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[EXEMPT FROM FILING FEES PURSUANT TO GOVERNMENT CODE SECTION 6103]

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF LOS ANGELES

PEOPLE OF THE STATE OF CALIFORNIA, Plaintiff, v. ELI LILLY AND COMPANY; NOVO NORDISK INC.; SANOFI-AVENTIS U.S. LLC; CAREMARKPCS HEALTH, LLC; CVS HEALTH CORP.; EXPRESS SCRIPTS, INC.; OPTUMRX, INC.; and DOES 1 through 100, inclusive, Defendants.	Case No. COMPLAINT FOR PERMANENT INJUNCTION, CIVIL PENALTIES, AND OTHER EQUITABLE RELIEF (Bus. & Prof. Code, § 17200, *et seq.*) [Verified Answer Required Pursuant to Civ. Proc. Code, § 446]

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Plaintiff, the People of the State of California, by and through Rob Bonta, Attorney General of the State of California, alleges the following on information and belief:

INTRODUCTION

1. Millions of Californians suffer from diabetes. For many diagnosed with this condition, access to insulin to regulate their blood sugar levels is a matter of life and death. Yet, the excessive price of insulin undermines their access to this century-old, life-sustaining drug.

2. Inexplicably, list prices for insulin have risen several hundred percent over the last two decades. Today, California diabetics who require insulin to survive and who are exposed to insulin's full price, such as uninsured consumers and consumers with high deductible insurance plans, pay thousands of dollars per year for insulin.

3. The excessive price of insulin disproportionately harms low-income communities who must choose between paying for insulin or everyday necessities, such as housing and food. To stretch dollars and insulin supplies, many Californians have turned to the dangerous practice of rationing insulin or skipping doses despite the severe risks of loss of sight, limbs, or death. These harms are further compounded for Black, Hispanic, and low-income communities in California as they are more likely to be diagnosed with diabetes and to be uninsured or underinsured.

4. The United States insulin market is an oligopoly. The defendants include three insulin manufacturers (Manufacturer Defendants)—Eli Lilly, Novo Nordisk, and Sanofi—who make nearly all of the insulin sold in the United States.

5. Also named as defendants are the three pharmacy benefit managers (PBM Defendants) that dominate the PBM market—CVS Caremark, Express Scripts, and OptumRx. PBMs are entities that administer prescription drug programs, which are a part of the essential benefits that health insurance plans must cover. One aspect of the PBM's role is determining the prescription drugs a given health insurance plan covers (known as a formulary). Another aspect of the PBM's role is negotiating confidential contracts that provide for post-sale discounts (rebates) that a drug manufacturer will provide to the PBM, not the consumer, if a consumer fills a prescription for the manufacturer's drug.

6. The conduct at issue in this Complaint has two main components. First, the Manufacturer Defendants aggressively raise the list price of insulin in lockstep with each other to artificial levels. The inflated and artificial insulin price increases have significantly exceeded inflation and are not justified by advances in the efficacy of the drugs or the cost of manufacturing. Insulin costs less than $10 a month to manufacture and its development costs have long been recouped.

7. Second, PBM Defendants obtain significant secret rebates, which are a percentage of the inflated and artificial list price, from the Manufacturer Defendants in exchange for favorable placement on the PBM's standard formularies. This rebating strategy incentivizes the Manufacturer Defendants to raise their list prices high and higher. The result is that the PBM Defendants' standard formularies promote the Manufacturer Defendants' high list-price insulin products over lower list-price insulins in California and nationwide.

8. The Manufacturer Defendants participate in this conduct because being listed on a PBM Defendant's standard national formulary is a financial boon. Like the insulin market in the United States, the PBM market in the United States is also oligopolistic. The PBM Defendants capture over 75% of the market. Being included on a PBM Defendant's standard national formulary drives higher sales volume and revenue.

9. The PBM Defendants participate in this conduct because their revenue is related to the size of the secret rebates they negotiate. Larger list prices support larger secret rebates because rebates are calculated as a percentage of the list price. Also, the PBM Defendants have a perverse incentive for ever-growing list prices. The PBM Defendants claim they can extract higher rebates due to their market power. If drug list prices grow, demand for their rebate negotiation services increases.

10. In addition to participating in conduct raising list prices, Defendants made misrepresentations about insulin prices and their actions in relation to insulin prices.

11. By increasing the list price of insulin, Defendants harm diabetic Californians who require insulin. They are exposed to insulin's unaffordable list price and do not benefit from the secret rebates.

12. Defendants are liable for the harms caused by their conduct under theories that protect consumers and competition. Defendants' conduct harms diabetic Californians who require insulin without a sufficient counterweighing benefit to them. Additionally, Defendants' conduct runs against several principles of honesty and fair dealing with competitors and consumers, including (a) prohibition on false discounts and prohibition on misleading statements made in furtherance of the false discounts, (b) prohibition on members of oligopolies abusing their market power in order to raise their product prices to unconscionable levels, (c) prohibition on middlemen in product distribution chains with large market share leveraging their market power to obtain secret rebates from manufacturers that are not granted to their smaller middlemen competitors, and (d) prohibition on members of oligopolies adopting practices that facilitate the coordination of price increases.

13. Defendants' actions therefore constitute unlawful, unfair, and deceptive acts and practices prohibited by the Unfair Competition Law (UCL), Business and Professions Code section 17200, and have unjustly enriched Defendants at the People's expense.

THE PARTIES

I. THE PLAINTIFF

14. Plaintiff is the People of the State of California. Rob Bonta is the Attorney General of the State of California and the chief law enforcement officer of the State under the California Constitution, article V, section 13.

II. DEFENDANTS

15. Collectively, the Manufacturer Defendants, PBM Defendants, and DOE defendants (as defined below) are referred to as "Defendants."

A. Manufacturer Defendants

16. Collectively, Eli Lilly, Novo Nordisk, and Sanofi (as defined below) are referred to as "Manufacturer Defendants."

1. Eli Lilly

17. Defendant Eli Lilly and Company (Eli Lilly) is an Indiana Corporation. Eli Lilly states its principal place of business is at Lilly Corporate Center, Indianapolis, Indiana, 46285.

18. Several of Eli Lilly's pharmaceutical products are insulins, including products with insulin lispro and insulin glargine as the primary active ingredients.

19. Eli Lilly is registered to do business in California.

20. Eli Lilly has a research center in San Diego, California.

21. Eli Lilly holds three active wholesaler and nonresident wholesaler permits with the California Pharmacy Board (License Nos. OSD 5372, WLS 467, OSD 6920). These permits allow Eli Lilly to manufacture, distribute, and sell its insulins in California.

22. Eli Lilly employs sales representatives throughout California to promote and sell its insulin products.

23. Eli Lilly directs advertising and informational materials, including through the internet and telephone, to California physicians, payers, and diabetics for the specific purpose of selling more insulin in California.

24. Eli Lilly attends conferences in California and promotes its insulins at those conferences.

25. At all relevant times, Eli Lilly transacted and continues to transact business in California, including Los Angeles County.

2. Novo Nordisk

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

27. Several of Novo Nordisk's pharmaceutical products are insulins, including products with insulin aspart and insulin detemir as the primary active ingredients.

28. Novo Nordisk is registered to do business in California.

29. Novo Nordisk has a research center in the San Francisco Bay Area.

30. Novo Nordisk employs sales representatives throughout California to promote and sell its insulin products.

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31. Novo Nordisk directs advertising and informational materials, including through the internet and telephone, to California physicians, payers, and diabetics for the specific purpose of selling more insulin.

32. Novo Nordisk attends conferences in California and promotes its insulins at those conferences.

33. At all relevant times, Defendant Novo Nordisk transacted and continues to transact business in California, including Los Angeles County.

3. Sanofi

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

35. Several of Sanofi's pharmaceutical products are insulins, including products with insulin lispro, insulin glulisine, and insulin glargine as the primary active ingredients.

36. Sanofi holds two active nonresident wholesaler permits with the California Pharmacy Board (License Nos. OSD 5471 and OSD 5472). These permits allow Sanofi to manufacture, distribute, and sell its insulins in California.

37. Sanofi employs sales representatives throughout California to promote and sell its insulin products.

38. Sanofi directs advertising and informational materials, including through the internet and telephone, to California physicians, payers, and diabetics for the specific purpose of selling more insulin.

39. Sanofi attends conferences in California and promotes its insulins at those conferences.

40. At all relevant times, Sanofi transacted and continues to transact business in California, including Los Angeles County.

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B. PBM Defendants

41. Collectively, CVS Caremark, Express Scripts, and OptumRx (as defined below) are referred to as "PBM Defendants."[1]

1. CVS Caremark

42. Defendant CaremarkPCS Health, LLC is a Delaware limited liability company. CaremarkPCS Health, LLC states its principal place of business is One CVS Drive, Woonsocket, Rhode Island, 02895.

43. CaremarkPCS Health, LLC is registered to do business in California.

44. CaremarkPCS Health, LLC is registered as a PBM with California's Department of Managed Health Care.

45. CaremarkPCS Health, LLC enters rebate contracts with Defendants Eli Lilly, Novo Nordisk, and Sanofi related to the purchase of insulins.

46. Defendant CVS Health Corporation (CVS Health) is a Delaware limited liability company. CVS Health states its principal place of business is One CVS Drive, Woonsocket, Rhode Island, 02895.

47. CaremarkPCS Health, LLC is a wholly owned subsidiary of CVS Health.

48. CVS Health holds itself out as deliberately directing, and is therefore responsible for, CaremarkPCS Health, LLC'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."

[1] As discussed more fully in the body of the Complaint, this lawsuit relates to the unlawful, unfair, and fraudulent inflation of insulin's price and the relationship of that inflation to the PBM Defendants' market power. It does not challenge the creation of custom formularies for a federal officer, such as for any Federal Employees Health Benefits Act or TRICARE governed health benefits plan. Furthermore, it does not seek to recover moneys paid by the federal government pursuant to such plans, nor does it seek the recovery of federally mandated co-pays that were paid by such plans' patients. As such, the Complaint does not seek relief from any PBM Defendants that is governed by or available pursuant to any claim(s) involving a federal officer associated with any Federal Employees Health Benefits Act or TRICARE-governed health benefits plan.

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. The website is interactive. Among other things, it allows customers to enter personal information, such as addresses.

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: (a) designs pharmacy benefit plans; and (b) negotiates with pharmaceutical companies to obtain discounted acquisition costs for many of the products on CVS Health's drug lists.

49. Defendants CaremarkPCS Health, LLC and CVS Health are referred to as "CVS Caremark."

50. At all relevant times, CVS Caremark transacted and continues to transact business in California, including Los Angeles County.

2. Express Scripts

51. Defendant Express Scripts, Inc. (Express Scripts) is a Delaware corporation. Express Scripts states its principal place of business is at 1 Express Way, St. Louis, Missouri, 63121.

52. Express Scripts describes itself as "a pharmacy benefit management (PBM) company serving more than 100 million Americans."

53. Express Scripts is registered to do business in California.

54. Express Scripts is a registered PBM with California's Department of Managed Health Care.

55. Express Scripts enters rebate contracts with Eli Lilly, Novo Nordisk, and Sanofi related to the purchase of insulins.

56. At all relevant times, Express Scripts transacted and continues to transact business in California, including Los Angeles County.

3. OptumRx

57. Defendant OptumRx, Inc. (OptumRx) is a California corporation. OptumRx states its principal place of business is at 2300 Main St., Irvine, California, 92614.

58. OptumRx is a registered PBM with California's Department of Managed Health Care.

59. OptumRx enters rebate contracts with Eli Lilly, Novo Nordisk, and Sanofi related to the purchase of insulins.

60. At all relevant times, OptumRx transacted and continues to transact business in California, including Los Angeles County.

C. Doe Defendants

61. Plaintiff is not aware of the true names and capacities of defendants sued herein as DOES 1 through 100, inclusive, and, therefore, sues these defendants by such fictitious names. Each fictitiously named defendant is responsible in some manner for the violations of law alleged. Plaintiff will amend this Complaint to add the true names of the fictitiously named defendants once they are discovered. Whenever reference is made in this Complaint to "Defendants," such reference shall include DOES 1 through 100 as well as the named defendants.

D. Civil Conspiracy

62. The Manufacturer Defendants—Eli Lilly, Novo Nordisk, and Sanofi—separately conspired with each PBM Defendant—CVS Caremark, Express Scripts, and OptumRx—to commit the violations alleged in this Complaint. Specifically, Eli Lilly separately conspired with each PBM Defendant to artificially inflate the list prices of Eli Lilly's insulin products, while agreeing to provide secret rebates to each PBM Defendant in an attempt to obtain preferred positions on the respective PBM Defendant's standard drug formularies. Likewise, 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 rebates to each PBM Defendant in an attempt to obtain preferred positions on the respective PBM Defendant's standard drug formularies. Finally, Sanofi separately conspired with each PBM Defendant to artificially inflate the list prices of Sanofi's insulin products, while agreeing to provide secret rebates 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

63. This Court has original jurisdiction over this action pursuant to California Constitution article VI, section 10. Plaintiff's claims brought under the UCL, Business and Professions Code section 17200, *et seq.*, and for unjust enrichment, arise under the laws of the State of California, are not preempted by federal law, do not challenge conduct within any federal agency's exclusive domain, and are not statutorily assigned to any other trial court.

64. Defendants did and continue to engage in substantial business in or affecting the State of California, and the injuries that have been sustained because Defendants' illegal conduct occurred in part in California, rendering jurisdiction over Defendants proper.

65. Venue in Los Angeles County Superior Court is proper pursuant to Code of Civil Procedure section 393, subdivision (a), because many of the acts giving rise to the claims asserted herein were committed in Los Angeles County and many of the injuries that have been sustained as a result of Defendants' illegal conduct occurred in part in Los Angeles County.

BACKGROUND INFORMATION

I. DIABETES IN GENERAL

66. Diabetes is a health condition classified by chronic high blood sugar (called hyperglycemia). After eating, the human body breaks down food into sugar (glucose) and releases the glucose into the bloodstream. When blood glucose levels rise, the pancreas releases insulin. Insulin instructs cells in the body to use blood glucose for energy.

67. The two main types of diabetes are type 1 and type 2.[2] According to the 2020 National Diabetes Statistics Report by the Centers for Disease Control and Prevention (CDC), approximately 5-10% of the total population diagnosed with diabetes have type 1 diabetes and the vast majority (90-95%) have type 2 diabetes.

68. Type 1 diabetes is thought to be caused by an autoimmune reaction, where the body attacks itself by mistake and kills the pancreas cells that produce insulin. Type 1 diabetes typically develops during childhood or adolescence but can develop at any age. There is no known way to prevent type 1 diabetes and there is no cure.

69. With type 2 diabetes, the body does not use insulin well and cannot keep blood sugar at normal levels. Type 2 diabetes is a progressive disease that usually develops over many years and is usually diagnosed in adults, although it can be diagnosed earlier.

70. Untreated type 1 diabetes triggers diabetic ketoacidosis. Diabetic ketoacidosis causes complications, including brain swelling, cardiac arrest, and kidney failure. These complications are acute. Untreated diabetic ketoacidosis is fatal in less than a week.

71. Over time, hyperglycemia from untreated type 2 diabetes can lead to heart disease, kidney disease, nerve damage (requiring amputation or causing blindness), and other problems with feet, oral health, vision, hearing, and mental health. These chronic conditions may cause premature death.

72. According to the American Diabetes Association, nationwide, average medical expenses are 2.3 times higher for those with diabetes. One national study indicates that improving medication adherence among people with diabetes could prevent nearly 700,000 emergency department visits, 341,000 hospitalizations, and save $4.7 billion annually.

A. The Prevalence Of Diabetes In California

73. Approximately 3 million Californians have diabetes. This is approximately 10% of the State's adult population.

74. According to the California Department of Public Health, the majority of persons with diabetes in the State are type 2 diabetics.

[2] There are other types of diabetes, including gestational and cystic fibrosis-related diabetes.

75. The burden of diabetes is not equally distributed in California. The prevalence of type 2 diabetes increases with age: from one in twelve Californians under the age of 65 to one in six Californians over the age of 65. Also, when compared to White Californians, Hispanic and Black people are twice as likely to be diagnosed with type 2 diabetes and twice as likely to die as a result of complications from type 2 diabetes.

B. The Discovery Of Insulin Over A Century Ago And The Development Of Modern Analog Insulin

76. Until the early 1920s, type 1 diabetes was a fatal disease. In 1922, animal-derived insulin was first used to treat diabetes. The inventors assigned their patent rights to the University of Toronto for $1 each, reasoning 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." One of the inventors, Sir Frederick Banting, MD, stated that "[i]nsulin does not belong to me, it belongs to the world."

77. After acquiring the patent rights, the University of Toronto contracted with Manufacturer Defendants Eli Lilly and Novo Nordisk to scale their production and distribute insulin to the millions of people diagnosed with diabetes around the globe.

78. In 1978, a synthetic human insulin was developed by the City of Hope National Medical Center in Duarte, California, and Genentech, Inc. in South San Francisco, California. Compared to animal-derived insulin, human insulin is cheaper to mass-produce and causes fewer allergic reactions.

79. The first human insulin was licensed to Defendant Eli Lilly and brought to market in 1982 as "Humulin."

80. Later in the 1980s, Novo Nordisk launched its own human insulin, "Novolin."

81. The advent of human insulin led to the decline in the use of the animal-based insulin products, which were subsequently removed from the United States market.

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82. In the 1990s and early 2000s, scientists modified the structure of human insulin. These altered forms of human insulin are called "analogs" because they are analogous to the human body's natural pattern of insulin release.[3]

83. Today, insulin is categorized by whether the insulin is analog or human, how quickly it acts (onset), and how long it lasts before it wears off (duration). Rapid-acting analogs (categorized as prandial) are typically used before mealtime to control glucose spikes after meals. Long-acting analogs (categorized as basal) are used once or twice a day and help overnight glucose control. Variations of both rapid and long-acting insulins are offered by the Manufacturer Defendants, including:

Type	Insulin Analog Molecule	Brand Name	Company	FDA Approval Year
Rapid-acting	insulin lispro	Humalog	Eli Lilly	1996
	insulin aspart	NovoLog	Novo Nordisk	2000
	insulin glulisine	Apidra	Sanofi	2004
Long-acting	insulin glargine	Lantus	Sanofi	2000
	insulin detemir	Levemir	Novo Nordisk	2005

84. The large majority of insulin presently used in the United States is analog insulin and not human insulin. In 2000, 96% of insulin users used human insulin versus 19% using analog insulin. By 2010, the ratio had switched; only 15% of patients used human insulin while 92% used analog insulin. In 2017, less than 10% of the units of insulin dispensed under Medicare Part D were human insulins.

85. The People bring this action to challenge Defendants' conduct with respect to analog insulins and their various rapid and long-acting insulin treatments.[4]

86. A typical vial of insulin contains 10 mL, or 1,000 "units" of insulin, although other concentrations are available. A typical injection pen of insulin contains 3 mL, or 300 "units" of insulin. A diabetic who requires insulin will typically need 2,000 to 3,000 units of insulin per month, sometimes more, with the type of insulin needed depending on the type of diabetes the

[3] While human insulins like Novolin and Humulin are available over-the-counter (OTC) without a prescription, analog insulin requires a prescription.

[4] The insulins discussed in this Complaint are injectable; inhaled insulin has failed to gain popular acceptance in the United States.

consumer has. A type 1 diabetic will require both rapid and long-acting insulins. Reports suggest that about 30% of type 2 diabetics require insulin.

87. Many rapid-acting insulin analogs are similar enough to be therapeutically equivalent. Likewise, long-acting analog insulins are similar enough to be therapeutically equivalent.

C. The Analog Insulin Market Is Not A Freely Competitive Market

88. An oligopoly is a market in which a few sellers dominate the sales of a product and where entry of new sellers is difficult or impossible. The analog insulin market is such a market.

1. There Are Significant Barriers To Entry For The Analog Insulin Market

89. The United States patent and FDA regulatory approval process imposes significant cost and legal barriers to entry that make it difficult for new entrants to sell analog insulin in the United States and in California.

90. A patent, issued by the U.S. Patent and Trademark Office (USPTO), grants an inventor the right, for a limited time, to exclude others from making, using, offering for sale, or selling the invention in the country and importing it to the United States. Through patent rights, a manufacturer that develops (or originates) a drug and secures a patent can exclude a follow-on, "copycat" drug during the period of exclusivity granted by the USPTO.

91. Until recently, most analog insulin products were protected by USPTO-issued patent exclusivity. USPTO patent protection on the insulin analog molecules expired in 2013 for insulin lispro, in 2014 for insulin aspart, in 2015 for insulin glargine, in 2018 for insulin glulisine, and in 2019 for insulin detemir.

92. The Food, Drug, and Cosmetic Act (FDCA) provides additional legal barriers to entry. The FDCA prohibits introducing "any new drug" into interstate commerce without prior approval by the FDA. (21 U.S.C., § 355, subd. (a).) Currently, there are several regulatory paths through which new drugs may obtain FDA approval. One path is the submission of a "new drug application" or NDA. (21 U.S.C., § 355, subd. (b).) After the FDA approves the originator drug

(brand product), other companies may seek approval to market a copycat drug (generic product) by filing an "abbreviated new drug application" or ANDA. (*Id.*, § 355, subd. (j).)

93. Different rules apply to the subset of drugs that are biological products. Unlike small molecule drugs which are chemically synthesized, biologic drug products are typically produced through natural processes, such as extraction from living cells. Under the Public Health Service Act, a company that seeks to market a new biologic must receive approval of a biological license application from the FDA. (42 U.S.C., § 262, subd. (a)(1).) Still, similar to small molecule drugs, once the FDA has approved the originator biologic, other companies may market a copycat drug (a biosimilar) after the approval of an abbreviated biological license application. (*Id.*, § 262, subd. (k).)[5]

94. The definition of biologic has changed overtime. Prior to March 2020, insulin products were approved via the NDA/ANDA pathway. Since March 2020, insulin products are approved via the biologic/biosimilar framework.

95. In addition to imposing legal hurdles, the FDA approval pathway imposes significant costs. The investment needed for a generic is reportedly two years and $1 to $4 million, whereas a biosimilar requires over seven years and $100 million.

2. The Three Manufacturer Defendants Dominate The Insulin Market

96. The insulin market is highly concentrated. Three companies, Defendants Eli Lilly, Novo Nordisk, and Sanofi, manufacture the majority of the insulin sold in United States and the world. By the early 2000s, Defendants Eli Lilly, Novo Nordisk, and Sanofi collectively captured over 95% of the insulin market globally.

[5] A difference between generics and biosimilars also deals with a pharmacist's ability to substitute medications. Generally, a pharmacist filling a prescription for a brand-name small molecule drug may typically substitute it with a generic without the patient's doctor writing a new prescription. (Bus. & Prof. Code, § 4073.) However, a pharmacist filling a prescription for a biologic drug may not substitute it with a biosimilar drug without the patient's doctor writing a new prescription. With biologic drugs, a pharmacist can only substitute drugs if the biosimilar has also been determined to be an "interchangeable" biosimilar by the FDA. (Bus. & Prof. Code, § 4073.5.) The FDA requires additional data for a biosimilar to be deemed an interchangeable biosimilar. (42 U.S.C., § 262, subd. (k)(4).)

97. In 2020, according to a researcher from Yale Law School, the Manufacturer Defendants' global insulin market shares were as follows:

Manufacturer Defendant	Global Market Share (by volume)	Global Market Share (by revenue)
Eli Lilly	23%	23%
Novo Nordisk	52%	41%
Sanofi	17%	32%

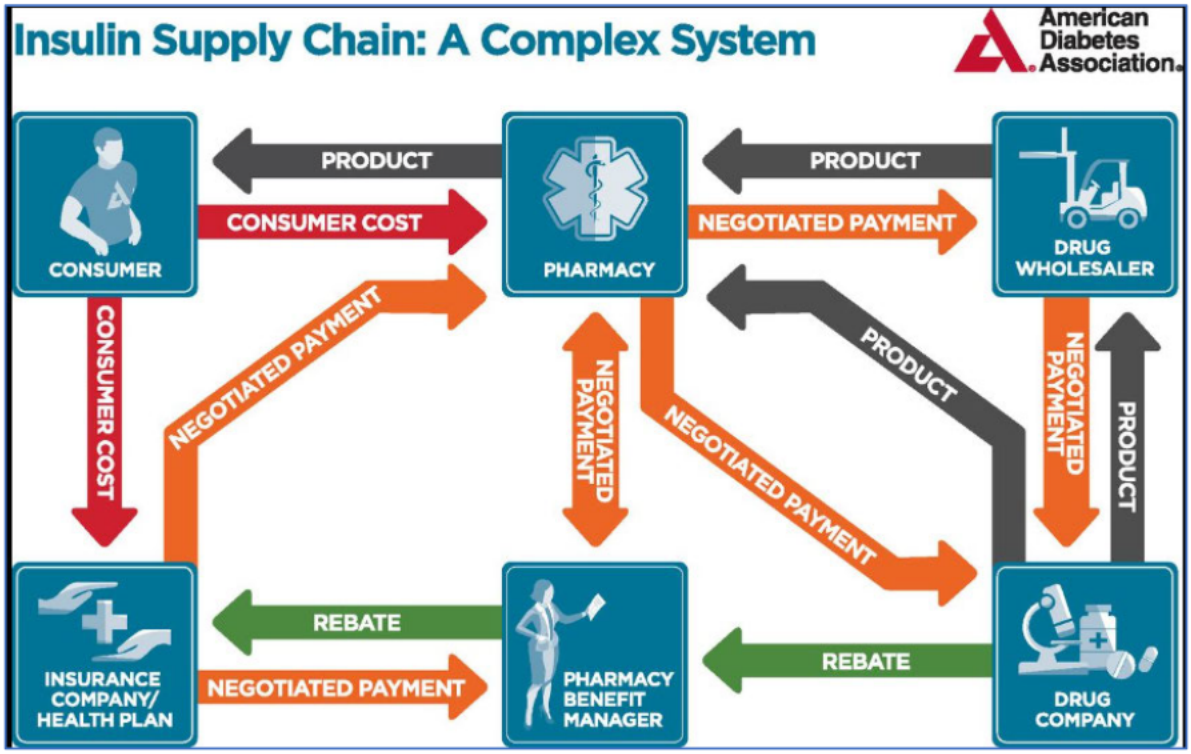
98. For years, the Manufacturer Defendants were the only entities that manufactured injectable insulin for the United States market.

99. In 2020, however, the FDA approved an application by Viatris Inc. and its partner Biocon Biologics Ltd., allowing biosimilar insulin glargine to come to market in the United States. Still, Viatris/Biocon has a low, single-digit market share.

II. How Consumers Obtain And Pay For Their Insulin

100. The process of getting pharmaceuticals, like insulin, to consumers involves multiple interactions among various key entities.

101. The American Diabetes Association created the visual below, which captures the entities involved in the distribution and payment supply chain.



William T. Cefalu, et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, Diabetes Care (May 11, 2018), available at https://diabetesjournals.org/care/article/41/6/1299/36487/Insulin-Access-and-Affordability-Working-Group. The pathways in this visual will be discussed in the following section of the Complaint.

A. Price-Setting And The Drug Distribution Chain

102. In general, the main players involved in the drug distribution chain are manufacturers, wholesalers, pharmacies, and consumers.

103. Manufacturers typically sell their drugs through wholesale distributors. Manufacturers set the drug's list price and wholesalers usually negotiate a discount off that list price.

104. The term "wholesale acquisition cost" or WAC is typically used in reference to a drug's undiscounted list price. WAC is defined by federal law as "the manufacturer's list price for [a] drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price. . . ." (42 U.S.C., § 1395w-3a, subd. (c)(6)(B).) Manufacturers, including Eli Lilly, Novo Nordisk, and Sanofi publish WAC prices, including WAC prices for analog insulins, in databases administered by third-party entities.

105. Wholesale distributors then sell the drugs to pharmacies. The sale price to pharmacies is based on the WAC.

106. Pharmacies then distribute the drugs to consumers. If a consumer lacks health insurance coverage for prescription drugs, the pharmacy charges the consumer the "cash price" for the drugs. A pharmacy's cash price is usually marked up from the price the pharmacy paid for the drug.

107. A December 2020 study from GoodRX, a company that tracks drug prices, showed that an increase in the WAC of a drug is correlated to an increase in the cash price of that drug.

108. Defendant Novo Nordisk has acknowledged that, for insulin, WAC is closely tied to the cash price. When testifying before Congress in 2019, Doug Langa, President of Defendant

Novo Nordisk stated that, "there is no doubt that the WAC price is a significant component" of "what patients ultimately pay at the pharmacy counter. . . ."

B. The Role Of Insurance On The Prices Consumers Pay For Drugs At Pharmacies

109. Health insurance in the United States is provided through a mix of public and private insurance, including for-profit and nonprofit insurers and health care providers.

110. The Kaiser Family Foundation reports that 47% of Californians in 2021 had health insurance through an employer, 7% had private coverage directly from an insurer, 27% benefit from Medi-Cal (California's Medicaid program), 12% benefit from Medicare, and 7% were uninsured. The Kaiser Family Foundation further reports that, in general, people of color are at higher risk of being uninsured.

111. This Complaint uses the following terminology when discussing prescription drug health insurance benefits:

a. *Co-insurance*: The percentage share that an insured consumer pays for a product or service covered by the plan. For example, an insurer may charge 10% co-insurance for a $100 prescription drug, making the consumer's out-of-pocket cost $10. Co-insurance is a cost-sharing mechanism.

b. *Co-payment or co-pay*: A fixed dollar amount that an insured consumer pays for a product or service covered by the plan. For example, an insurer may charge a $20 co-payment for a prescription drug. A co-pay is also a cost-sharing mechanism.

c. *Deductible*: The amount an insured is required to pay for health care services or products before his or her insurance plan begins to provide coverage. An enrollee in a high-deductible health plan with a $2,000 deductible would be responsible for paying for the first $2,000 in health care services. A deductible is another cost-sharing mechanism.

d. *Out-of-pocket maximum*: The maximum amount an insured consumer must pay in a year before their health insurance plan covers 100% of health benefits.

e. *Formulary*: A list of prescription drugs covered by an insurance plan.

f. *Formulary tier*: Some formularies have different levels of coverage, with the lower tiers associated with a lower out-of-pocket cost to the insured.

g. *Exclusion list:* A list of drugs excluded from a formulary.

112. When a consumer with health insurance visits a pharmacy to fill a prescription, the amount the consumer pays out-of-pocket typically depends on the drug's WAC, whether the drug is on formulary or the formulary's exclusion list (and if it is on formulary, the formulary tier), the co-pay or co-insurance required by their insurance, whether the consumer has a deductible or out-of-pocket-maximum, and how much money the consumer has already paid. As discussed on Pages 41–42, *infra*, an insured consumer may be required to pay a drug's full cash price.

C. The Role Of PBMs On What Drug Insurers Cover And What Rebates Manufacturers Pay

113. Most health payers in the United States, including insurers, contract with PBMs to administer their prescription drug coverage benefits. Generally, PBMs develop a formulary and negotiate post-purchase discounts (or rebates) that brand-name drug manufacturers must pay the insurer when consumers fill prescriptions for their drugs. PBMs also maintain a network of pharmacies where plan beneficiaries can fill prescriptions. In addition, PBMs negotiate and process the insurance plans' payments to pharmacies for drugs dispensed.

1. The PBM Market Is Highly Concentrated

114. In recent decades, the PBM industry has grown and consolidated dramatically. According to a market research firm, Health Industries Research Companies, the PBM Defendants captured significant market shares for prescription claims managed in 2020. In the United States, 34% of claims were administered by Defendant CVS Caremark, 24% by Defendant Express Scripts, and 21% by Defendant OptumRx.

115. In 2019, a bipartisan U.S. Senate Finance Committee began to investigate why insulin medication was unaffordable. In 2021, at the conclusion of its investigation, the Committee issued a report titled "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug" (Senate Insulin Report).

116. The Senate Insulin Report included a chart referencing the number of insured persons (covered lives) associated with each PBM that reflects market shares similar to the estimates noted above:

PBM	Covered Lives (as of 2019)
CVS Caremark	105 million
Express Scripts	More than 80 million
OptumRx	More than 65 million

Using the figures from the Senate Insulin Report, and an approximate United States population of 328 million persons in 2019, CVS Caremark was associated with 32% of the United States population, Express Scripts 24%, and OptumRx 20%.

117. The PBM Defendants made sizable gains through consolidation. For example:

a. In 2009, CVS Caremark merged with PBM AdvancePCS Inc. in a merger valued at $6 billion.

b. In 2012, Express Scripts acquired PBM Medco Health Solutions, Inc. in a transaction valued at nearly $30 billion.

c. In 2015, OptumRx acquired PBM Catamaran Corp. in a transaction valued at nearly $13 billion.

118. PBM Defendants also work to enhance their market share, especially with respect to rebate negotiations (discussed below) through the use of "group purchasing organizations" or GPOs. Each PBM Defendant has set up a GPO. Express Scripts formed Ascent Health Services; CVS Caremark formed Zinc; and OptumRx formed Emisar Pharma Services. Ascent Health Services negotiates rebates on behalf of Express Scripts and a smaller PBM, Prime Therapeutics LLC, among others. Each of these GPOs was formed outside the United States.

2. The PBM Defendants' Standard Formularies

119. Each of the PBM Defendants offers standard (also known as off-the-shelf or template) formularies.

120. Most PBM health plan customers adopt a standard formulary, but some adopt custom or partially custom formularies. PBM Defendants encourage their customers to adopt a standard formulary and give price concessions for use of a standard formulary.

121. For many years, the PBM Defendants included nearly all available drugs in their standard formularies. That changed in and around 2014 when the PBM Defendants started excluding a growing number of drugs from their standard formularies.

122. Because the PBM Defendants control a significant market share, a drug's exclusion from a standard formulary can significantly impact its sales. Drugs are most likely to be filled and purchased by an insured consumer if the drug is placed on the standard formulary.

3. The PBM Defendants' Rebate Negotiations And Contracts

123. Manufacturer Defendants negotiate for and enter into contracts with the PBM Defendants that provide financial incentives for the PBMs' customers to use the manufacturers' drugs.[6] These incentives include:

a. Base formulary post-sale discounts (rebates) for placing the manufacturer's brand-name drug on the PBM's standard formulary.

b. Formulary rebate enhancements for placing the manufacturer's brand-name drug on a preferred formulary tier and, potentially, excluding the drug's competitors on that tier.

c. Market-share rebates for higher usage of the manufacturer's brand-name drug.

d. Price protection rebates that require a manufacturer to pay the PBM additional rebates when the manufacturer raises the list price above an agreed-upon percentage or dollar threshold.

124. Rebate contracts do not require PBMs to pass rebates directly onto consumers acquiring drugs at pharmacies, and usually PBMs do not pass the rebates directly onto the consumer acquiring the drug at the pharmacy.

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[6] The Senate Insulin Report stated that PBM-Manufacturer rebate "contracts and subsequent amendments can stretch over hundreds of pages and cover multiple therapies offered by a manufacturer. The base contracts and subsequent amendments are updated frequently—sometimes multiple times a year. . . ."

125. Rebate contracts usually include administration fees paid by the manufacturer to the PBM. These administration fees are typically reflected as a percentage of WAC. Administrative fees can result in significant payments to PBMs.

126. The PBM market in general, and rebate negotiations and contracts specifically, are cloaked in secrecy. The rebate contracts between PBM Defendants and Manufacturer Defendants are confidential and nonpublic. Likewise, the actual rebate payments made by Manufacturer Defendants to the PBM Defendants are confidential and nonpublic.

127. As a former attorney for the United States Justice Department and Federal Trade Commission testified to the Senate in mid-2022 during a hearing on drug prices:

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

THE DEFENDANTS' ARTIFICIAL INFLATION OF THE PRICE OF ANALOG INSULIN

128. Drugstore ads from the 1960s published in The Washington Post advertised insulin for $1 to $2 per vial. In the late 1990s, insulin could be obtained for less than $25. That is no longer the case. Today, consumers needing insulin products must pay hundreds of dollars for their monthly supply.

I. MANUFACTURER DEFENDANTS SIGNIFICANTLY RAISE ANALOG INSULIN'S LIST PRICE

129. National Public Radio reported that in the past twenty years, the list price of the Manufacturer Defendants' analog insulins increased by more than 600%.

130. Below is a visual depiction of that increase:

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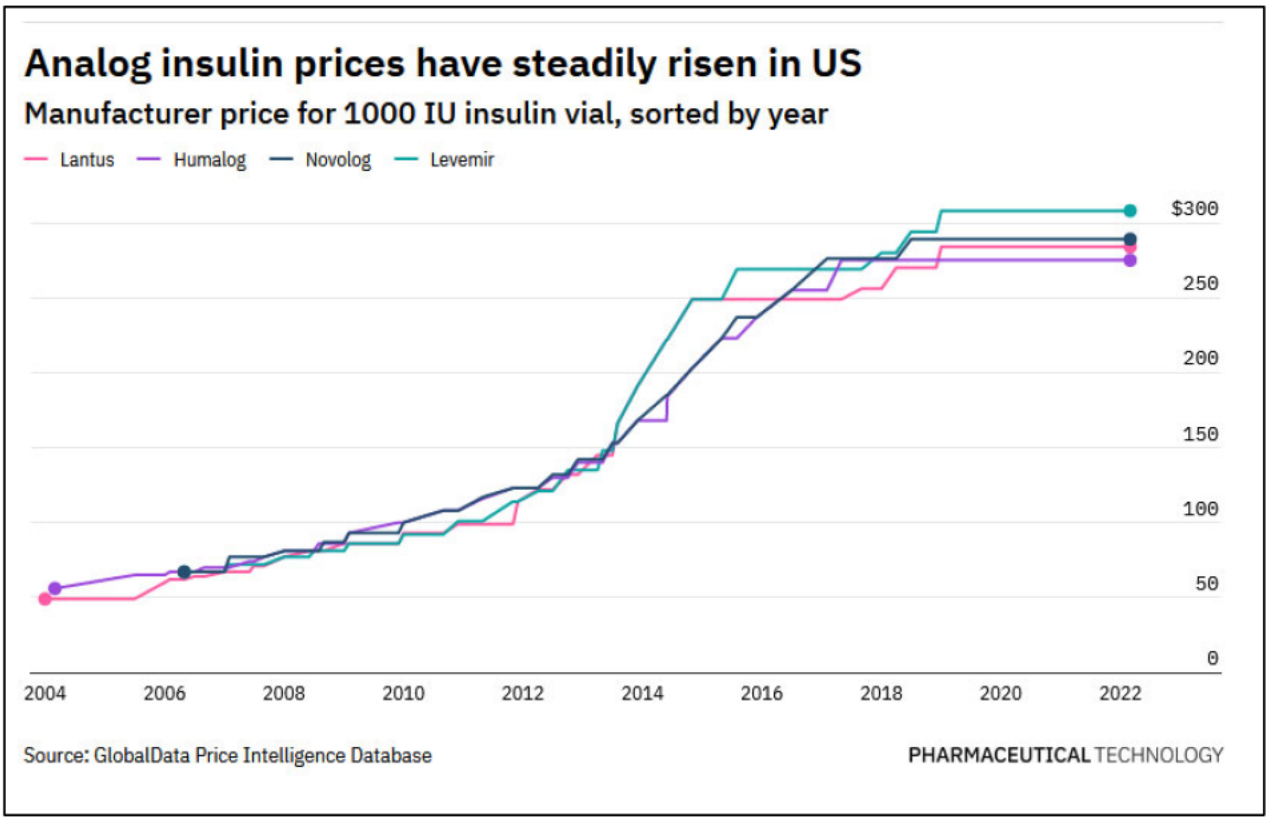

William Newton, *Insulin pricing: could an e-commerce approach cut costs?*, Pharmaceutical Technology (Mar. 31, 2022) (https://www.pharmaceutical-technology.com/analysis/insulin-pricing-could-an-e-commerce-approach-cut-costs/).

131. The Insulin Initiative, an advocacy group, published the following graph comparing the price increase of Humalog to the price increase that other consumer goods experienced:

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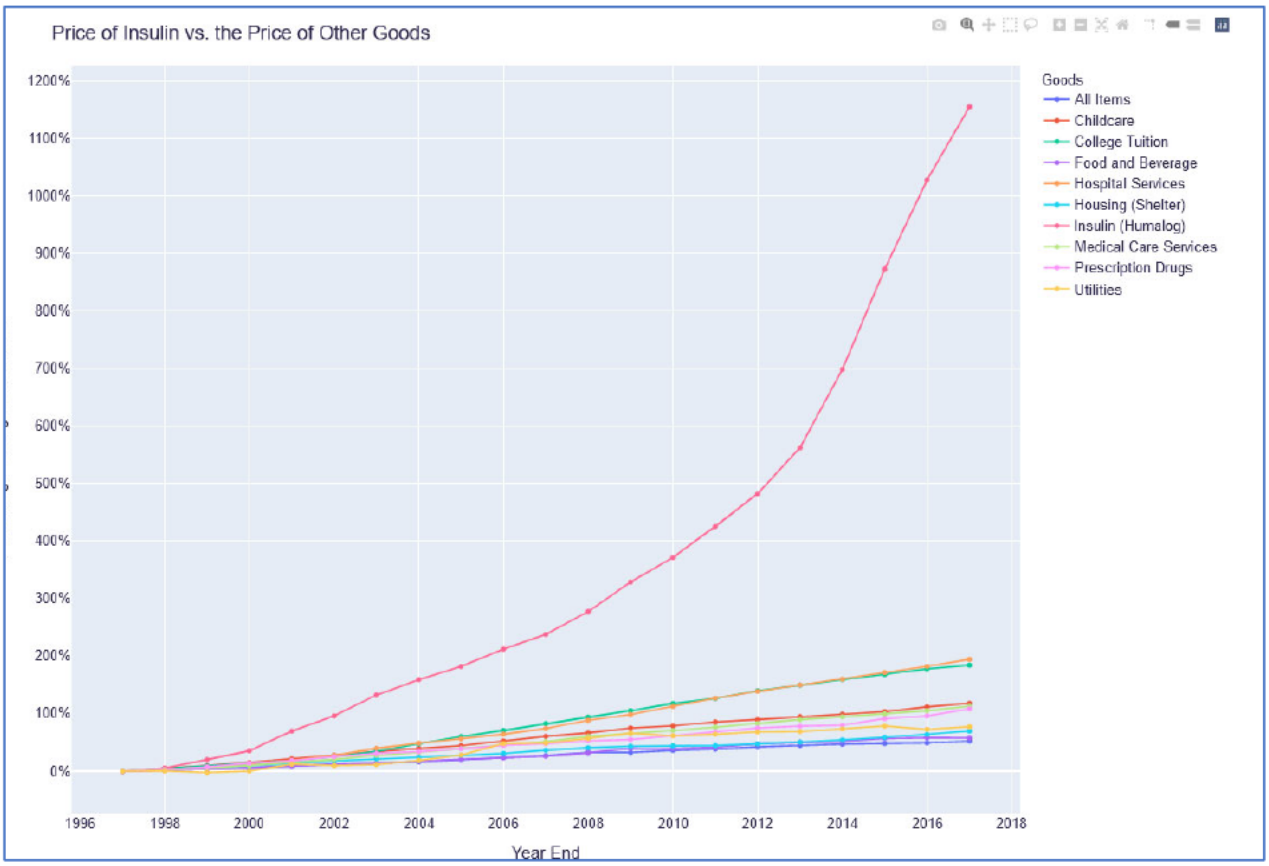


The Insulin Initiative, The List Price, https://www.theinsulininitiative.com/the-list-price, (last visited Jan 9, 2023).

132. Each Manufacturer Defendant has also engaged in a practice of introducing what they claim are new insulin products at or exceeding the artificially inflated price of its existing insulin products. These claimed new products, however, only contain minor modifications of the existing insulin products.

II. THE INCREASE IN THE MANUFACTURER DEFENDANTS' ANALOG INSULIN PRICES IS ARTIFICIAL

A. Analog Insulin's Price In The United States Is Not Justified By Manufacturers' Costs Or Improvements In Insulin

133. Insulin's high price is not justified by the Manufacturer Defendants' research and development costs. Indeed, the insulin molecules that are on the market have either been available in the same form for decades or are biologically equivalent to insulins that have been on the market for decades.

134. Nor is insulin's high price justified by the Manufacturer Defendants' manufacturing costs. A 2018 study published in BMJ Global Health calculated that insulin costs less than $10 a vial to manufacture. The study estimated that a reasonable price for a one-year supply—which accounts for profits to manufacturers—could cost a person between $78 and $133 for analog insulins.

135. In discussing the Manufacturer Defendants, the Senate Insulin Report stated that, "[i]nsulin [research and development, or R&D] spending was a fraction of manufacturers' revenue and sales and marketing expenses." The Senate Insulin Report further stated that, "[i]nsulin manufacturers appear to focus their R&D efforts on new insulin-related devices, equipment, and other mechanical parts which are separate from insulin's formulation."

136. In fact, in 2019, Sanofi announced it was ceasing research and development in the diabetes space, although it would continue selling analog insulin.

B. The Manufacturer Defendants Raised Insulin's List Prices In Lockstep

137. The Manufacturer Defendants raised the list prices of analog insulins in lockstep with each other.

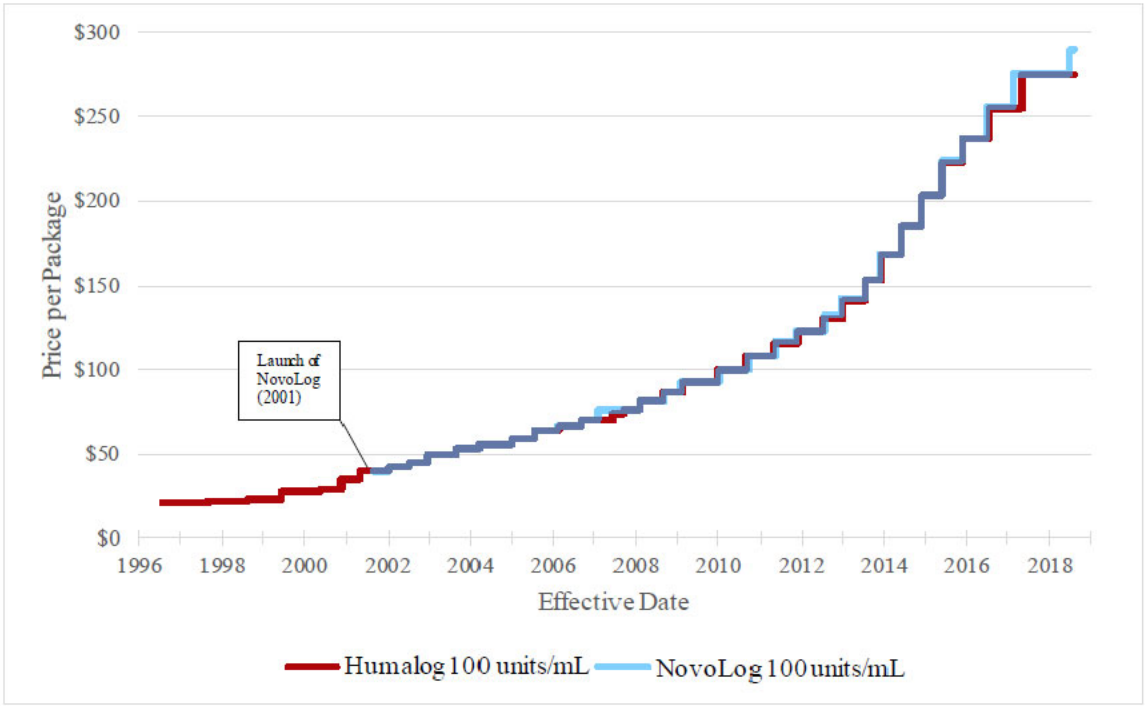
138. The fact that the Manufacturer Defendants raised their list prices for analog insulin in lockstep further confirms that the rising list prices are artificial.

139. These lockstep increases are well recognized. Both scholars and the Senate Insulin Report determined that when one insulin manufacturer increases the price for a given insulin formulation, other insulin manufacturers often increase their prices by a similar amount shortly thereafter.

140. The lockstep nature of the list price increases was also recognized by the United States House of Representatives. In December 2021, the United States House of Representatives Committee on Oversight and Reform issued a Drug Pricing Investigation Report. The report included figures showing the tethered relationship between each of the Manufacturer Defendants' list prices for analog insulins.

141. The Drug Pricing Investigation Report included a figure comparing price increases for Defendants Eli Lilly and Novo Nordisk's rapid acting insulins.

Figure 6: Comparison of Rapid-Acting-Insulin Price Increases—Humalog (Eli Lilly) and Novolog (Novo Nordisk), 1996–2018



142. The Drug Pricing Investigation Report also stated that "Sanofi also engaged in shadow pricing with its rapid-acting insulin products, including Apidra. . . . [W]hen its competitors raised prices on their fast-acting insulins, Sanofi followed suit."

143. The Drug Pricing Investigation Report also included a figure comparing price increases for Defendants Sanofi and Novo Nordisk's long-acting insulins.

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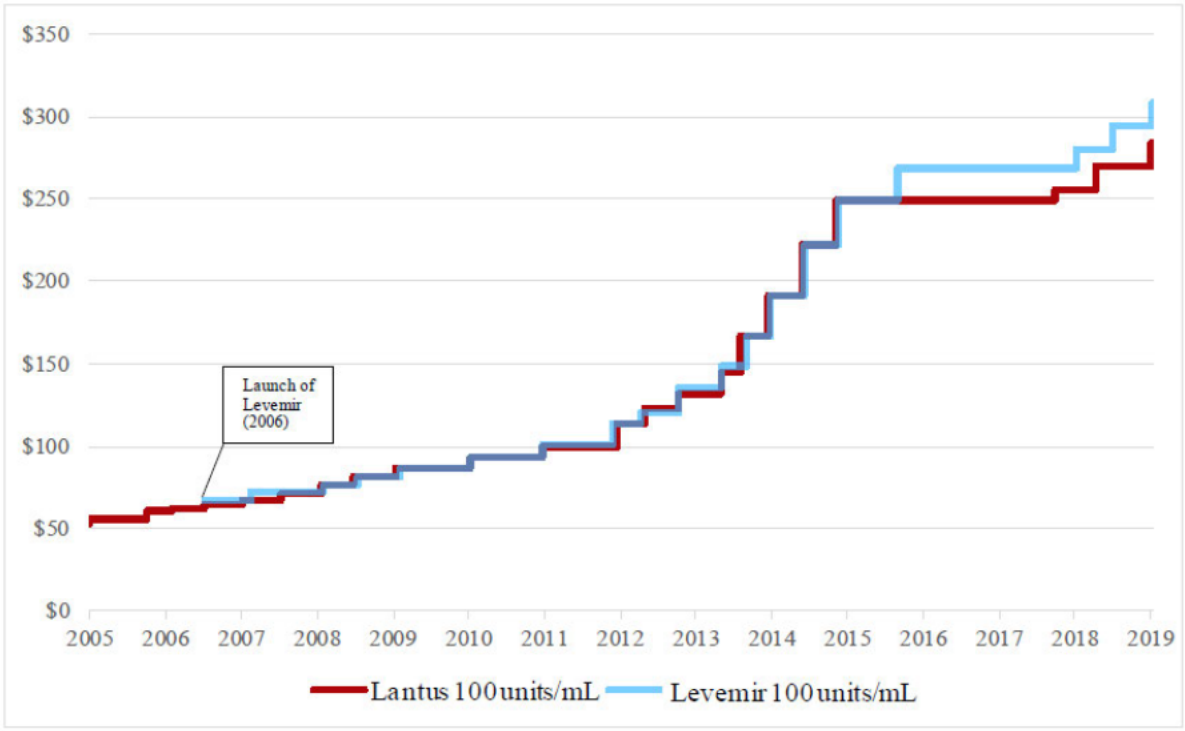
Figure 7: Comparison of Long-Acting-Insulin Price Increases—Lantus (Sanofi) and Levemir (Novo Nordisk), 2005–2019



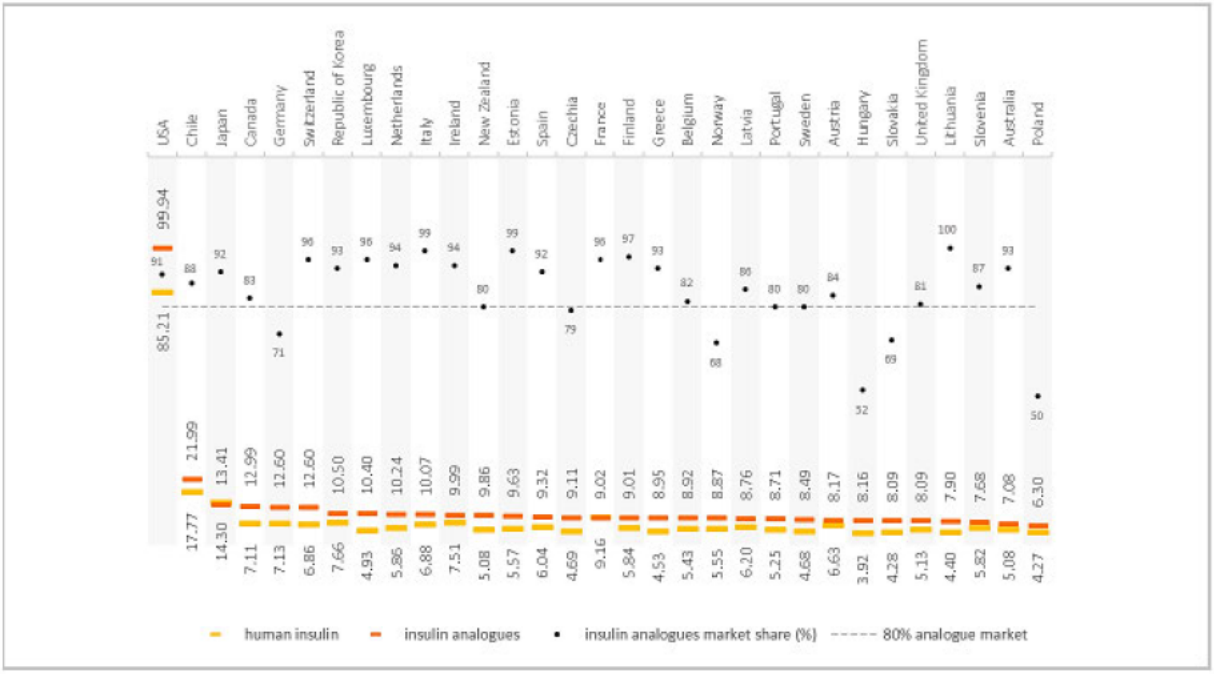
C. Consumers In The United States Pay Exorbitant Prices For Analog Insulin Compared To Other Countries

144. In 2020, a nonprofit research organization, the RAND Corporation, compared insulin prices in the United States to those of other countries. The report found that, on average, U.S. consumers pay ten and eight times what those outside the U.S. pay for rapid- and long-acting insulin, respectively.

145. The RAND report noted that some United States payers, such as health insurance plans, do not pay the full list price for insulin. Rather, they may receive rebates or other discounts that are passed on by the PBMs. Even so, the RAND Report noted that what payers pay for insulin is still several-fold more than the price consumers outside the United States pay for insulin.

146. A 2021 report from the World Health Organization also reported the price disparity of analog insulin between the United States and other countries.

Fig. 3.3. Average ex-manufacturer prices[a] of insulin per standard unit[b], by type of insulin and country



[a] In US dollars. [b] For the purposes of this table, a standard unit of insulin refers to a unit vial as per IQVIA's data provided to Mulcahy, Schwam & Edenfield (*28*).

That persons outside the United States pay less for the Manufacturer Defendants' analog insulin is further confirmation that their prices are artificially high.

III. THE PBM DEFENDANTS SUPPORT THE ARTIFICIAL INCREASE IN THE LIST PRICE OF ANALOG INSULIN THROUGH REBATES

A. Amount Of Rebates Paid On Analog Insulin Has Grown

147. According to a 2020 study in the Journal of the American Medical Association, the insulin rebates for non-Medicaid consumers have grown from 13% of the list price in 2007 to 70% in 2018.

148. Similarly, the Senate Insulin Report stated that, "in July 2013, Sanofi offered rebates between 2% and 4% for preferred placement on CVS Caremark's client's commercial formulary. Five years later, in 2018, Sanofi rebates were as high as 56% for preferred formulary placement." The Senate Insulin Report further stated that, "in 2017, 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."

B. Rebates Are Correlated To List Price Increases

149. According to a study conducted by the nonprofit, nonpartisan Center for Medicine in the Public Interest, in 2015, rebates accounted for 77% of total manufacturer list price increases.

150. Similarly, according to a study by the University of Southern California Schaeffer Center, a $1 increase in formulary rebates on a drug equated to a $1.17 increase in list price of that drug.

C. PBM Defendants Require Large, Secret Rebates For Preferential Formulary Placement

151. The Senate Insulin Report revealed that the growth in insulin's list price was because PBM Defendants mandated ever growing rebates in exchange for formulary access.

152. The Senate Insulin Report confirmed as much, finding that:

> Eli Lilly executives raised the possibility that PBMs would object to a list price reset because it would result in (1) a reduction in administrative fees for PBMs, (2) a reduction in rebates, which would impact PBMs' ability to satisfy rebate guarantees with some clients, and (3) impair their clients' ability to lower premiums for patients, thereby impacting their market competitiveness.

153. The Senate Insulin Report further stated that, "Novo Nordisk's board of directors voted down a proposed insulin price decrease due to financial downsides, risk of backlash from PBMs and payers, and expected pressure to take similar action on other products."

154. According to the Senate Insulin Report, "Sanofi also faced increased pressure from its payer and PBM clients to offer more generous rebates and price protection terms or face exclusion from formularies. . . ."

155. Each of the Manufacturer Defendants confirmed that insulin list price growth is to support rebates needed to secure formulary access.

156. In 2019, testifying before Congress, Doug Langa, President of Defendant Novo Nordisk, issued a statement explaining these considerations:

> Recently, pharmaceutical companies have come under pressure to explain the increasing out-of-pocket costs for certain medicines, including insulin. While increased competition in a marketplace would usually lead to lower prices, our current healthcare system is built on misaligned incentives that

> have led to rising costs in medicines. Chief among these misaligned incentives is the fact that the rebates pharmaceutical companies pay to PBMs are calculated as a percentage of WAC price. That means a pharmaceutical company fighting to remain on formulary is constrained from lowering WAC price, or even keeping the price constant, if a competitor takes an increase. This is because PBMs will then earn less in rebates and potentially choose to place a competitor's higher-priced product on their formulary to the exclusion of others.

157. Also testifying before Congress in 2019, Kathleen Tregoning, Executive Vice President of Sanofi, identified similar financial pressures. Tregoning stated: "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."

158. Enrique Conterno, former senior vice president at Defendant Eli Lilly, told The Washington Post in 2015 that as the price of insulin increases, drug makers give deeper rebates to PBMs, and that if they do not, the drug maker might receive less favorable formulary placement.

159. The conduct of PBM Defendants following the launch of biosimilar and authorized generic analog insulins illustrates how a lower list price harms the chance of making it onto PBM Defendants' standard formularies.

160. For instance, the Express Scripts standard formulary covered Eli Lilly's high list price branded insulin lispro, but not the low list price version.

161. As Mike Mason, Senior Vice President of Defendant Eli Lilly testified before Congress in 2019:

> Our experience to date, however, is that most PBMs continue to prefer branded Humalog even when the net cost is comparable because that option offers more total rebate dollars, and many of their health plan and employer clients value the total rebate dollars that they receive when their members purchase prescription medications. As described further below, those health plans and employers use the rebate dollars they receive to marginally reduce premiums for all of their insureds, rather than using them to reduce patients' out-of-pocket costs for insulin at the pharmacy counter. As a result, most PBMs have indicated that they are considering several approaches for Insulin Lispro, such as excluding Insulin Lispro entirely from formularies, offering the [authorized generic] only on "niche" formularies, or placing the product on formulary but at a higher cost-sharing tier.

162. Additionally, as previously discussed, Viatris/Biocon recently launched its biosimilar insulin glargine. In late 2021, Viatris/Biocon started offering both low and high list price versions. The lower list price version was not included on any of the PBM Defendants' standard formularies when it was launched in the United States. However, the higher list price version secured placement on Defendant Express Scripts' standard formulary.

D. PBM Defendants Facilitated Horizontal Rebate Information Exchanges For The Manufacturer Defendants

163. The PBM Defendants facilitated and continue to facilitate coordination of Manufacturer Defendants' behavior regarding list prices by serving as a horizontal conduit for information exchanges involving rebates.

164. The PBM Defendants claim that they pit drug manufacturers, including the Manufacturer Defendants, against each other for formulary access.

165. This description is misleading. The PBM Defendants' actions entrench the Manufacturer Defendants in a vicious cycle of ever-increasing list prices necessary to obtain access to the PBM Defendants' standard formularies.

166. The Senate Insulin Report identified an instance when, in 2016, Defendant Express Scripts communicated to Defendant Sanofi that Defendant Eli Lilly was offering rebates on its insulin glargine product in the mid-60 percent range.

167. Such disclosures of a competitor's rebate efforts ensure the Manufacturer Defendants do not deviate from the high-WAC price and high-rebate strategy for insulin. Disclosing such information confirms the participation in this rebate conduct by others and encourages other Manufacturer Defendants to fall in line if they wish to secure placement on PBM Defendants' standard formularies.

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E. Large, Secret Insulin Rebates Benefit Defendants

1. The Manufacturer Defendants Benefit From Large, Secret Insulin Rebates

168. As stated in the Senate Insulin Report, Manufacturer Defendants, by increasing their insulin prices to accommodate larger rebates, gain continued access to lucrative placement on PBM Defendants' standard formularies.

169. Manufacturer Defendants profit from this arrangement. As the Senate Insulin Report uncovered, even after deducting manufacturer discounts and rebates from WAC list price, the moneys retained by the Manufacturer Defendants (the net price) is still higher than what they retained a decade ago.

170. Similarly, according to the December 16, 2022 "Report to Congress on the Affordability of Insulin," the U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, stated: "[A] review of literature demonstrates that net prices of insulin (even after rebates) are high and have grown substantially over time."

171. The Senate Insulin Report also indicates that although the Manufacturer Defendants' net prices have shrunk in recent years, these net prices would have been much less absent the conduct described in this Complaint.

172. Further, the net price of insulin sold in the United States is still significantly higher than the price of insulin in other countries. A report suggests that although the United States comprises only 15% of the global insulin market, it accounts for almost 50% of the Manufacturer Defendants' insulin-related revenue.

2. The PBM Defendants Benefit From Large, Secret Insulin Rebates

173. Because rebates are a percentage of an insulin's list price, PBM Defendants retain more money when they place high list price insulins on formularies. This preference has caused a widening gap between insulin's artificially inflated list price and its net price (the amount retained by the Manufacturer Defendants). The widening gap between list price and net price is problematic because it enriches the PBM Defendants at the expense of consumers and competition.

174. OptumRx's CEO admitted as much in an October 15, 2016 interview with Modern Healthcare, stating that the PBM Defendants "benefit from price increases."

175. PBM Defendants' preference for high list price insulins creates a system that reinforces their control of the market at the expense of smaller PBMs:

a. PBM Defendants use their large size to extract higher secret rebates from the Manufacturer Defendants, compared to smaller PBMs. For instance, CVS Caremark states on its website: "We bring our size, scale and expertise as the largest purchaser of prescription drugs in the United States to the negotiating table – working to reach the lowest prices possible with drug manufacturers."

b. The PBM Defendants can offer larger rebate guarantees to their clients, health insurers, and other payers. For instance, the Senate Insulin Report references an instance where an Eli Lilly executive stated that PBMs may object to lowering the list price of insulin because it would result in "a reduction in rebates, which would impact PBMs ability to satisfy rebate guarantees with some clients." These larger rebate guarantees by the PBM Defendants hurt smaller PBMs.

176. The PBM Defendants also benefit from insulin's inflated list price because they manage pharmacy networks and their payment processing. All PBM Defendants have been accused of engaging in improper clawbacks from pharmacies. A clawback happens when a pharmacy receives more money from a consumer in the form of cost-sharing than the pharmacy paid to acquire the drug. The higher the list price of a drug, the more likely there will be a PBM clawback.

IV. DEFENDANTS KNOW THE PRICE OF ANALOG INSULIN IS TOO HIGH

177. In 2019, before the U.S. House Energy and Commerce Committee meeting titled "Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin," all Defendants testified that the price of insulin is too high.

178. Mike Mason, Senior Vice President of Defendant Eli Lilly stated that, "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. . . ."

179. Doug Langa, President of Defendant Novo Nordisk, stated, "[W]e do know that more patients are facing an affordability challenge." He further acknowledged that "the number of patients struggling to afford their medicines has grown in recent years."

180. Kathleen Tregoning, Executive Vice President at Sanofi, testified, "Patients are rightfully angry about rising out-of-pocket costs for many medicines 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 . . . ."

181. Thomas Moriarty, Chief Policy and External Affairs Officer and General Counsel for CVS Health testified to similar concerns. He stated, "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."

182. Amy Bricker, Senior Vice President, Supply Chain, for Express Scripts also testified to facts depicting the urgent need. She said, "[O]ver seven million Americans diagnosed with diabetes use insulin. For some patients, the increasing price of insulin limits access and adherence."

183. Dr. Sumit Dutta, Chief Medical Officer of OptumRx testified, "[T]he price of insulin remains too high." Dr. Dutta also acknowledged that the price increases "have a real impact on consumers in the form of higher out-of-pocket costs."

DEFENDANTS MAKE MISLEADING STATEMENTS TO SUPPORT AND FURTHER THE INFLATION OF ANALOG INSULIN'S ARTIFICIAL LIST PRICE

184. Each of the Defendants have made misleading statements in furtherance of their efforts to inflate insulin's list price.

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I. MANUFACTURER DEFENDANTS' MISLEADING STATEMENTS ABOUT INSULIN'S LIST PRICE

185. The Manufacturer Defendants made two categories of misrepresentations to support insulin's excessively high price.

A. Manufacturer Defendants Misrepresent That Insulin List Price Increases Are Unimportant Due to Alleged Declining Net Prices

186. First, the Manufacturer Defendants have publicly represented that the prices for their analog insulins are justified because they claim insulin's net price is decreasing.

187. These statements about insulin's net price are echoed by the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA is a trade group for pharmaceutical manufacturers. Executives of each of the Manufacturer Defendants are on PhRMA's Board of Directors. PhRMA takes the position in advertisements that insulins are cheaper today than fifteen years ago because the net price has decreased.

188. As discussed on Pages 27-31, *supra*, these statements are misleading. Net prices are inflated when compared to the Manufacturer Defendants' costs and the amounts paid by persons in other countries. Further, by focusing attention on net price trends, and not the increasing list price trend, Manufacturer Defendants obscure the fact that list price competition has been undercut and that many consumers have had larger out-of-pocket costs imposed as a result.

B. Manufacturer Defendants Misrepresent Their Efforts To Control Insulin Price Increases And Address Consumer Affordability

189. Second, the Manufacturer Defendants have publicly represented that they are taking actions to address the public outcry about insulin affordability.

190. Each of the Manufacturer Defendants claims to offer support programs, including coupons, to help consumers afford their insulin.

191. 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."

192. But these statements are misleading.

193. Despite having consumer support programs, not all consumers are eligible and studies continue to report that many diabetics who require insulin cannot afford their insulin.

194. Other reports indicate that the Manufacturer Defendants do not sufficiently advertise such support programs, resulting in limited awareness by consumers. Studies also suggest that consumers have been turned away from insulin consumer assistance programs due to their strict eligibility requirements.

195. GoodRX reports that for consumer assistance programs in general, "many see the sign-up process as deliberately confusing and tedious."

196. In December 2019, United States Senator Elizabeth Warren (D-Mass.) and Senator Richard Blumenthal (D-Conn.) released a report showing that in 83% of pharmacies surveyed, generic Insulin Lispro was not in stock. Additionally, in most cases where the pharmacies indicated that they did not have the generic drug in stock they also indicated that they could not order the drug.

II. PBM DEFENDANTS' MISLEADING STATEMENTS ABOUT INSULIN'S LIST PRICE

197. The PBM Defendants make misrepresentations that only reinforce insulin's excessive price by claiming to be interested in lowering costs for consumers by lowering insulin's net price.

198. For instance, in its 2017 Drug Report, CVS Caremark stated that it "[m]anage[s] formulary and leverage competition to negotiate for lowest-net cost" and its "formulary and utilization management options helped reduce cost for antidiabetic drugs for clients." Allegedly with respect to insulin, CVS Caremark claimed it provided "[p]referred formulary placement for drugs with lower member out-of-pocket costs."

199. Further, Larry Merlo, head of CVS Caremark stated in 2017 that "[a]ny suggestion that PBMs are causing prices to rise is simply erroneous."

200. Similarly, in 2017, Express Scripts' Chief Executive Officer Tim Wentworth stated on CBS News that PBMs play no role in rising drug prices, claiming that PBMs work to "negotiate with drug companies to get the prices down."

201. Additionally, Express Scripts' publicly available code of conduct states that, "[a]t Express Scripts we're dedicated to keeping our promises to patients and clients . . . [A]ll our collective efforts are focused on our mission to make the use of prescription drugs safer and more affordable."

202. Moreover, OptumRx's website has a company video stating that PBMs like OptumRx "negotiate with drug companies for the best medication prices. . . ."

203. These statements are echoed by the Pharmaceutical Care Management Association (PCMA). PCMA is a trade group for PBMs. Executives of each of the PBM Defendants are on PCMA's Board of Directors. PCMA states on its website that it is dedicated to reducing the cost of insulin: "PBMs . . . are the only entity in the prescription drug supply and payment chain dedicated to reducing drug costs."

204. As discussed on Pages 31-36, *supra*, as to analog insulin, these statements are misleading. The PBM Defendants fail to state that they benefit from higher insulin list prices and discourage competition on list prices.

205. By focusing attention on net price trends instead of the increasing list price trend, PBM Defendants obscure the fact that they are actively driving up the price of insulin, while reinforcing their control of the market, at the expense of consumers who end up paying larger out-of-pocket costs. As stated in the recent Report to Congress on the Affordability of Insulin, the "largest concern with growing list prices—even as rebates grow as well—is that patients do not benefit because rebates are not passed on to beneficiaries, meaning their out-of-pocket spending remains pegged to the very high list prices."

CONSUMERS ARE HARMED BY EXPOSURE TO INSULIN'S INFLATED CASH PRICE

206. Defendants' conduct has harmed, and is continuing to harm, the People through insulin's inflated and artificial list price.

207. Insulin's inflated and artificial list prices have, and are, likely to deceive the People into paying more for insulin than they otherwise would have paid absent Defendants' conduct.

I. DIABETICS CANNOT AVOID PAYING EXCESSIVE AMOUNTS DUE TO INSULIN'S INFLATED AND ARTIFICIAL LIST PRICE

208. Diabetics without insurance who require insulin must pay the full cash price of insulin every time they fill their prescriptions. As a result, uninsured patients have paid increasingly higher insulin prices for years on end and continue to do so.

209. Even with health insurance, a consumer may be required to pay the full cash price of insulin due to their insurance's deductible phase. This is significant since a large and growing percentage of persons who receive health insurance through their employer have a high-deductible health plan.[7] The CDC stated that among persons with private health insurance, enrollment in high-deductible health plans has increased from 25.3% in 2010 to 45.8% in 2018. As the name reflects, the deductible in such plans is high—typically involving thousands of dollars.

210. Co-insurance is another example of how a consumer may be exposed to the full inflated cash price of insulin. Many insurance plans require consumers to pay co-insurance (or a percentage of the total cost) for drugs instead of co-payments, meaning that they pay more as the list price (and consequently, cash price) increases.

211. Similarly, diabetics with Medicare prescription drug coverage (Part D) who require insulin may also be exposed to insulin's inflated cash price at the pharmacy counter. Many Medicare Part D plans have a deductible phase and may require co-insurance during the coverage phase. Additionally, once the coverage phase limit is reached, the consumer enters the Medicare Part D coverage gap phase. In the coverage gap phase, the consumer either pays the full cash price or some discount percentage off the full cash price until they reach the threshold for the ensuing catastrophic phase. The deductible amount, thresholds between the different phases, and the amounts due under the coverage gap phase vary by year.

[7] For 2022, the Internal Revenue Service defined a high-deductible health plan as any plan with a deductible of at least $1,400 for an individual or $2,800 for a family.

212. Government plans, like Medicare, may offer qualifying consumers subsidies to help pay for their prescriptions. The income limits for government subsidies, however, are strict and many persons do not qualify. Also, the subsidies do not help persons with employer-provided health insurance.

213. Indeed, because so many consumers are exposed to insulin's increasingly inflated list prices, the out-of-pocket cost to consumers has been significant. In 2019, the Health Care Cost Institute published a study of persons with employer sponsored health insurance that concluded that from 2012 to 2016 the annual out-of-pocket cost of insulin for type 1 diabetics doubled, increasing from $2,864 to $5,705.

214. Similarly, diabetic participants in a 2020 study of the psychological effects of the high cost of insulin reported paying between $75 to over $2,000 a month for insulin, depending on their insulin needs and insurance coverage.

II. MANY DIABETICS WHO REQUIRE INSULIN CANNOT AFFORD THEIR INSULIN, EXACERBATING THE HARM DUE TO INSULIN'S INFLATED AND ARTIFICIAL PRICE

215. In addition to financial losses due to overpayment, for many diabetic Californians who require insulin to survive, Defendants' conduct has also cost them their health and emotional well-being.

216. Inability to afford insulin can force consumers to ration or skip insulin doses.

217. During a 2019 U.S. House of Representatives Energy & Commerce Oversight and Investigations Subcommittee hearing, a professor from Yale University reported that in the previous year, due to the price of insulin, 25% of people reported using less insulin than prescribed. That figure was reported in a 2019 article published by the Journal of the American Medical Association.

218. Earlier this year, California's Health and Human Services Agency (CalHHS) echoed this figure, reporting that "[n]ational data suggests as many as 1 in 4 diabetics cannot afford their insulin, and thus ration or stop taking insulin altogether."

219. A 2021 nationwide study of type 1 diabetics found that more than 50% of survey respondents considered access to affordable insulin and diabetes drugs was their primary concern.

220. More recently, in October 2022, a study indicated that 16% of diabetics who require insulin ration insulin due to costs. The study found that younger persons (20.4%) were more likely to ration insulin than seniors (11.2%); middle-income persons (19.8%) were more likely to ration insulin than both higher-income persons (10.8%) and lower income persons (14.6%); Black persons (23.2%) were more likely to ration insulin than White and Hispanic persons (16%); uninsured (49.2%) were more likely to ration insulin than those with private insurance (18.8%), Medicare (13.5%), or Medicaid (11.6%).

221. As discussed on Page 14, *supra*, rationing or skipping insulin, however, is not recommended by medical professionals and can lead to severe consequences. Taking less than the prescribed amount of insulin leads to poor blood sugar regulation, which can contribute to severe conditions, such as diabetic ketoacidosis, especially in type 1 diabetics, renal failure, loss of sight or limbs, and even death.

222. Moreover, insulin's inflated list price exacerbates disparities among people of color, lower-income communities, and other historically marginalized groups. For example, a recent study found that the share of Mexican Americans taking insulin who achieved good blood sugar control sharply dropped to 10% during the period of 2013 to 2020 from 25% during 1988 to 1994. In contrast, the proportion of non-Hispanic White people with good blood sugar management has stayed roughly the same, with 33% achieving it in the most recent period.

223. Those most affected by insulin's high list price are also most at risk of experiencing complications due to diabetes, which further limits a consumer's ability to work, earn an income, and lead healthy lives.

224. But even persons who do not ration or skip their insulin are affected by insulin's inflated list price. As stated by an author of the study referenced in paragraph 217 *supra*, "[t]hat one-in-four number only reflects people who actually used less insulin because of costs, but other people make trade-offs. . . . They may be spending less on food or other necessary items, even on other medications."

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FIRST CAUSE OF ACTION (BUSINESS AND PROFESSIONS CODE SECTION 17200) UNLAWFUL, FRAUDULENT, AND UNFAIR PRONGS

(AGAINST ALL DEFENDANTS)

225. The People incorporate by reference and re-allege, as though fully set forth herein, each and every allegation set forth in the preceding paragraphs of this Complaint.

226. Business and Professions Code section 17200, which is part of the UCL, prohibits any person engaged in business in California from engaging in "any unlawful, unfair or fraudulent business act or practice."

227. Each Defendant is a "person" within the meaning of Business and Professions Code section 17201.

228. Defendants are engaged in business in California and have engaged, aided and abetted, conspired to engage, and continue to engage in acts or practices that are unlawful, unfair, or fraudulent, and which constitute unfair competition within the meaning of Business and Professions Code section 17200.

229. Defendants' acts or practices are unlawful, as that term is used in the UCL, and include, but are not limited to, violating the California Consumer Legal Remedies Act, Civil Code section 1770, subdivision (a), subpart (13), by making false or misleading statements of fact concerning reasons for, existence of, or amounts of, price reductions to analog insulin.

230. Defendants' acts or practices are unfair, as that term is used in the UCL, irrespective of the violation of any other law, and include, but are not limited to:

a. artificially inflating the list prices of analog insulin, and maintaining an artificially inflated net price of analog insulin, in a way that harms consumers and does not provide a sufficient offsetting benefit to the consumers that are injured by the price increase;

b. artificially inflating the list prices of analog insulin to, and maintaining an artificially inflated net price of insulin at, unconscionable levels;

c. using secret rebates for analog insulin in a way that harms consumers and does not benefit competition; or

d. facilitating explicit or tacit collusion through facilitating practices, including the exchange or disclosure of competitively sensitive information.

231. Defendants' acts or practices are fraudulent, as that term is used in the UCL, and include, but are not limited to:

a. artificially inflating the list prices of analog insulin; or

b. making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by the Manufacturer Defendants to PBM Defendants.

SECOND CAUSE OF ACTION (UNJUST ENRICHMENT)

(AGAINST ALL DEFENDANTS)

232. The People incorporate by reference and re-allege, as though fully set forth herein, each and every allegation set forth in the preceding paragraphs of this Complaint.

233. A cause of action for unjust enrichment arises where a benefit is conferred upon a defendant who knowingly accepts it and who retains it under such circumstances that it would be inequitable for the defendant to keep it.

234. Defendants, through their conduct in unconscionably, deceptively, misleadingly, and artificially inflating the list price of analog insulin, received and continue to receive a financial windfall at the expense of the People. The People would not have overpaid for analog insulin if not for Defendants' conduct.

235. Defendants knowingly accepted and retained such benefits.

236. Defendants' financial benefits resulting from their unlawful, unfair, and deceptive conduct are economically traceable to overpayments for analog insulin products by the People.

237. It is inequitable for Defendants to retain these benefits.

PRAYER FOR RELIEF

WHEREFORE, the People pray for judgment against Defendants, jointly and severally, as follows:

A. Pursuant to Business and Professions Code section 17203, that Defendants, their successors, agents, representatives, employees, and all persons who act in concert with them be

permanently enjoined from committing any acts of unfair competition as defined in Business and Professions Code section 17200, including, but not limited to, the acts and practices alleged in this Complaint;

B. Pursuant to Business and Professions Code section 17203, that the Court make such orders or judgments as may be necessary, including preliminary injunctive or ancillary relief, to prevent the use or employment by any Defendant of any act or practice that constitutes unfair competition;

C. Pursuant to Business and Professions Code section 17203, that the Court make such orders or judgments as may be necessary to restore to any person in interest any money or property, real or personal, which may have been acquired by any Defendant through any act or practice that constitutes unfair competition;

D. That the Court make an order awarding all equitable monetary relief available from Defendants as a result of their acts of unjust enrichment;

E. Pursuant to Business and Professions Code section 17206, that the Court assess a civil penalty of $2,500 against each Defendant for each violation of Business and Professions Code section 17200 in an amount according to proof;

F. Pursuant to Business and Professions Code section 17206.1, in addition to any penalties assessed under Business and Professions Code section 17206, that the Court assess a civil penalty of $2,500 against each Defendant for each violation of Business and Professions Code section 17200 perpetrated against a senior citizen or disabled person, in an amount according to proof;

G. Pursuant to Business and Professions Code section 17206.2, except as disclaimed in Footnote 1 as to the PBM Defendants, in addition to any penalties assessed under Business and Professions Code section 17206, that the Court assess a civil penalty of $2,500 against each Defendant for each violation of Business and Professions Code section 17200 that occurred on or after its effective date, perpetrated against a service member or veteran, in an amount according to proof;

H. That the People recover their costs of suit;

I. That the People receive all other relief to which they are legally entitled; and

J. For such other and further relief that the Court deems just and proper.

Dated: January 12, 2023

Respectfully submitted,

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