli Lilly developed the first analog insulin, Humalog, in 1996. 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 in and regulated by the body.

46. After the initial creation of analog insulin, more variations on analog insulin became possible. Rapid-acting, intermediate, and long-acting insulin products were developed, along with concentrated insulin products for a smaller injection volume. (See figure below for timeline of insulin product developments.)



47. Even though insulin was first extracted nearly one hundred years ago, insulin products are still only manufactured by three companies, Eli Lilly and the two Defendant Manufacturers, in the United States.

48. Many of the at-issue medications are now off-patent. However, the Manufacturers have engaged in illicit tactics to maintain their complete market dominance.

49. Due in large part to their ability to stifle all competition, the Manufacturers make 99% of the insulin products on the market today.

Current Insulin Landscape

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

51. 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.

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

53. 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."

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

55. Dr. Kasia Lipska, a Yale researcher and author of a 2018 study in the Journal of the American Medical Association commented on insulin costs: "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."

56. Nor have the production or research and development costs increased. In fact, in the last ten 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.

57. Another recent study noted anecdotal evidence that the manufacturers could be profitable even if charging under $2 a vial. While the study estimated the total cost (including device and cold-chain distribution) to produce a vial of analog insulin was $2.50, the study noted that even if the estimates were slightly inaccurate, they favored the manufacturers by actually overestimating the cost. "In a discussion with Biocon (a foreign insulin manufacturer) we were told insulin price in India was [around] $2 a vial and Biocon is 'comfortably profitable' at that level. In another discussion we were told Sanofi offered Lantus at under $1.60 in certain emerging markets and national tenders."

58. These figures stand in stark contrast to the annual average of $5,705 that a diabetic in the United States spent on insulin in 2016.

59. Further, while research and development costs often make up a large percentage of the price of a drug, the original drug discovery and patient trials on insulin were performed one hundred years ago. Even the more recent costs, such as developing the recombinant DNA fermentation process and the creation of insulin analogs, were incurred decades ago.

60. 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 of insulin drugs.

61. Despite these decreases in production costs and the lack of new research and development costs, the reported price of insulins has risen astronomically over the last fifteen years.

Insulin Adjuncts: Type 2 Medications

62. Over the past decade, Manufacturer Defendants have also released combination or non-insulin medications that help control the level of insulin in the bloodstream of Type 2 diabetics. Novo Nordisk released Victoza in 2010, and in 2017 released a second such drug, Ozempic. Soliqua, a combination insulin and insulin adjunct, was released by Sanofi in 2016.

63. Victoza and Ozempic are medications known as glucagon-like peptide-1 receptor antagonists (GLP-1) and are similar to the GLP-1 hormone that is already produced in the body. Each of these drugs can be used in combination with insulins to control diabetes.

64. Today, Manufacturer Defendants, along with Eli Lilly, have a dominant market position for all diabetes medications. The relevant medications are detailed in Figure 1 below.

Figure 1: Drugs at issue in this litigation[9]

Insulin Type	Action	Name	Company	FDA Approval	Current Price
Human	**Rapid-Acting**	Humulin R	Eli Lilly	1982	$178 (vial)
		Humulin R 500	Eli Lilly	1994	$1,784 (vial) $689 (pens)
		Novolin R	Novo Nordisk	1991	$165 (vial) $312 (pens)
	Intermediate	Humulin N	Eli Lilly	1982	$178 (vial) $566 (pens)
		Humulin 70/30	Eli Lilly	1989	$178 (vial) $566 (pens)
		Novolin N	Novo Nordisk	1991	$165 (vial) $312 (pens)
		Novolin 70/30	Novo Nordisk	1991	$165 (vial) $312 (pens)
Analog	**Rapid-Acting**	Humalog	Eli Lilly	1996	$342 (vial) $636 (pens)
		Novolog	Novo Nordisk	2000	$347 (vial) $671 (pens)
		Apidra	Sanofi	2004	$341 (vial) $658 (pens)
	Long-Acting	Lantus	Sanofi	2000	$ 340 (vial) $510 (pens)
		Levemir	Novo Nordisk	2005	$ 370 (vial) $ 555 (pens)
		Basaglar (Kwikpen)	Eli Lilly	2016	$392 (pens)
		Toujeo (Solostar)	Sanofi	2015	$466 (pens) $622 (max pens)
		Tresiba	Novo Nordisk	2015	$407 (vial) $610 (pens – 100u) $732 (pens – 200u)
Type 2 Medications		Trulicity	Eli Lilly	2014	$1,013 (pens)
		Victoza	Novo Nordisk	2010	$813 (2 pens) $1,220 (3 pens)
		Ozempic	Novo Nordisk	2017	$1,022 (pens)
		Soliqua	Sanofi	2016	$927.90 (pens)

[9] Although Eli Lilly is not a defendant to this litigation, its insulin products are part of the landscape of available treatments for diabetes and thus are included in various charts throughout this Complaint.

B. The Dramatic Rise in the Price of Diabetes Medications

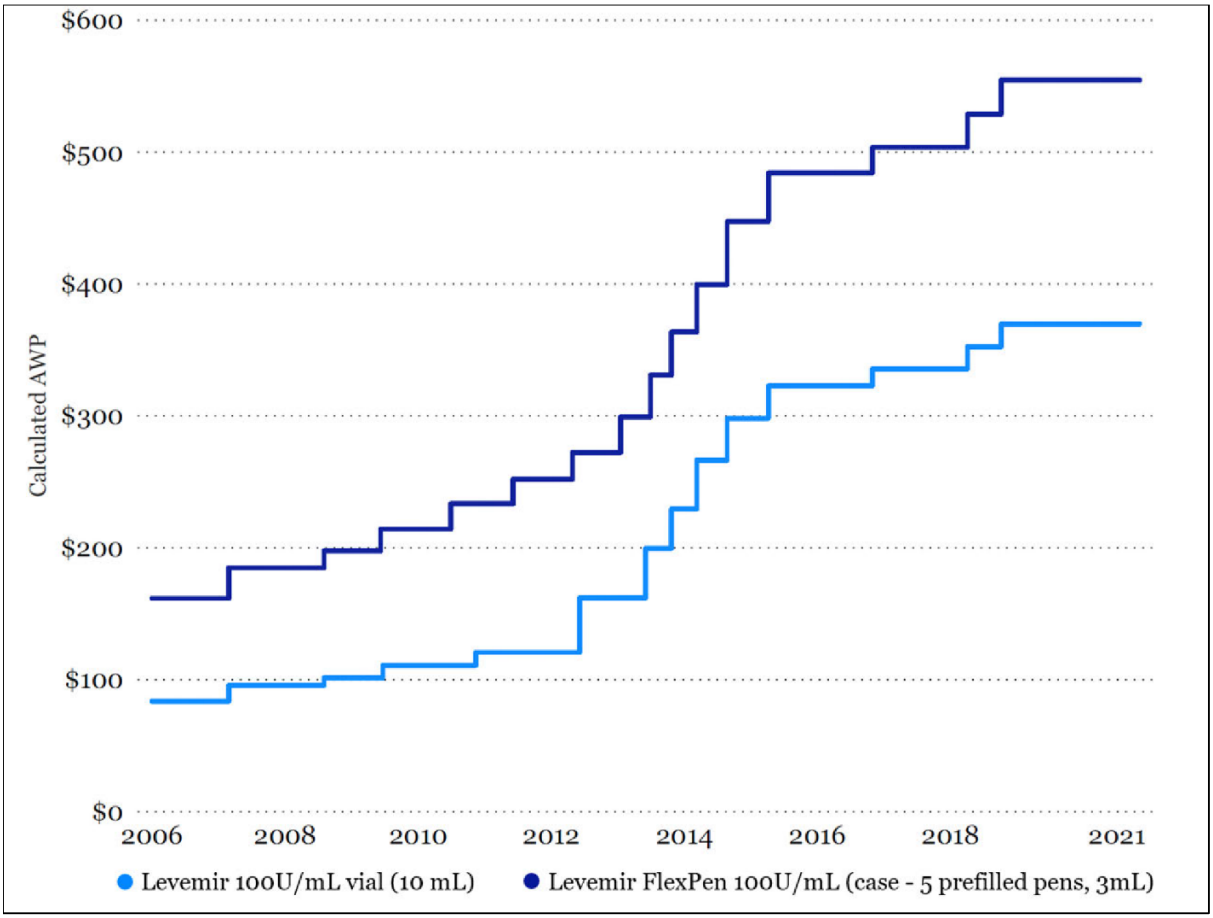
65. In 2003, PBMs began their rise to power. That same year, the price of insulin began its dramatic climb to its current exorbitant level.

66. Since 2003, the list price of certain insulins has increased in some cases by more than 1000%; in comparison the general inflation rate for that time period is 8.3%.

67. By 2016, the average price per month of the four most popular types of insulin rose to $450. Costs have continued to rise, causing up to 25% of diabetics to skimp on or skip lifesaving doses. This behavior is extremely dangerous to a diabetic's health and can lead to a variety of complications, including death.

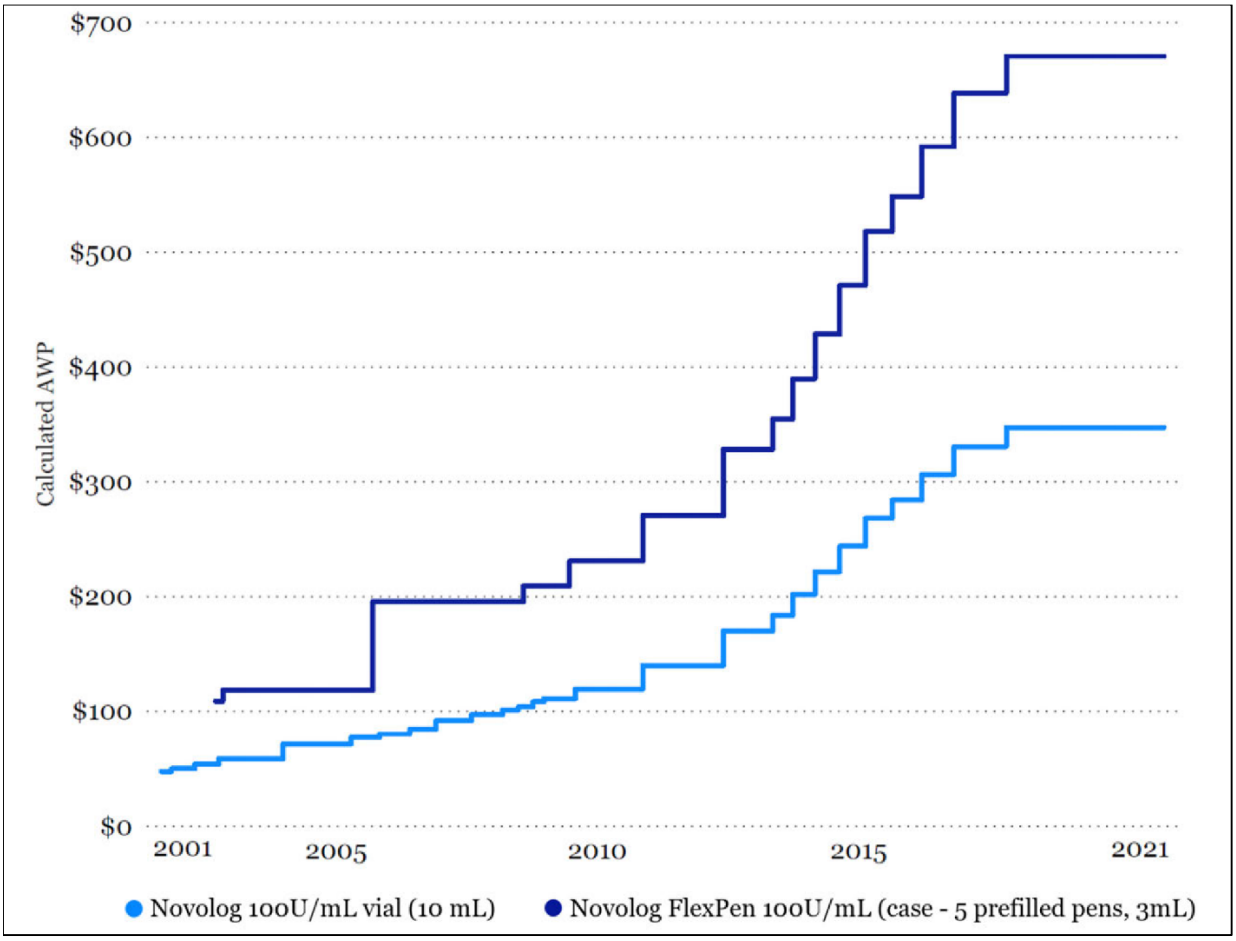
68. Since 2006, Novo Nordisk has falsely inflated its list prices for Levemir, which rose from $162 to $555 for pens and from under $100 to $370 per vial between 2006 and 2020. (See Figure 2.)

Figure 2: Rising reported prices of Levemir from 2006 – 2021



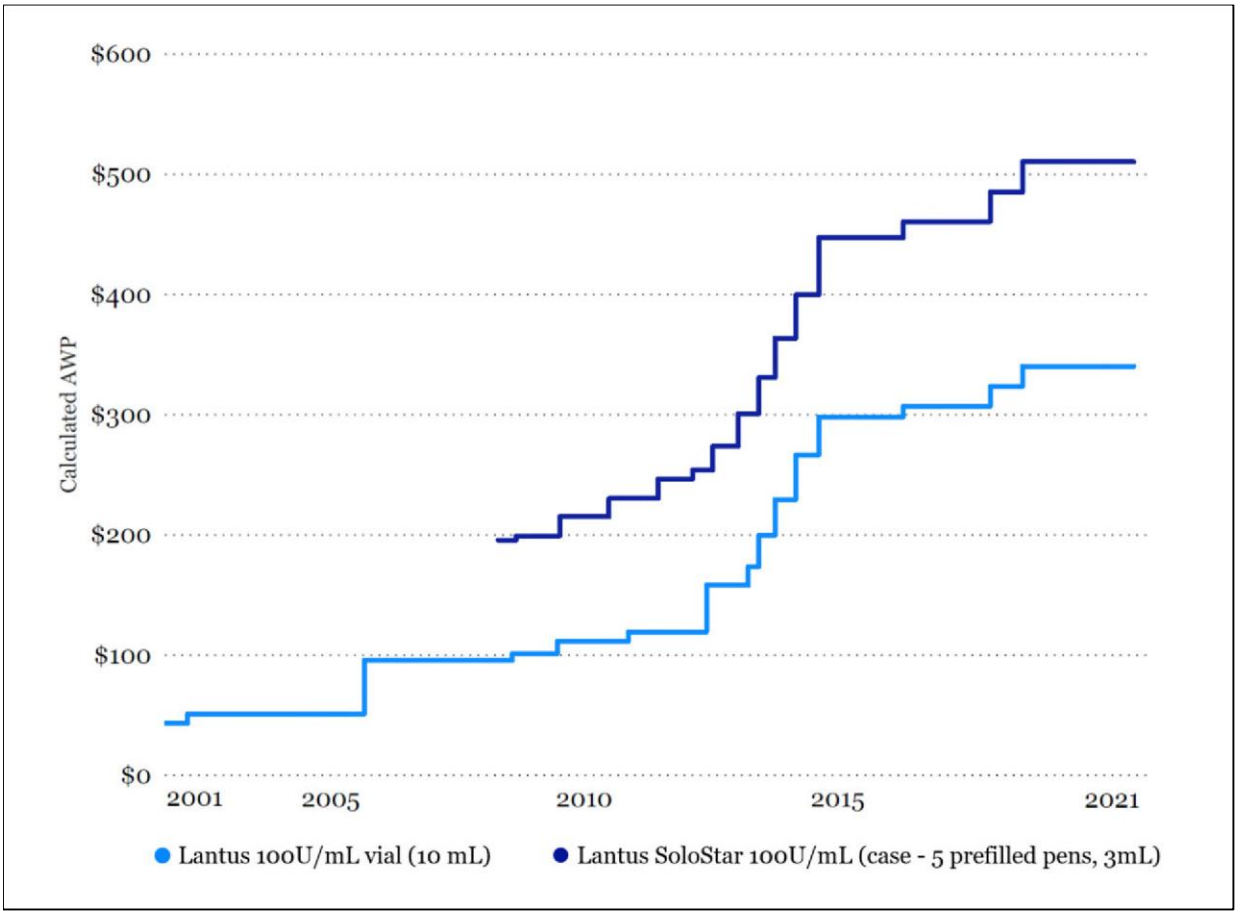
69. From 2002 to 2020, Novo Nordisk falsely inflated the list price of Novolog from $108 to $671 for a package of pens and from less than $50 to $347 for a vial. (See Figure 3.)

Figure 3: Rising reported prices of Novolog vials and pens from 2002 – 2021



70. Defendant Sanofi has kept pace as well, falsely inflating the list price for Lantus, the top-selling analog insulin, from less than $200 in 2006 to over $500 in 2020 for a package of pens, and from less than $50 to $340 for a vial. (See Figure 4.)

Figure 4: Rising reported prices of Lantus vials and pens from 2001 – 2021



71. Manufacturer Defendants' non-insulin diabetes medications have experienced similar recent price increases.

72. Driven by these price hikes, payors' and diabetics' spending on diabetes medications has skyrocketed with totals in the tens of billions of dollars.

73. 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.

74. In thirteen instances since 2009, competitors Sanofi and Novo Nordisk raised the reported 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.

75. 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."

76. 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.

77. Sanofi and Novo Nordisk have engaged in the same lockstep behavior with respect to their long-acting insulins, Levemir and Lantus. Eli Lilly and Novo Nordisk have engaged in the same lockstep behavior with respect to their rapid-acting analog insulins, Humalog and Novolog. Figure 5 demonstrates this collusive behavior with respect to Lantus and Levemir. Figure 6 demonstrates this behavior with respect to Novolog and Humalog.

Figure 5: Rising reported prices of long-acting insulins

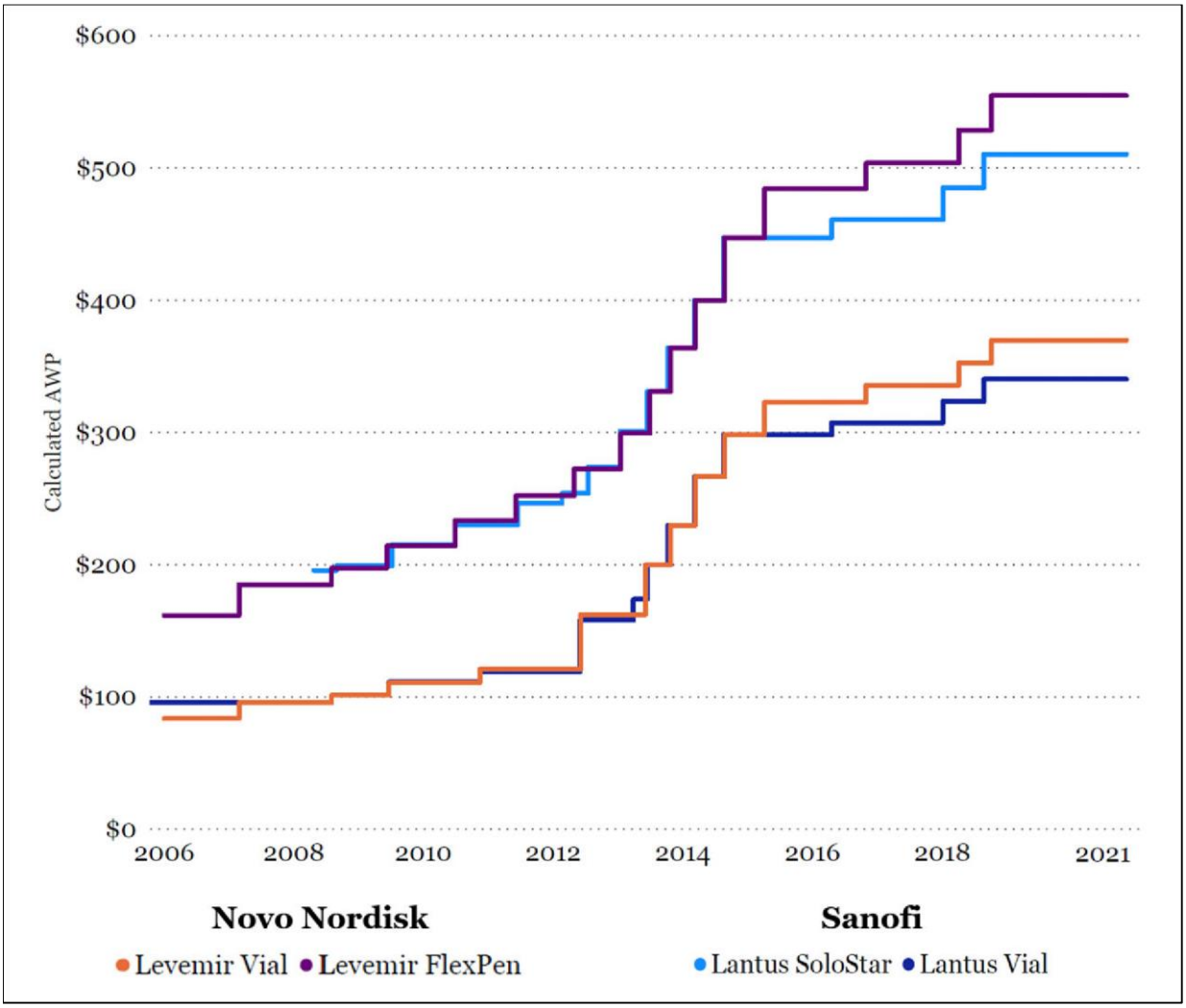
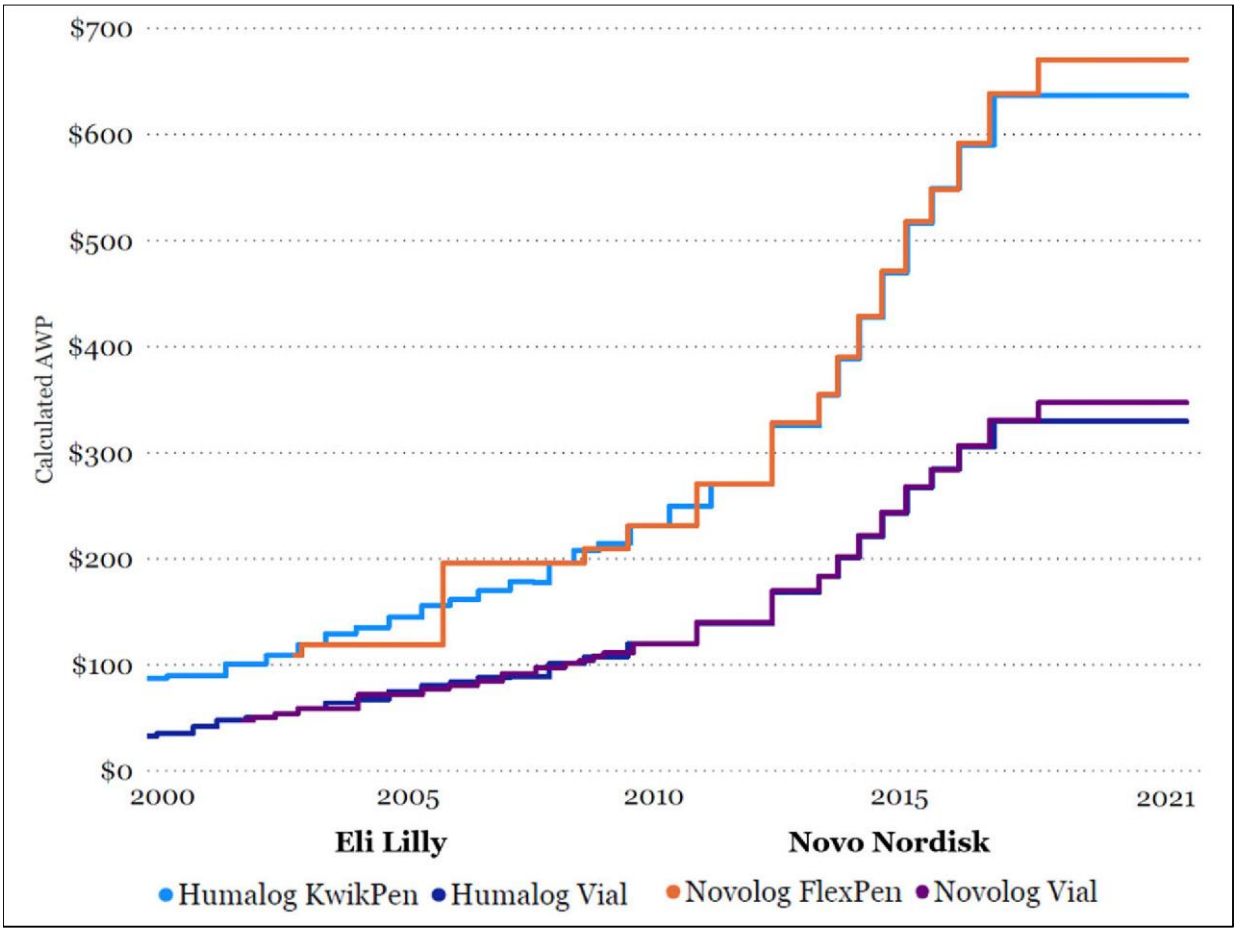
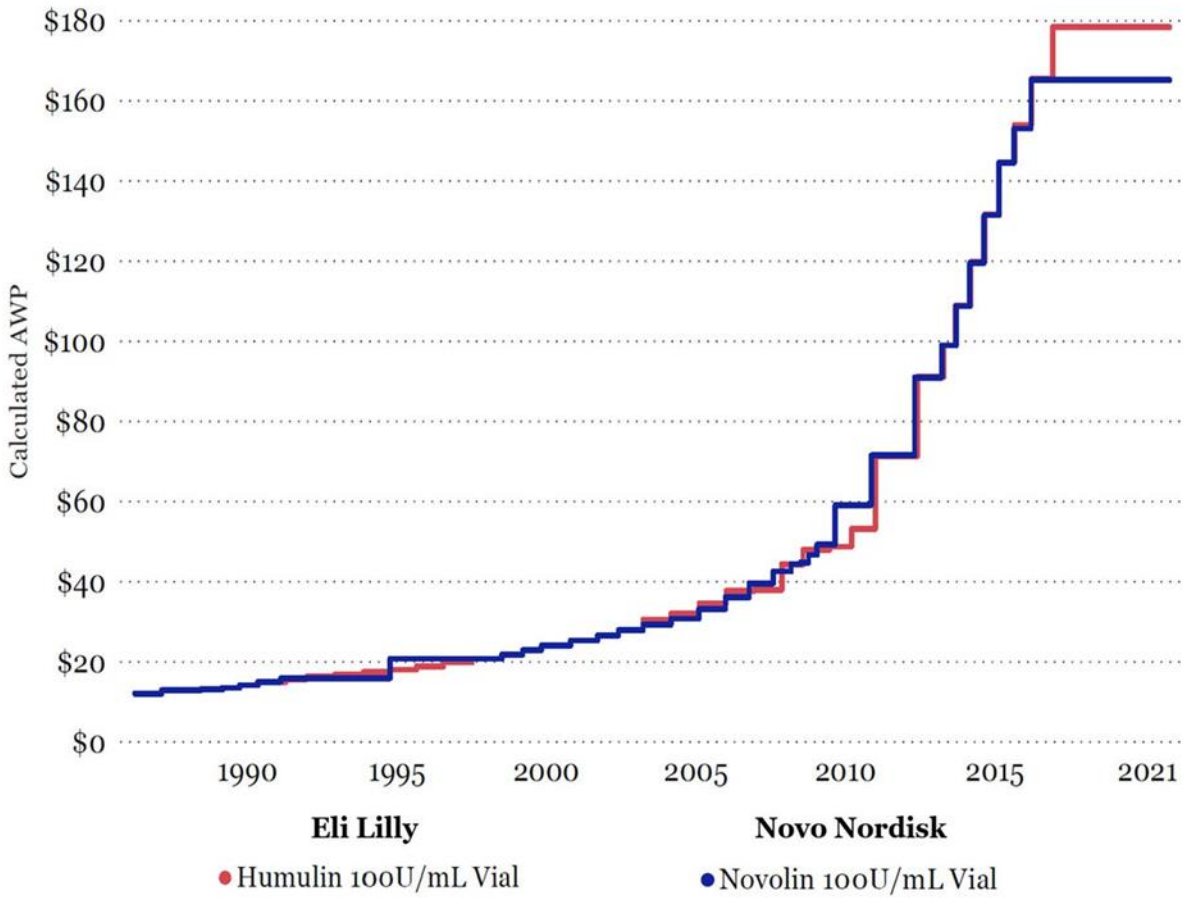


Figure 6: Rising reported prices of rapid-acting insulins



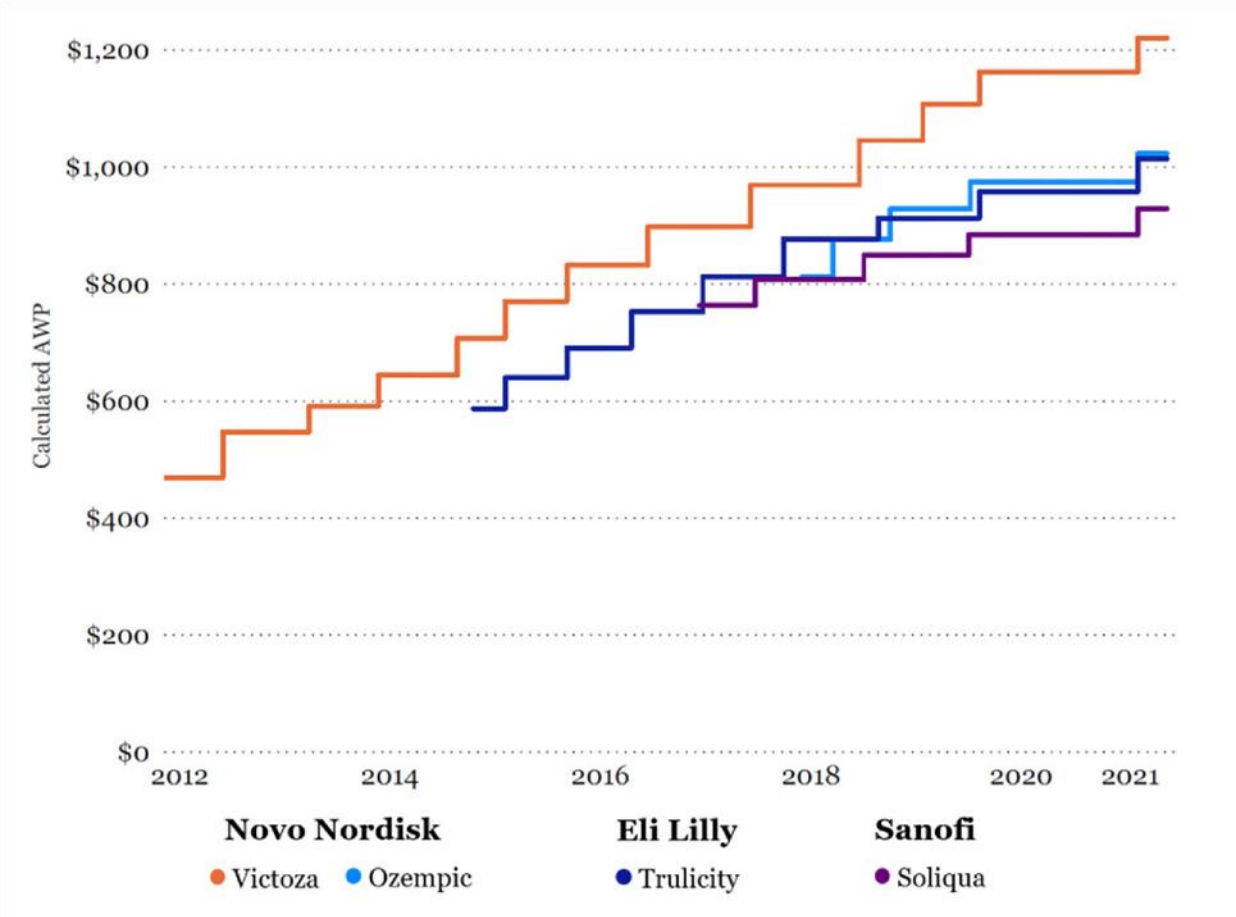
78. Figure 7 demonstrates this behavior with respect to human insulins, Eli Lilly's Humulin and Novo Nordisk's Novolin.

Figure 7: Rising reported price increases for human insulins



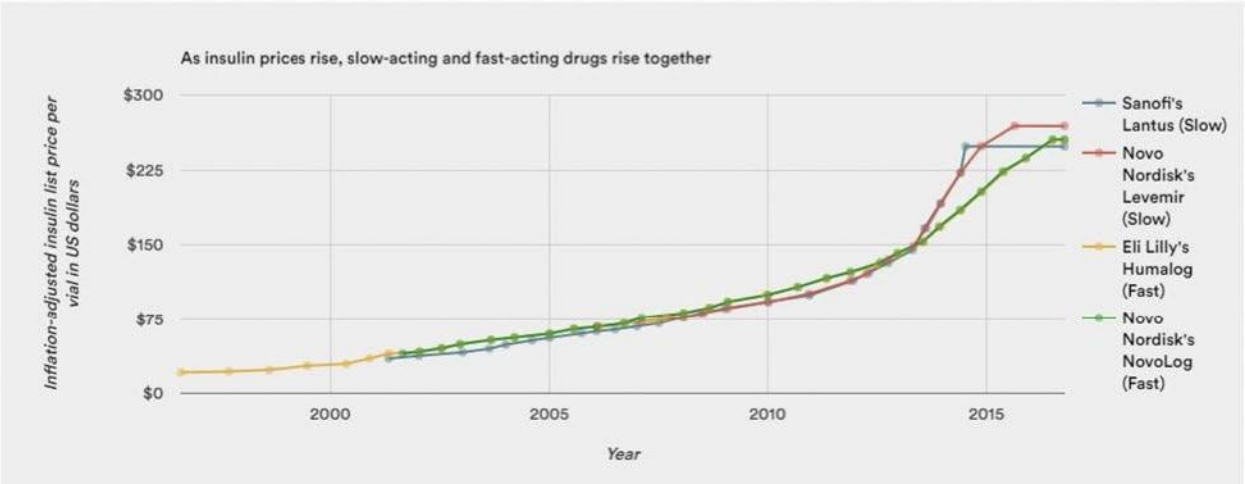
79. Figure 8 demonstrates Manufacturer Defendants' lockstep price increases for their Type 2 drugs, Trulicity, Victoza, Ozempic and Soliqua.

Figure 8: Rising reported prices of Type 2 drugs



80. Figure 9 shows how Manufacturer Defendants have collectively raised the prices of insulin products in near-perfect unison.

Figure 9: Lockstep insulin price increases



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

C. Insulin Costs and the Pharmaceutical Payment and Supply Chain

Overview: The Prescription Drug Payment and Supply Chain

82. 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 (PBMs) and patients.

83. 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.

84. The pharmaceutical industry 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 each entity in the pharmaceutical chain pays for a drug is directly tied to the manufacturer's list price.

85. There is no transparency in this pricing system; typically, only a brand drug's list price—also known as its Average Wholesale Price (AWP) or the mathematically-related Wholesale Acquisition Cost (WAC)—is available. To note, the WAC is not the final price that wholesalers (or any other entity in the pharmaceutical pricing chain) pay for the Manufacturers' drugs. The final price that a wholesaler pays the Manufacturers is less than WAC because of post-purchase discounts.

86. Drug manufacturers self-report AWP or other prices upon which AWP is based to publishing compendiums such as First Databank, Redbook, and others who then publish that price.

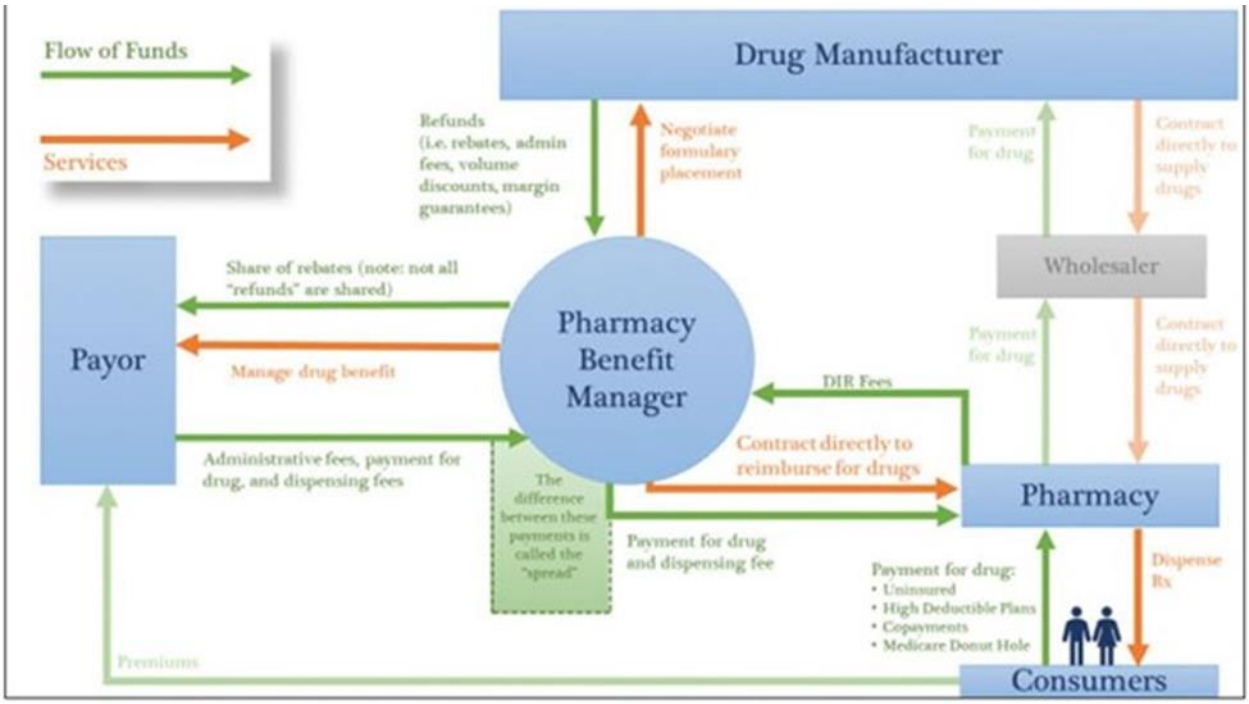
87. As further described herein, due to the structure of the pharmaceutical payment chain and the role of PBMs, AWP persists as the most commonly and continuously used reported price in reimbursement and payment calculations and negotiations for both payors and patients.

PBM's Role in the Pharmaceutical Payment Chain

88. When they first came into existence in the 1960's, 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.

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

Figure 10: Insulin distribution and payment chain



90. PBMs establish standard drug formularies, which are the lists of offered drugs that will be covered by a health care plan. By controlling placement on a drug formulary, the PBMs drive drug utilization; the more accessible a drug is on the PBM's standard formularies, the more that drug will be used throughout Indiana.

91. PBMs also 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 for the drugs utilized by a payor's beneficiaries.

92. In taking on the role of setting prices through negotiations with drug manufacturers, PBMs affirmatively represented that they were using their leverage to drive down drug prices on behalf of payors.

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

94. PBMs also own mail-order, retail, and specialty pharmacies that purchase and take possession of prescription drugs, including those at issue here, and directly supply those drugs to patients.

95. Often times PBMs purchase drugs from the Manufacturers and dispense them to the patients through these mail-order and specialty pharmacies.

96. Even in instances when a PBM's pharmacies purchase drugs from wholesalers, those costs are set by direct contracts with the Manufacturers.

97. In addition, and of particular significance here, PBMs contract with pharmaceutical manufacturers including the Defendants. PBMs receive rebates, fees, and other consideration from the Manufacturers ("Manufacturer Payments").

98. These relationships allow PBMs to exert tremendous influence over what drugs are available throughout Indiana, on what terms, and at what prices.

99. In the early 2000's, PBMs started buying pharmacies.

100. When a PBM combines with a pharmacy, it has additional incentive to collude with manufacturers to keep certain prices high.

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

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

103. In total, nearly forty different PBM entities have merged or otherwise been absorbed into only a handful of dominant PBMs. Moreover, each of the dominant PBMs are now owned by other significant players within the pharmaceutical chain. Express Scripts merged with Cigna in a $67 billion dollar deal. Caremark was bought by the largest pharmacy in the United States, CVS, for $21 billion; CVS now owns Aetna following a $69 billion dollar deal. OptumRX was acquired by the largest health insurance company in the United States, UnitedHealth Group.

104. After merging or acquiring all of their competitors and now backed by multi-billion-dollar corporations, the few dominant PBMs have taken over the market in the past decade—controlling over 75% of the market and managing pharmacy benefits for over 270 million Americans. These few dominant PBMs collectively report more than $300 billion in annual revenue.

105. 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 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."

The Insulin Pricing Scheme

106. Given the market power possessed by the dominant PBMs and the crucial role their standard formularies play in the pharmaceutical pricing chain, Manufacturer

Defendants understand that the PBMs wield enormous control over drug prices and drug purchasing behavior.

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

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

109. PBMs, however, do not want prices for diabetes medications to decrease because they make more money on higher prices. The Manufacturers also benefit from the higher prices.

110. Consequently, the market for insulin products does not function as a normal market in which competition leads to a decrease in prices. Instead, Manufacturer Defendants and PBM Defendants have developed a way to game the system for their mutual benefit—the Insulin Pricing Scheme.

111. PBM formularies are at the center of the Insulin Pricing Scheme. Given the asymmetry of information between payors and PBMs and the costs associated with making formulary changes, most payors accept the standard formularies offered by the PBMs.

112. Controlling the standard formularies gives PBMs a crucial point of leverage over the system. Manufacturers recognize that due to the dominant market share of the largest PBMs, any exclusion of a particular diabetes medication from their standard

formularies (or placement in a non-preferred position) could mean billions of dollars in profit loss for Manufacturer Defendants.

113. Manufacturer Defendants recognize that the PBMs' profits are directly tied to the manufacturers' list prices. Manufacturer Defendants also know that—contrary to their public representations—PBMs make more money from increasing prices, rather than from negotiating the lowest possible prices for their payors.

114. Thus, the Insulin Pricing Scheme works as follows: to gain formulary access from the PBM Defendants for their diabetic products, Manufacturer Defendants first artificially and willingly raise their prices, and then pay a significant undisclosed portion of that false list price back to the PBM Defendants ("Manufacturer Payments").

115. As described in the prior paragraph, these Manufacturer Payments include all payments or financial benefits of any kind conferred by the Manufacturer Defendants to the PBM Defendants or their related entities, either directly via contract or directly via manufacturer-controlled intermediaries, and include rebates, administrative fees, inflation fees, pharmacy supplemental discounts, volume discounts, price or margin guarantees, and any other form of consideration exchanged. Though Manufacturer Payments are provided under a variety of labels, they all share a common trait: all are quid pro quo for formulary inclusion on the PBM Defendants' standard offerings.

116. Manufacturer Defendants' list prices for the at-issue diabetic medications are so untethered from the actual prices realized that they constitute a false price.

117. The PBM Defendants grant preferred status on their standard formularies based upon the highest false price list, which is then used as the basis for pricing benchmarks such as AWP and WAC. The overages are passed through the supply chain through the PBM

Defendants' other contracts, generating the largest possible profits for the Manufacturer Defendants.

118. In this "best of both worlds" scenario, the Manufacturer Defendants' Manufacturer Payments secure their preferred formulary position, which significantly increases their revenue, but does not impact their profit margins due to the inflated false pricing scheme.

119. The PBM Defendants' clear financial incentive to participate in the Insulin Pricing Scheme includes: (1) retaining a significant—yet undisclosed—percentage of the secret Manufacturer Payments; (2) using the false list price created by the scheme to generate profits from pharmacies in their networks; and (3) relying on the same false list prices to drive up the PBM Defendants' profits through their own pharmacies.

120. Thus, while the PBM Defendants represent that they use their market power to drive down prices for diabetes medications, these representations are patently false. Instead, the PBM Defendants and Manufacturer Defendants work together to intentionally drive the prices for diabetic products up.

121. The insular nature of the pharmaceutical industry has provided Manufacturer Defendants ample opportunity for contact and communication with PBM Defendants and competitors in order to devise and agree to the Insulin Pricing Scheme.

122. To ensure the success of the Insulin Pricing Scheme, Manufacturer Defendants:

- Communicate constantly with the PBM Defendants, regularly meeting and exchanging information to construct and refine the PBM formularies that fuel the scheme, including direct involvement in determining not only where their

own diabetes medications are placed on the PBM formularies and with what restrictions, but also determining the same for competing products;

- Glean shared confidential and proprietary information with the PBM Defendants in furtherance of the Insulin Pricing Scheme, such as market data from PBM drug utilization tracking efforts and mail order pharmacy claims, internal medical efficacy studies, and financial data, then use that information in coordination to set the false prices for the at-issue medications;
- Engage in coordinated outreach programs with PBM Defendants directly to patients, pharmacies, and prescribing physicians to convince them to switch to the diabetes medications that are more profitable for the PBM and Manufacturer Defendants, even drafting and editing letters in tandem to send out to diabetes patients on behalf of PBM Defendants' payor clients.

123. 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. In fact, executives from each Manufacturer Defendant are part of the members of the PhRMA board of directors and/or part of the PhRMA executive leadership team.

124. Manufacturer Defendants also communicate through direct interaction with the PBM Defendants and other manufacturers at PBM trade associations and industry conferences. Each of the major PBMs has executives on the board of the main PBM trade association, the Pharmaceutical Care Management Association ("PCMA"), and each Manufacturer Defendant is an affiliate member of this organization.

125. The PCMA annual conferences appear to be at the center of the Insulin Pricing Scheme. Every year, high-level representatives and corporate officers from both Manufacturer and PBM Defendants attend these conferences to meet in person and engage in discussions, including those in furtherance of the scheme. Notably, many of the forums at the 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 Defendants and pharma executives."

126. From at least 2010 to 2019, representatives from each Manufacturer Defendant met privately with representatives from each major PBM during both the Annual Meetings and the Business Forum conferences that the PCMA held each year. Prior to these meetings, dedicated teams of executives from each Defendant would spend weeks preparing PCMA "pre-reads" and reports. These reports not only demonstrate the deep involvement of each Manufacturer Defendant in the Insulin Pricing Scheme, but they also reflect the tangled web that gave rise to the scheme.

127. Notably, key lockstep price increases as described herein occurred shortly after the Manufacturer 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 hosted private rooms and executives from each Manufacturer Defendant engaged in several meetings with PBM Defendants' executives throughout the conference. Several days later, on October 1, 2017, Sanofi increased Lantus's list price by 3% and Toujeo's list by 5.4%. A few weeks later Novo Nordisk recommended that

the company make a 4% list price increase to match the Sanofi increase, which was approved on November 3, 2017 to go into effect on January 1, 2018.

128. Likewise, on May 31, 2014, Novo Nordisk raised the list price on Levemir several hours after Sanofi took its list price increase on Lantus. These increases occurred only a few weeks after a PCMA spring conference in Washington, D.C.

129. Far from using their prodigious bargaining power to lower drug prices as they claim, PBM Defendants use their dominant positions to coordinate with Manufacturer Defendants to generate billions of dollars of profit at the expense of the State of Indiana and its diabetic residents.

D. Manufacturer Defendants Admit to Insulin Pricing Scheme and Its Harm

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

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

132. Further, Defendants explicitly admitted that the price that diabetics have to pay out-of-pocket for insulin is too high. For example:

- Dr. Sumit Dutta, Chief Medical Officer of OptumRx, stated, "A lack of meaningful competition allows the manufacturers to set high [reported] prices and continually increase them which is odd for a drug that is nearly 100 years old and which has seen no significant innovation in decades.

These price increases have a real impact on consumers in the form of higher out-of-pocket costs."

- Thomas Moriarty, Chief Policy and External Affairs Officer and General Counsel for CVS Health, testified, "A real barrier in our country to achieving good health is cost, including the price of insulin products which are too expensive for too many Americans. Over the last several years, [reported] prices for insulin have increased nearly 50 percent. And over the last ten years, [reported] price of one product, Lantus, rose by 184%.
- Kathleen Tregoning, Executive Vice President of External Affairs at Sanofi, testified, "Patients are rightfully angry about rising out-of-pocket costs and we all have a responsibility to address a system that is clearly failing too many people…we recognize the need to address the very real challenges of affordability…since 2012, average out-of-pocket costs for Lantus have risen approximately 60 percent for patients…"
- Doug Langa, Executive Vice President of Novo Nordisk, stated, "On the issue of affordability…I will tell you that at Novo Nordisk we are accountable for the [reported] prices of our medicines. We also know that [reported] price matters to many, particularly those in high-deductible health plans and those that are uninsured.

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

134. None of the Manufacturer 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 Manufacturers are collectively solely responsible for the price of almost every single vial of insulin sold in the United States.

135. Manufacturer Defendants admitted that they agreed to and did participate in the Insulin Pricing Scheme and that the rise in prices was a direct result of the scheme. For example:

- Novo Nordisk's President, Doug Langa, explained his company's role in perpetuating the "perverse incentives" of the scheme along with the PBMs: "[T]here is this perverse incentive and misaligned incentives (in the insulin pricing system) and this encouragement to keep [reported] prices high. And *we've been participating in that system* because the higher the [reported] price, the higher the rebate…There is significant demand for rebates. We spent 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).
- At the same hearing, Sanofi Executive Vice President for External Affairs Kathleen Tregoning 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."

136. The PBM Defendants' executives have also corroborated the scheme, admitting that they grant preferred, or even exclusive, formulary position because of higher

Manufacturer Payments made by Manufacturer Defendants. Amy Bricker, President of Express Scripts, explained that a lower-priced insulin was not given preferred formulary status by saying, "Manufacturers do give higher [payments] for exclusive [formulary] position…"

137. While all Manufacturer Defendants acknowledged their participation in the Insulin Pricing Scheme before Congress, in an effort to avoid culpability for the precipitous price increase, Manufacturer Defendants pointed their finger at the PBM Defendants while PBM Defendants blamed the Manufacturers.

138. PBM Defendant executives specifically testified to Congress that Manufacturers are solely responsible for their price increases and that the Manufacturer Payments that the PBMs receive are not correlated to rising insulin prices. This statement is objectively false; a February 2020 study by the Leonard D. Schaeffer Center for Health Policy & Economics at the University of South Carolina titled "The Association Between Drug Rebates and List Prices" found that an increase in the amount that 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. The study concluded that reducing or eliminating Manufacturer Payments could result in lower prices and reduced out-of-pocket expenditures.

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

140. The Manufacturers have argued before Congress that the PBMs are to blame for high insulin prices because of their demands for higher Manufacturer Payments in exchange for formulary placement. Manufacturer Defendants claimed that they have not been profiting off of insulin due to declining net prices of these drugs. Those statements are also untrue. A 2020 study by JAMA recently published in the Wall Street Journal provides data suggesting that the net prices (reported list prices less Manufacturer Payments) of branded insulin products have actually increased by 51% in the past ten years.

141. In addition, 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 insulin products regardless of any Manufacturer Payments they are sending back to the PBMs. During the same time period when insulin price increases were at their steepest, distributions to Manufacturer Defendants' shareholders in the form of cash dividends and share repurchases totaled $122 billion. In fact, during this time period the Manufacturer Defendants spent a significantly lower proportion of profits on research and development compared to shareholder payouts.

142. In January 2021 the U.S. Senate Finance Committee issued a report titled "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug" that detailed Congress' findings after reviewing over 100,000 pages of internal company documents from Sanofi, Eli Lilly, Novo Nordisk, and the largest PBMs. The Senate insulin report concluded, *inter alia:*

- Manufacturer Defendants are retaining more revenue from insulin than in the 2000's;
- Manufacturer Defendants have aggressively raised the list price of their insulin products absent significant advances in the efficacy of the drugs; and
- Manufacturer Defendants only spend a fraction of their revenue related to the at-issue drugs on research and development—Sanofi spent $902 million on R&D costs for insulin products between 2014 and 2018, during which time the company generated $37 billion in revenue on those drugs; Novo Nordisk failed to provide requested R&D spending to the Committee.

143. The truth is—despite their finger pointing in front of Congress—both PBM and Manufacturer Defendants are responsible for their concerted efforts in creating the Insulin Pricing Scheme. This reality was echoed in a statement from the Senate report, summarizing Congress' findings of their two-year probe into the scheme as follows: "[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."

E. The Effects of Illegal Insulin Pricing

144. For Manufacturers, the Insulin Pricing Scheme affords them the ability to pay Defendant PBMs significant, yet undisclosed, Manufacturer Payments in exchange for formulary placement—which garners Manufacturer Defendants greater revenues from sales without decreasing their profit margins.

145. 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 reported price.

146. During the relevant time period, Indiana diabetics were dispensed the at-issue drugs and made out-of-pocket payments based on the false list prices generated by the scheme.

147. In addition, as a large government employer, the State provides health benefits to its employees, retirees, and their dependents and has spent millions of dollars a year on the at-issue diabetes medications.

148. The State also spends millions of dollars a year purchasing the at-issue diabetes medications for use in state-run hospitals, prisons, and other facilities.

149. The State also pays for the at-issue medications through its administration of the state Medicaid program, which provides medical care including pharmacy benefits to the State's most vulnerable citizens, many of whom are diabetic.

150. At all times during the relevant time period, Defendants knew that diabetics and payors, including the State, relied on the false list prices generated by the Insulin Pricing Scheme to pay for the at-issue drugs and, in fact, paid prices for such medications based off of such falsely inflated prices.

151. Defendants knew that Indiana diabetics and payors, including the State, expected and desired to pay the lowest fair-market price possible for the at-issue drugs.

152. Defendants knew that the artificially inflated list prices generated by the Insulin Pricing Scheme were false and completely untethered from the actual prices that Defendants were paid for the drugs.

153. As the list prices for the at-issue drugs detached completely from actual prices, the list prices became increasingly misrepresentative to the point of becoming unlawful.

154. Despite this knowledge, Defendants caused the false list prices generated by the Insulin Pricing Scheme to be published throughout Indiana through publishing compendia and in various promotional and marketing materials distributed by entities downstream in the drug supply chain.

155. Manufacturer Defendants also published these prices to the PBMs and their pharmacies who then used the false prices to set the amount payors, like the State of Indiana, and diabetics pay for the at-issue drugs.

156. By publishing their prices throughout Indiana, the Manufacturer Defendants held these prices out as a reasonable price by which to base the prices diabetics and payors pay for the at-issue drugs.

157. These representations are false. Manufacturer Defendants knew that their false list prices were not remotely related to the actual price Manufacturer Defendants receive for the at-issue drugs and were not based upon transparent or competitive factors such as cost of production or research and development.

158. Notably, during the relevant time period, Manufacturer Defendants published prices in Indiana of $300 - $400 for the same at-issue drugs that they had profitably priced at $1.60 in markets that have not been corrupted by the Insulin Pricing Scheme.

159. Manufacturer Defendants' false list prices were artificially and arbitrarily inflated in furtherance of the Insulin Pricing Scheme to generate profits for the Manufacturer Defendants and their PBM Defendant conspirators.

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

161. Manufacturer Defendants do not disclose the details of their agreements with Defendant PBMs or the Manufacturer Payments they make to Defendant PBMs; likewise, the PBM Defendants do not disclose the details of the agreements nor the Manufacturer Payments they receive.

162. Manufacturer Defendants do not disclose the actual prices for the at-issue drugs.

163. Defendants conceal their false and deceptive conduct by signing confidentiality agreements with any entity in the supply chain who knows the actual prices of the at-issue drugs.

164. Defendants' efforts to conceal their pricing structures for the at-issue drugs is additional evidence that each Defendant knows its conduct is false and deceptive.

165. Indiana diabetics and payors, including the State, have no choice but to pay based on Defendants' false list prices because diabetics need these medications to survive and Manufacturer Defendants make virtually all of the diabetes medications available in Indiana.

166. Indiana diabetics and payors, including the State, have paid for the at-issue diabetic medications at the false prices generated by the Insulin Pricing Scheme because they relied on these prices as reasonable bases for their life-sustaining medications.

167. Indiana diabetics and payors, including the State, did not know that (i) the list prices were falsely inflated; (ii) the list prices were manipulated to satisfy profit demands; and (iii) the list prices bore no relationship to the price paid for, or the pricing structure of,

the at-issue drugs as they were sold to PBMs. This lack of knowledge is due to Defendants' efforts to affirmatively conceal the truth.

168. Defendants' Insulin Pricing Scheme has cost the State of Indiana hundreds of millions of dollars in overcharges.

169. The State of Indiana has been directly damaged by the Insulin Pricing Scheme as a payor/purchaser for Manufacturer Defendants' at-issue diabetes medications.

170. The State pays for the diabetic drugs through its health plans, administration of its Medicaid program, and by purchases for use in state-run facilities. Each purchase or repayment has been based on false list prices generated by the Insulin Pricing Scheme.

171. Importantly, because of Defendants' success in hiding the Insulin Pricing Scheme, no payor, including the State, knew that the prices for these particular medications were falsely inflated such that the prices are unlawful.

172. The acts and practices of Defendants have had the purpose or effect, or the tendency or capacity, of unreasonably restraining competition and injuring competition by preventing competition for the diabetes medications at issue, and have directly resulted in an increase in prices for those drugs.

173. By unreasonably and illegally restraining competition for the diabetes medications at issue, Defendants have deprived the State and its consumers of the benefits of competition that the state antitrust laws are designed to promote, preserve and protect.

174. As a direct and proximate result of the unlawful conduct alleged herein, the State and its consumers were not and are not able to purchase the at-issue diabetes medications at prices determined by a market unhindered by the impact of Defendants' anticompetitive behavior. Instead, they have been and continue to be forced to pay

artificially high prices. Consequently, they have suffered substantial injury in that they have paid more and continue to pay more for the medications at issue than they would have paid in an otherwise competitive market.

175. As a result, the State has unknowingly overpaid millions of dollars every year for Manufacturer Defendants' diabetes medications. Indiana's Medicaid program alone spends more than $170 million per year on diabetes medications. As the State continues to pay for the at-issue drugs based on the false prices generated by the scheme, the harm to the State is ongoing.

176. The rising prices for diabetic medications have a devastating effect on the health of diabetics. They have also caused a staggering increase in overall healthcare costs to the State.

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

178. One national model projected that improved adherence to medication protocols would avert almost 700,000 emergency department visits and over 340,000 hospitalizations annually for diabetics, representing a savings of $4.7 billion. Combined with other related costs, the total annual impact to the health care systems of non-adherence to diabetic medications is an estimated $8.3 billion.

179. Much of the increased healthcare costs caused by the Insulin Pricing Scheme are shouldered by the State. The amounts spent by Indiana each year on diabetes-related health care costs has risen dramatically during the relevant time period, now totaling more than $1 billion a year.

180. Lack of adherence to diabetes medications also has a global impact on the general welfare of the State due to its effect on labor productivity. Through absenteeism, lack of productivity when present, and disability, the decrease in work productivity has damaged the State by injuring its economy and decreasing its tax revenue.

181. The most morally repugnant impact of the Insulin Pricing Scheme has been to Indiana diabetics themselves. Not only have diabetic residents been overcharged by millions of dollars in out-of-pocket costs, for many patients the scheme has also cost them their health and emotional well-being. Unable to afford Defendants' price increases, many diabetics in Indiana have begun to engage in highly risky behaviors with respect to their disease such as rationing their insulin, skipping their refills, injecting expired insulin, reusing needles, and avoiding doctors' visits. To compensate for their lack of insulin, some patients starve themselves, foregoing one or more meals a day.

182. 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.

183. The Insulin Pricing Scheme has pushed, and will continue to push, access to these lifesaving drugs out of reach for many diabetes patients in Indiana. This harm is ongoing.

CLAIMS FOR RELIEF

I. VIOLATIONS OF THE INDIANA DECEPTIVE CONSUMER SALES ACT—ALL DEFENDANTS

184. Plaintiff realleges and incorporates by reference each of the allegations contained in the preceding paragraphs as if fully alleged herein.

185. Plaintiff, State of Indiana, on behalf of itself and its citizens, seeks all remedies available against Defendants under the Deceptive Consumer Sales Act, Indiana Code § 24-5-0.5-1 *et seq*, including, without limitation, injunctive relief, restitution, and other equitable relief such as disgorgement, costs, and penalties. Plaintiff maintains that Defendants' acts, omissions, or practices were and are unfair, abusive, or deceptive and substantially injurious to the state fisc, the public welfare, and to all citizens of the State.

186. All Defendants are suppliers within the meaning of Indiana Code § 24-5-0.5-2(a)(3).

187. The acts, omissions, or practices alleged in the preceding paragraphs are unfair, abusive, or deceptive with the meaning of Indiana Code § 24-5-0.5-3.

188. All Defendants knowingly committed the acts, omissions, or practices alleged in the preceding paragraphs.

189. All Defendants committed incurable deceptive acts, and the acts, omissions, or practices alleged in the preceding paragraphs as part of a scheme, artifice, or device with intent to defraud or mislead.

190. Manufacturer Defendants' repeated and continuing violations of DCSA include:

a. Intentionally and falsely misleading the state or its subdivisions or agencies regarding the costs and amounts paid for the at-issue diabetes medications;

b. Intentionally and falsely inflating the list prices for the at-issue diabetes medications;

c. Using to their advantage and helping to perpetuate an opaque system of contracts regarding the provision of pharmacy services such that payments and services can be misrepresented and hidden due to the lack of transparency;

d. Using deception to obtain or attempt to obtain payments to which they were not entitled;

e. Receiving payments to which they were not entitled;

f. Receiving payments in a greater amount than that to which they were entitled;

g. Failing to clearly and accurately report prices and costs of the at-issue medications such that the State and its citizens could adequately determine the fair market costs of the products;

h. Deceptively labeling and misrepresenting amounts paid to PBMs ("Manufacturer Payments") to conceal their purpose;

i. Engaging in business practices that result in higher AWP and other benchmark prices, which serves to continuously increase drug prices over time;

j. Engaging in business practices that cause the State's health care costs to increase over time; and

k. Causing financial and physical harm to Indiana consumers who require the at-issue medications.

191. PBM Defendants' repeated and continuing violations of DCSA include:

a. Conspiring to intentionally and falsely mislead the state regarding the costs and amounts paid for the at-issue diabetes medications;

b. Conspiring to intentionally and falsely inflate the list prices for the at-issue diabetes medications;

c. Using to their advantage and helping to perpetuate an opaque system of contracts regarding the provision of pharmacy services such that payments and services can be misrepresented and hidden due to the lack of transparency;

d. Using deception to obtain or attempt to obtain payments to which they were not entitled;

e. Receiving payments to which they were not entitled;

f. Receiving payments in a greater amount than that to which they were entitled;

g. Conspiring to fail to clearly and accurately report prices and costs of the at-issue medications such that the State and its citizens could adequately determine the fair market costs of the products;

h. Conspiring to deceptively label and misrepresent amounts received from Manufacturer Defendants ("Manufacturer Payments") to conceal their purpose;

i. Engaging in business practices that result in higher AWP and other benchmark prices, which serves to continuously increase drug prices over time;

j. Engaging in business practices that cause the State's health care costs to increase over time; and

k. Causing financial and physical harm to Indiana consumers who require the at-issue medications.

192. Defendants' continuing and systematic acts, practices, or omissions meant to manipulate the prices paid for diabetic medications are unfair, abusive, or deceptive and are likely to cause substantial harm to the State.

193. All actions described herein create potential for further financial harm to the State and its citizens through the increased costs of health care.

194. The practices alleged herein constitute a pattern of unfair, abusive, or deceptive acts, omissions, or practices in violation of Indiana Code § 24-5-0.5-1 *et seq.*

195. Each at-issue purchase made within the State for diabetes medications at the prices generated by the Insulin Pricing Scheme constitutes a separate violation of DCSA.

196. Pursuant to Indiana Code § 24-5-0.5-4(c), the Attorney General has the right to seek injunctive relief to restrain Defendants' violations of DCSA.

197. Pursuant to Indiana Code §§ 24-5-0.5-4(g) and 24-5-0.5-8, the Attorney General has the right to seek civil penalties for each knowing violation, including enhanced civil penalties for "incurable" violations committed.

198. Pursuant to Indiana Code § 24-5-0.5-4(c), the Attorney General may seek any relief necessary to return money unlawfully received from Defendants' violations of DCSA.

II. VIOLATIONS OF THE INDIANA MEDICAID FALSE CLAIMS ACT—MANUFACTURER DEFENDANTS

199. Plaintiff realleges and incorporates by reference each of the allegations contained in the preceding paragraphs as though fully alleged herein.

200. By virtue of the acts alleged above, the conduct of the Defendants violates Indiana law regarding Medicaid False Claims, Indiana Code § 5-11-5.7-1 *et seq*. Defendants' false and fraudulent claims, misrepresentations, illegal remuneration, and defrauding of the State medical assistance programs as set forth above constitute violations of Indiana Code § 5-11-5.7-1 *et seq*.

201. Defendants manipulated and concealed pricing records in order to cause false and fraudulent claims for reimbursement from the state's Medicaid program to be submitted for prescription drugs whose costs it knew were being misrepresented and concealed through a series of opaque contracts hiding false pricing that Defendants themselves created in violation of Indiana Code § 5-11-5.7-1 *et seq*.

202. Defendants have fraudulently concealed the true costs of their diabetes products. Defendants have manipulated pricing through the Insulin Pricing Scheme such that their list prices are an illegal false price that bears no resemblance to the net prices actually paid for the drugs by the PBMs. These prices have been intentionally concealed by the Defendants through opaque contracts and hidden payments.

203. Defendants knowingly presented or caused to be presented a false or fraudulent claim for payment or approval from the State's Medicaid program for prescription drugs, whose costs they knew were being misrepresented and concealed through a series of opaque contracts hiding false pricing that Defendants themselves created in violation of Indiana Code § 5-11-5.7-2(a)(1).

204. Defendants knowingly made, used, or caused to be made or used, false records or statements that are material to false or fraudulent claims for payment or approval from the State's Medicaid program for prescription drugs, whose costs they knew were being misrepresented and concealed through a series of opaque contracts hiding false pricing that Defendants themselves created in violation of Indiana Code § 5-11-5.7-2(a)(2).

205. Defendants had possession, custody, or control of property or money used, or to be used, by the state and knowingly delivered, or caused to be delivered, less than all of the money or property through the State's Medicaid program for prescription drugs, whose costs they knew were being misrepresented and concealed through a series of opaque contracts hiding false pricing that Defendants themselves created in violation of Indiana Code § 5-11-5.7-2(a)(3).

206. Defendants were authorized to make or deliver a document certifying receipt of property used, or to be used, by the state and, with intent to defraud the state, authorized

issuance of receipts without knowing that the information on the receipts was true through the State's Medicaid program for prescription drugs, whose costs they knew were being misrepresented and concealed through a series of opaque contracts hiding false pricing that Defendants themselves created in violation of Indiana Code § 5-11-5.7-2(a)(4).

207. Defendants knowingly made, used, or caused to be made or used, false records or statements concerning obligations to pay or transmit money or property to the state through the State's Medicaid program for prescription drugs, whose costs they knew were being misrepresented and concealed through a series of opaque contracts hiding false pricing that Defendants themselves created in violation of Indiana Code § 5-11-5.7-2(a)(6)(A).

208. Defendants knowingly concealed or knowingly and improperly avoided or decreased obligations to pay or transmit money or property to the state through the State's Medicaid program for prescription drugs, whose costs they knew were being misrepresented and concealed through a series of opaque contracts hiding false pricing that Defendants themselves created in violation of Indiana Code § 5-11-5.7-2(a)(6)(B).

209. Defendants acted in concert to perform the acts described in paragraphs 200 through 208 in violation of Indiana Code § 5-11-5.7-2(a)(7).

210. Defendants caused or induced other persons to perform the acts described in paragraphs 200 through 208 in violation of Indiana Code § 5-11-5.7-2(a)(8).

211. As the actual and proximate result of Defendants' violations, as outlined above, the State has suffered actual damages which will be determined at trial.

212. In addition to actual damages, pursuant to Indiana Code § 5-11-5.7-2(b), the State is entitled to all civil fines and penalties proscribed since Defendants have violated the State's prohibitions against improper payments as outlined above.

213. In addition to the actual damages and civil penalties provided and imposed, Defendants shall further pay to the State all interest and costs provided by Indiana Code § 5-11-5.7-2(b).

III. VIOLATIONS OF THE INDIANA ANTITRUST ACT

214. Plaintiff realleges and reincorporates by reference each of the allegations contained in the preceding paragraphs as though fully alleged herein.

215. The acts alleged in the preceding paragraphs constitute violations of the Indiana Antitrust Act, Indiana Code § 24-1-2-1.

a. The acts alleged in the preceding paragraphs involving agreements between Manufacturer Defendants and agreements between individual Manufacturer Defendants and PBM Defendants to adhere to the Insulin Pricing Scheme constitute schemes, contracts, or combinations in restraint of trade or commerce or are otherwise illegal under Indiana Code § 24-1-2-1.

b. Indiana seeks all relief available under the Indiana Antitrust Act, on behalf of the state, political subdivisions, and natural persons residing in Indiana including, without limitation, the following:

i. Appropriate injunctive or other equitable relief, including disgorgement of any gains derived from the violations, pursuant to Indiana Code §§ 24-1-2-5.1(a), 24-12-5.1(b);

ii. Injuries or damages sustained directly or indirectly by the state or political

subdivisions or natural persons as a result of the violations, pursuant to Indiana Code §§ 24-1-2-5.1(a), 24-12-5.1(b);

iii. Civil penalties pursuant to Indiana Code § 24-1-2-5.1(c);

iv. Costs and fees pursuant to Ind. Code § 24-1-2-5.1; and

v. Other remedies as the Court finds necessary to redress and prevent recurrence of each Defendant's violations.

IV. UNJUST ENRICHMENT—ALL DEFENDANTS

216. Plaintiff realleges and reincorporates by reference each of the allegations contained in the preceding paragraphs as though fully alleged herein.

217. In the alternative, Defendants have benefited from the grossly inflated prices for diabetes products resulting from the unlawful and inequitable acts alleged herein.

218. The State has conferred on Defendants an economic benefit, in the nature of profits resulting from the grossly inflated prices for diabetes products, to the economic detriment of the State.

219. The economic benefit derived by Defendants is a direct and proximate result of Defendants' unlawful practices.

220. The financial benefit derived by Defendants rightfully belongs to the State, as the State incurred the costs of the grossly inflated prices paid for diabetes products.

221. It would be inequitable for Defendants to be permitted to retain any of the profits derived from their unfair and unconscionable methods, acts and practices described herein.

222. Defendants should be compelled to disgorge for the benefit of the State all unlawful or inequitable proceeds received by them.

223. The State has no adequate remedy at law.

JURY DEMAND

224. Plaintiff, State of Indiana, hereby demands a trial by jury on all claims so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that, in due course, the Court issue a permanent injunctive order against Defendants, including any employees, agents, contractors, and those persons in active concert or participation with them, to restrain, enjoin, and prohibit Defendants from:

1. Engaging in any activity in violation of DCSA;
2. Engaging in any activity in violation of the Indiana Medicaid False Claims Act;
3. Engaging in any activity in violation of the Indiana Antitrust Act;
4. Obfuscating or otherwise manipulating prices and payments made for diabetic products;
5. Any other provisions that are found to be equitable after a trial of this matter.

Plaintiff further prays that, in due course, the Court issue an Order that Defendants pay restitution to the State of Indiana for all expenses reasonably related to their practices described herein through any manner deemed practicable by the Court.

Plaintiff further prays that, in due course, the Court issue an Order requiring Defendants to reimburse the Office of the Attorney General for all costs and expenses incurred in the investigation and prosecution of this action, including attorney's fees under the DCSA, Indiana Antitrust Act, and Indiana Medicaid False Claims Act.

Plaintiff further prays for judgment in favor of Plaintiff and against Defendants under DCSA for restitution, disgorgement and civil penalties under Indiana Code §§ 24-5-0.5-4(g) and 24-5-0.5-8 for Defendants' violations.

Plaintiff further prays for judgment in favor of Plaintiff and against Defendants under the Indiana Antitrust Act for damages, civil penalties, costs, and disgorgement as allowed under Indiana Code § 24-12-5.1 for Defendants' violations.

Plaintiff further prays for judgment in favor of Plaintiff and against Defendants under Indiana Code § 5-11-5.7-2 for actual damages incurred by Plaintiff as a result of Defendants' violations, a civil penalty in the amount of two times the amount of damages sustained by the State, and costs and expenses for the investigation and enforcement action regarding Defendants' violations.

Plaintiff further prays for all additional civil penalties allowable under law.

Plaintiff further prays for all additional damages allowable under law.

Plaintiff further prays that this Court grant any further relief that it finds justice may require or is otherwise equitable.

RESPECTFULLY SUBMITTED this 19th day of March, 2024.

THEODORE E. ROKITA,
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