

COMMONWEALTH OF KENTUCKY
48TH JUDICIAL CIRCUIT
FRANKLIN CIRCUIT COURT
DIVISION II

THE COMMONWEALTH OF
KENTUCKY, *EX REL.* DANIEL
CAMERON, KENTUCKY ATTORNEY
GENERAL

PLAINTIFF,

V.

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

DEFENDANTS.

Civil Action No. 19-CI-473

Jury Trial Demanded

FIRST AMENDED COMPLAINT

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Comes the Plaintiff, the Commonwealth of Kentucky *ex rel.* Daniel Cameron, Attorney General, brings this action on behalf of the Commonwealth of Kentucky (the “Commonwealth” or “Plaintiff”), for violations of the Kentucky Consumer Protection Act, KRS 367.110, *et. seq.* (“KCPA”), the Kentucky False Advertising Statute, KRS 517.030, *et. seq.* (“KFAS”), and the Kentucky common law against the above-named Defendants and alleges upon personal knowledge as to the Commonwealth and the Commonwealth’s own acts, and upon information and belief as to all other matters as follows:

I. INTRODUCTION

1. Insulin is a hormone necessary for metabolizing and storing glucose, the human body’s main energy source. Without insulin, the human body cannot turn glucose into energy, and instead turns fat into energy. The process of turning fat into energy releases ketones—a biochemical form of energy—into the bloodstream.

2. If the body releases too many ketones, blood will be turned to acid, resulting in a fatal condition called “ketoacidosis.” Other complications from uncontrolled diabetes include blindness and immune dysfunction that can turn a minor infection into a need for amputation.

3. Diabetes is a chronic condition that affects how the body produces or uses insulin. In type 1 diabetes, the body does not produce sufficient insulin, and, in type 2 diabetes, the body is resistant to the insulin it produces.

4. Diabetes is an epidemic and a public health crisis in Kentucky as approximately 13.6% of its population—over 450,000—are living with diabetes. An additional 1.2 million Kentucky residents have prediabetes, which is when a person’s

blood sugar level is higher than it should be and signifies that the person is at greater risk for developing diabetes.

5. Diabetes is a leading cause of blindness, kidney failure, and lower limb amputations and is the sixth leading cause of death in Kentucky despite the availability of effective treatment.

6. The economic impact of diabetes is staggering. The total estimated cost of diagnosed diabetes in Kentucky is \$3.6 billion per year. One in four health care dollars is spent caring for people with diabetes.

7. Nearly all diabetics in Kentucky either rely exclusively on daily insulin treatments to survive, or use either oral medications, insulin or a combination of both to treat and control diabetes.

8. Defendants Eli Lilly, Novo Nordisk and Sanofi (collectively, “Manufacturer Defendants” or “Manufacturers”) manufacture the vast majority of insulins and other diabetic medications available in the United States and Kentucky. This leaves Kentucky residents with diabetes at the Manufacturer Defendants’ mercy as to how much they must regularly pay merely to stay alive, and Defendants have not been merciful.

9. Defendants CVS Caremark, Express Scripts, and OptumRx (“PBM Defendants” or “PBMs”) collectively dominate the pricing system for the at-issue drugs. Their dominance results from the reality that these three corporate actors are, at once (1) the largest pharmacy benefit managers in the United States and in Kentucky (controlling approximately 80% of the PBM market) and (2) the largest

pharmacies in the United States and in Kentucky (making up 3 of the top 5 dispensing pharmacies in the U.S.) These PBM conglomerates sit at 4th (CVS Caremark), 5th (OptumRx) and 13th (Express Scripts) on the Fortune 500 list ranking largest corporations by revenue.

10. As part of their work, PBM Defendants establish standard formulary offerings (i.e., approved drug lists). If a drug is not included on a formulary, then it is not covered by health insurance.

11. PBM Defendants understand that their standard formulary offerings drive drug utilization.

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

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

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

15. The unfair, unconscionable, and deceptive scheme at the root of this Complaint—the Insulin Pricing Scheme—was born from this mutual understanding.

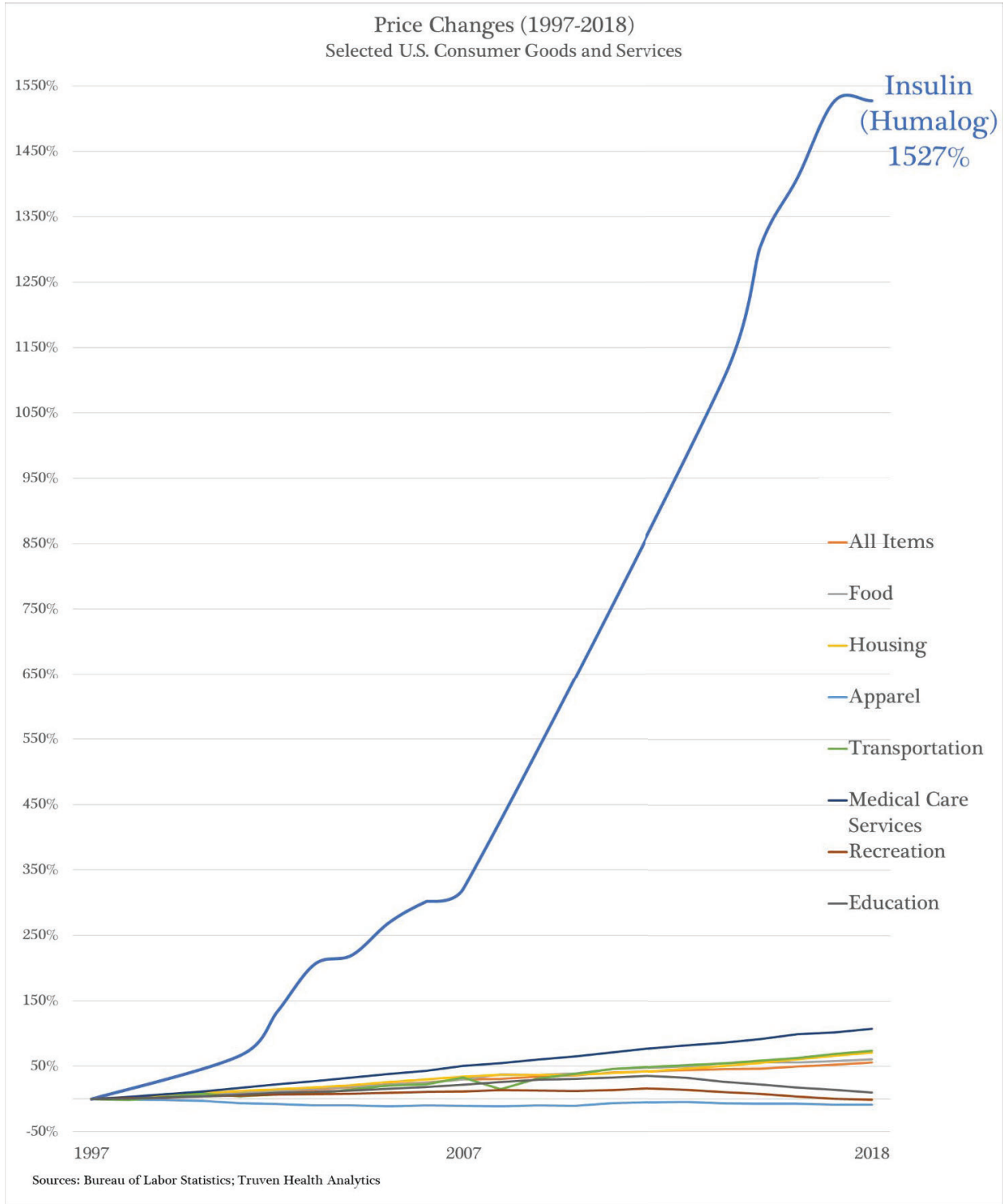
16. Over the course of the last fifteen years, and pursuant to the Insulin Pricing Scheme, Manufacturer Defendants have in lockstep raised the prices of their respective diabetes drugs in an astounding manner despite the fact that the cost to produce these drugs has decreased during that same time period.

17. Insulins, which today cost Manufacturer Defendants less than \$2 to produce and which were originally priced at \$20 when released in the late 1990s, now range between \$300 and \$700.

18. In the last decade alone, Manufacturer Defendants have in tandem increased the prices of their insulins up to 1000%, often down to the decimal point within a few days of each other.

19. Figure 1 illustrates the rate in which Defendant Eli Lilly raised the price of its analog insulin, Humalog, compared to the rate of inflation for other consumer goods and services from 1997-2018.

Figure 1: Price Increase of Insulin vs. Selected Consumer Goods from 1997-2018



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

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

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

23. Specifically, the Insulin Pricing Scheme works as follows: first, to gain formulary access from the PBM Defendants for their diabetic treatments, Manufacturer Defendants artificially and willingly raise their list prices, and then pay a significant, yet undisclosed, portion of that price back to the PBMs. These Manufacturer Payments¹ are provided under a variety of labels, yet, however they are described, these Manufacturer Payments, along with the inflated list prices, are *quid pro quo* for formulary inclusion on the PBMs' standard offerings.

¹ In the context of this Complaint, the term "Manufacturer Payments" is defined as all payments or financial benefits of any kind conferred by the Manufacturer Defendants to PBM Defendants (or a subsidiary, affiliated entity, or group purchasing organization or rebate aggregator acting on the PBM's behalf), either directly via contract or indirectly via Manufacturer-controlled intermediaries. Manufacturer Payments include rebates, administrative fees, inflation fees, pharmacy supplemental discounts, volume discounts, price or margin guarantees, price concessions, indirect purchase fees and rebates, and any other form of consideration exchanged. This broad definition is necessary because PBMs historically have continued to change and evolve the nature of their payment streams to avoid disclosure to clients and disclosure pursuant to state transparency laws. While the route by which the payment streams reach the PBMs has evolved, the fact that the payments do, in fact, reach the PBMs has remained the same.

24. The list prices for the at-issue drugs have become so untethered from the net prices realized by the Manufacturers as to constitute a false price.

25. PBMs then grant preferred status on their standard formularies based upon the largest Manufacturer Payment and the highest inflated list price (while at the same excluding lower priced insulins)—which the PBMs know to be artificially inflated and which the PBMs insist that their payor clients use as the basis for the price they pay for the at-issue drugs.

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

27. PBM Defendants profit off the inflated list prices that result from the scheme in numerous ways, including: (1) retaining a significant—yet undisclosed—percentage of the Manufacturer Payments, either directly or through wholly owned rebate aggregators, (2) using the inflated list price produced by the Insulin Pricing Scheme to generate profits from pharmacies in their networks and (3) relying on those same inflated list prices to drive up the PBMs’ profits through their own pharmacies.

28. Thus, while the PBM Defendants represent both publicly and to their clients that they use their market power to drive down prices for diabetes medications, these representations are patently false and intended to be deceptive and misleading.

29. Rather, the PBMs are intentionally driving up the price of the at-issue drugs. Indeed, the Manufacturer Payments the PBMs receive in exchange for

preferred formulary position, along with the PBMs' actual formulary construction, are directly responsible for the skyrocketing price of the at-issue diabetes medications.

30. Because the price paid by nearly every diabetic and payor is based upon the artificially inflated list prices generated by Defendants' scheme, the Insulin Pricing Scheme directly harms every diabetic and payor in Kentucky who purchase these life-sustaining drugs.

31. The consequence to Kentucky public health and the public from the outrageous price increases caused by the Insulin Pricing Scheme cannot be overstated.

32. Individual patients pay for their diabetes medications out of pocket based on the inflated prices generated by the Insulin Pricing Scheme. Thus, Kentucky diabetics have been overcharged millions of dollars a year in out-of-pocket costs as a result of the Insulin Pricing Scheme.

33. For Kentucky diabetics, the physical, emotional, and financial tolls of paying such excessive prices for diabetes medications is devastating. Unable to afford the drugs their doctors prescribe, many diabetics ration or under-dose their insulin, inject expired insulin, reuse needles, and starve themselves to control their blood sugars. This behavior is extremely dangerous and has led to serious complications or even death.

34. In addition to the immeasurable human costs, the Insulin Pricing Scheme also adds substantial costs to the Kentucky health care system by increasing preventable complications. For example, one national model found that all people with diabetes adhering to their diabetes medications would save \$8.3 billion in direct

medical costs per year by averting one million emergency department visits and 618,000 hospitalizations.

35. The Commonwealth shoulders the burden for much of these increased healthcare costs, spending billions of dollars annually in healthcare related costs for diabetes and diabetes-associated complications. The amount the Commonwealth has spent on diabetes related costs has steadily increased throughout the relevant time period and could grow exponentially in the near future given the high prevalence of prediabetes in Kentucky.

36. Insulin rationing and the resulting otherwise-avoidable health complications caused by the Insulin Pricing Scheme also leads to a loss in productivity and tax revenue, further damaging the Commonwealth.

37. The Honorable Daniel Cameron, Attorney General brings this action on behalf of Kentucky diabetics to protect the health and economic well-being of the Commonwealth as a whole and the health and economic well-being of Kentucky residents.

38. This action asserts causes for Defendants' violations of the KCPA, KFAS, unjust enrichment, and civil conspiracy.

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

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

II. PARTIES

A. Plaintiff

41. **Plaintiff, the Commonwealth of Kentucky.** The Commonwealth of Kentucky is the sole Plaintiff in this action, brought in its name on relation of the Attorney General, the Honorable Daniel Cameron. Acting as the chief law officer for the Commonwealth possessing all the power and authority under the common law and statute, the Attorney General institutes this action to protect the Commonwealth's sovereign interest in the health and economic interests of its residents and its own interests and the integrity of its marketplace.

42. By virtue of his office, Attorney General Daniel Cameron is the chief legal officer for the Commonwealth of Kentucky. The Commonwealth of Kentucky works to safeguard, protect and preserve the health, safety, and welfare of the citizens of Kentucky.

43. The Commonwealth of Kentucky has a sovereign interest in the economic and physical well-being of Kentucky residents and in the maintenance of the integrity of Kentucky's economic and healthcare system.

44. The Commonwealth is charged with, among other things, enforcing and seeking redress for violations of consumer protection laws, including the KCPA and KFAS. KRS 367.190 authorizes him to bring this action in the name of the Commonwealth of Kentucky, and he has determined it to be in the public interest to do so.

B. Manufacturer Defendants

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

46. Eli Lilly is registered to do business in Kentucky and may be served through its registered agent: National Registered Agents, Inc. 306 West Main Street, Suite 512, Frankfort, Kentucky 40601.

47. Eli Lilly holds 4 active licenses with the Board of Pharmacy in Kentucky.

48. These licenses allow Eli Lilly to manufacture, distribute, and sell its at-issue drugs in Kentucky.

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

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

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

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

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

54. Eli Lilly also directs advertising and informational materials to Kentucky physicians, payors, pharmacies, and diabetics for the specific purpose of

selling more of the at-issue drugs in Kentucky and profiting from the Insulin Pricing Scheme.

55. At all times relevant hereto, in furtherance of the Insulin Pricing Scheme, Eli Lilly caused its artificially inflated list prices for the at-issue diabetes medications to be published throughout Kentucky with the express knowledge that Kentucky diabetics' and the Commonwealth's payment and reimbursement would be based on those prices.

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

57. Kentucky diabetics and payors paid for all of the Eli Lilly diabetes medications related to the at-issue transactions in Kentucky based on the specific inflated list prices Eli Lilly caused to be published in Kentucky in furtherance of the Insulin Pricing Scheme.

58. **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.

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

60. Sanofi holds 3 active licenses with the Board of Pharmacy in Kentucky.

61. These licenses allow Sanofi to manufacture, distribute, and sell its at-issue drugs in Kentucky.

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

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

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

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

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

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

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

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

70. Kentucky diabetics and payors paid for all of the Sanofi diabetes medications related to the at-issue transactions in Kentucky based on the specific

inflated prices Sanofi caused to be published in Kentucky in furtherance of the Insulin Pricing Scheme.

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

72. Novo Nordisk may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware.

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

74. Novo Nordisk’s global revenues in 2019 were \$2.89 billion from Novolog, \$973 million from Levemir, \$968 million from Tresiba, \$2.29 billion from Victoza, and \$1.17 billion from Ozempic.

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

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

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

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

79. At all times relevant hereto, in furtherance of the Insulin Pricing Scheme, Novo Nordisk caused its artificially inflated list prices for the at-issue diabetes medications to be published throughout Kentucky with the express knowledge that Kentucky diabetics paid for the at-issue drugs based on these prices.

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

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

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

C. PBM Defendants

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

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

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

86. During the relevant time, CVS Health (or its predecessor)² has repeatedly, continuously, and explicitly stated that *CVS Health*:

- “design[s] pharmacy benefit plans that minimize the costs to the client while prioritizing the welfare and safety of the clients’ members and helping improve health outcomes;”³
- “negotiate[s] with pharmaceutical companies to obtain discounted acquisition costs for many of the products on [CVS Health’s] drug lists, and these negotiated discounts enable [CVS Health] to offer reduced costs to clients;”⁴
- “utilize[s] an independent panel of doctors, pharmacists and other medical experts, referred to as its Pharmacy and Therapeutics Committee, to select drugs that meet the highest standards of safety and efficacy for inclusion on [CVS Health’s] drug lists.”⁵

87. CVS Health publicly represents that CVS Health constructs programs that lower the cost of the at-issue diabetes medications. For example, in 2016, CVS

² Until 2014, CVS Health was known as “CVS Caremark.” In September 2014, “CVS Caremark Corporation announced that it is changing its corporate name to CVS Health to reflect its broader health care commitment and its expertise in driving the innovations needed to shape the future of health.”

³ CVS Caremark/CVS Health, Annual Reports (Form 10-K) (Dec. 31, 2009-2019).

⁴ CVS Caremark/CVS Health, Annual Reports (Form 10-K) (Dec. 31, 2009-2013).

⁵ CVS Caremark/CVS Health, Annual Reports (Form 10-K) (Dec. 31, 2009-2019).

Health announced a new program to “reduce overall spending in diabetes” that is available in all states, including Kentucky, stating:

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

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

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

90. Manufacturer Defendants have explicitly recognized that effectuating the Insulin Pricing Scheme requires “intimacy and connect[ion]” between the Manufacturer Defendants’ leaders and CVS Health’s leaders in order to align on “strategic formulary management initiatives to ensure profitable access across all [standard] formularies.”

91. On a regular basis throughout the relevant period, the Manufacturer Defendants’ executive teams—which at times included their CEOs—met with CVS

Health executives to discuss their coordinated efforts related to the at-issue drugs.

Examples include:

- In at least 2011, 2012, 2014, and 2016 the leaders of CVS Health and Novo Nordisk participated in executive exchange meetings, in furtherance of the Insulin Pricing Scheme. These meetings included the Executive Vice President of CVS Health, the Chief Medical Officer of CVS Health, members of CVS Health’s Enterprise Operating Committee, and key executives from Novo Nordisk.
- In at least 2012, 2013, and 2017, the leaders of CVS Health and Eli Lilly participated in numerous executive meetings in furtherance of the Insulin Pricing Scheme. These meetings included the CEO of CVS Health, the COO of CVS Health, members of CVS Health’s Enterprise Operating Committee, the President of Eli Lilly, and the Senior Vice President of Managed Care at Eli Lilly, among others.
- In at least 2012 and 2016, the leaders of CVS Health and Sanofi participated in executive meetings which included discussions in furtherance of the Insulin Pricing Scheme. These meetings included the CEO of CVS Health, the COO of CVS Health and members of CVS Health’s Enterprise Operating Committee, among others.

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

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

94. CVS Pharmacy owns and operates hundreds of pharmacies throughout Kentucky that were directly involved in and profited from the Insulin Pricing Scheme.

95. In its capacity as a retail pharmacy, CVS Pharmacy, working in conjunction with its corporate affiliate entities, knowingly assisted the CVS Health family in profiting from the artificially inflated list prices produced by the Insulin Pricing Scheme by pocketing the spread between acquisition cost for the drugs at issue (an amount well below the list price generated by the Insulin Pricing Scheme), and the amounts received from payors (which amounts were based on the artificially inflated list prices and, in many cases, were set by CVS Caremark in its capacity as a PBM).

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

97. CVS Pharmacy is registered to do business in Kentucky and may be served through its registered agent: CT Corporation System, 306 West Main Street, Suite 512, Frankfort, Kentucky 40601.

98. CVS Pharmacy holds 1 active license with the Board of Pharmacy in Kentucky.

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

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

101. Caremark Rx, L.L.C. is a wholly owned subsidiary of Defendant CVS Pharmacy.

102. Caremark Rx, L.L.C. may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

103. During the relevant time period, Caremark Rx, L.L.C. provided PBM and mail order pharmacy services in Kentucky that gave rise to the Insulin Pricing Scheme and damaged diabetics and payors in Kentucky.

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

105. Caremark, L.L.C. is registered to do business in Kentucky and may be served through its registered agent: CT Corporation System, 306 West Main Street, Suite 512, Frankfort, Kentucky 40601.

106. Caremark, L.L.C. holds 5 active licenses with the Kentucky Board of Pharmacy and 2 active licenses with the Board of Insurance in Kentucky.

107. During the relevant time period, Caremark, L.L.C. provided PBM and mail order pharmacy services in Kentucky that gave rise to the Insulin Pricing Scheme, which damaged diabetics and payors in Kentucky.

108. **Defendant CaremarkPCS Health, L.L.C.** is a Delaware limited liability company whose principal place of business is at the same location as CVS

Health. CVS Health is the direct or indirect parent company of CaremarkPCS Health LLC.

109. CaremarkPCS Health, L.L.C. provides pharmacy benefit management services.

110. CaremarkPCS Health, L.L.C. is registered to do business in Kentucky and may be served through its registered agent: CT Corporation System, 306 West Main Street, Suite 512, Frankfort, Kentucky 40601.

111. CaremarkPCS Health, L.L.C. holds 2 active licenses with the Board of Insurance in Kentucky.

112. During the relevant time period, CaremarkPCS Health, L.L.C. provided PBM services in Kentucky, which gave rise to the Insulin Pricing Scheme and damaged diabetics and payors in Kentucky.

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

- During the relevant time period, these parent and subsidiaries have had common officers and directors. Examples include:
 - Thomas S. Moffatt was Vice President and Secretary of Caremark Rx, L.L.C., CaremarkPCS Health L.L.C., and Caremark, L.L.C at the same time he was a Vice President, Assistant Secretary, and Assistant General Counsel at CVS Health and Director, Vice President, and Secretary at CVS Pharmacy;

- Melanie K. Luker was the Assistant Secretary of CVS Pharmacy, Caremark Rx, L.L.C., CaremarkPCS Health, L.L.C, and Caremark, L.L.C. at the same time she was a Senior Manager of Corporate Services at CVS Health;
 - Jonathan C. Roberts was an Executive Vice President and Chief Operating Officer at CVS Health at the same time he was CEO of Caremark Rx, L.L.C.;
 - Daniel P. Davison was the President of CaremarkPCS Health L.LC at the same time he was a Senior Vice President at CVS Health;
 - Annie E. Klis was a Vice President at CVS Health at the same time she was CEO of Caremark, L.L.C.
- CVS Health directly or indirectly owns all the stock of CVS Pharmacy, Caremark Rx, L.L.C., Caremark L.L.C. and CaremarkPCS Health L.L.C.
 - All of the executives of CaremarkPCS Health, L.L.C., Caremark, L.L.C., Caremark Rx, L.L.C., and CVS Pharmacy ultimately report to the executives at CVS Health, including the President and CEO of CVS Health.
 - CVS Health, as a corporate family, does not operate as separate entities. The public filings, documents, and statements of CVS Health presents its subsidiaries, including CVS Pharmacy, CaremarkPCS Health, L.L.C., Caremark, L.L.C., and Caremark Rx, L.L.C. as divisions or departments of one unified “diversified health services company” that “works together across our disciplines” to “create unmatched human connections to transform the health care experience.” The day-to-day operations of this corporate family reflect these public statements. These entities are a single business enterprise and should be treated as such as to all legal obligations discussed in this Complaint. The CVS Health enterprise and each of these entities, both individually and collectively, engaged in the at-issue conduct that gave rise to the Insulin Pricing Scheme.

114. Collectively, Defendants CVS Health, CVS Pharmacy, Caremark Rx, L.L.C., Caremark, L.L.C., and CaremarkPCS Health, L.L.C, including all predecessor and successor entities, are referred to as “CVS Caremark.”

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

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

117. CVS Caremark has the largest PBM market share based on total prescription claims managed, representing approximately 33% of the total national market. CVS Caremark's pharmacy services segment generated \$141.5 billion in total revenues last year.

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

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

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

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

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

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

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

125. At all times relevant hereto, CVS Caremark had express agreements with Defendants Novo Nordisk, Sanofi, and Eli Lilly related to the Manufacturer

Payments paid to CVS Caremark and placement on CVS Caremark's standard formularies, as well as agreements related to the Manufacturers' at-issue drugs sold through CVS Caremark's mail order and retail pharmacies, including those located in Kentucky.

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

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

128. Evernorth, through its executives and employees is directly involved in shaping the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs, related to the Insulin Pricing Scheme. For example, during the relevant time period Evernorth's CEO Tim Wentworth was involved in communications with the Manufacturer Defendants related to the at-issue drugs and at-issue Manufacturer Payments.

129. Evernorth's conduct has had a direct effect in Kentucky and damaged diabetics and payors in Kentucky.

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

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

132. Manufacturers recognize that effectuating the Insulin Pricing Scheme requires enhanced relationships at C Suite level between the Manufacturers and Evernorth to maximize business opportunities.

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

- In at least 2013, 2014, 2015, 2017, and 2018 the leaders of Evernorth and Eli Lilly participated in executive meetings in furtherance of the Insulin Pricing Scheme. These meetings included the CEO of Evernorth, Senior Director of Express Scripts Pharmaceutical Strategies & Solutions, CEO of Eli Lilly, Head of Eli Lilly's diabetes division (Enrique Conterno), among others.
- In at least 2013, 2014, and 2016, the leaders of Evernorth and Novo Nordisk participated in executive meetings in furtherance of the Insulin Pricing Scheme.
- In at least 2014, 2015, 2016, and 2017 the leaders of Evernorth and Sanofi participated in “Customer Exchange” and PCMA executive meetings, which included discussions in furtherance of the Insulin Pricing Scheme. These meetings included the Chairman and CEO of Evernorth, the former President and current CEO, the Global CEO of Sanofi and Chief Medical Officer of Sanofi, among others.

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

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

136. In each annual report for at least the last decade, Evernorth has repeatedly, continuously, and explicitly stated:⁶

- “[Evernorth] is one of the largest PBMs in North America . . . [and Evernorth] help[s] health benefit providers address access and affordability concerns resulting from rising drug costs while helping to improve healthcare outcomes.”
- “[Evernorth] manage[s] the cost of the drug benefit by . . . assist in controlling costs; evaluat[es] drugs for efficacy, value and price to assist[ing] clients in selecting a cost-effective formulary; [and] offer[s] cost-effective home delivery pharmacy and specialty services that result in cost savings for plan sponsors [and better care for members] leveraging purchasing volume to deliver discounts to health benefit providers.”
- “[Evernorth] works with clients, manufacturers, pharmacists and physicians to increase efficiency in the drug distribution chain, to manage costs in the pharmacy benefit chain and to improve members’ health outcomes.”

⁶ Express Scripts Annual Reports (Form 10-K) (Dec. 31, 2009-2019).

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

138. Express Scripts, Inc. is registered to do business in Kentucky and may be served through its registered agent: CT Corporation System, 306 West Main Street, Suite 512, Frankfort, Kentucky 40601.

139. Express Scripts, Inc. holds 1 active license with the Board of Insurance in Kentucky.

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

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

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

143. Express Scripts Administrators, LLC is registered to do business in Kentucky and may be served through its registered agent: CT Corporation System, 306 West Main Street, Suite 512, Frankfort, Kentucky 40601.

144. Express Scripts Administrators, LLC holds 2 active licenses with the Board of Insurance in Kentucky.

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

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

147. Medco may be served through its registered agent: CT Corporation System, 306 West Main Street, Suite 512, Frankfort, Kentucky 40601.

148. Prior to 2012, Medco provided the at-issue PBM and mail order services in Kentucky, which gave rise to the Insulin Pricing Scheme and damaged diabetics and payors in Kentucky.

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

150. Prior to the merger Express Scripts and Medco were two of the largest PBMs in the United States and in Kentucky.

151. Prior to the merger, Medco provided the at-issue PBM and mail-order services in Kentucky, which gave rise to the Insulin Pricing Scheme and damaged diabetic Kentucky residents.

152. Following the merger, all of Medco’s PBM and mail order pharmacy functions were combined into Express Scripts. The combined company (Medco and Express Scripts) continued under the name Express Scripts with all of Medco’s payor

customers becoming Express Scripts' customers. The combined company covered over 155 million lives at the time of the merger.

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

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

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

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

157. ESI Mail Pharmacy Service, Inc. holds 6 active licenses with the Board of Pharmacy in Kentucky.

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

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

160. Express Scripts Pharmacy, Inc. may be served through its registered agent: CT Corporation System, 306 West Main Street, Suite 512, Frankfort, Kentucky 40601.

161. Express Scripts Pharmacy, Inc. holds 6 active licenses with the Board of Pharmacy in Kentucky.

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

163. As a result of numerous interlocking directorships and shared executives, Evernorth and Express Scripts, Inc. are directly involved in the conduct of and control Express Scripts Administrators, LLC, Medco Health Solutions, Inc., ESI Mail Pharmacy Service, Inc., and Express Scripts Pharmacy, Inc.'s operations, management and business decisions related to the at-issue formulary construction,

Manufacturer Payments, and mail order pharmacy services to the ultimate detriment of Kentucky diabetics. For example:

- During the relevant time period, these parent and subsidiaries have had common officers and directors:
 - Officers and/or directors that have been shared between Express Scripts, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; David Queller, President; Jill Stadelman, Secretary; Timothy Smith, Vice President; and Scott Lambert, Treasury Manager Director;
 - Executives that have been shared between Express Scripts Administrators, LLC and Evernorth include Bradley Phillips, Chief Financial Officer; and Priscilla Duncan, Associate Secretary;
 - Officers and/or directors that have been shared between ESI Mail Pharmacy Service, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; Priscilla Duncan, Associate Secretary; and Joanne Hart, Associate Treasurer;
 - Officers and/or directors that have been shared between Express Scripts Pharmacy, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; Jill Stadelman, Secretary; Scott Lambert, Treasury Manager Director; and Joanne Hart, Associate Treasurer; and
 - Officers and/or directors that have been shared between Medco Health Solutions, Inc. and Evernorth include David Queller, President and Senior VP of Sales & Accounting, Christine Houston, VP and COO, Timothy Smith, VP and Treasurer and all of the officers of Medco Health Solutions are also officers of Express Scripts, Inc.
- Evernorth directly or indirectly owns all the stock of Express Scripts Administrators, LLC, Medco Health Solutions, Inc., ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc. and Express Scripts, Inc.
- The Evernorth corporate family does not operate as separate entities. The public filings, documents, and statements of Evernorth presents its subsidiaries, including Express Scripts Administrators, LLC, Medco Health Solutions, Inc., ESI Mail Pharmacy Service, Inc., Express Scripts

Pharmacy, Inc., and Express Scripts, Inc. as divisions or departments of a single company that “unites businesses that have as many as 30+ years of experience . . . [to] tak[e] health services further with integrated data and analytics that help us deliver better care to more people.” The day-to-day operations of this corporate family reflect these public statements. All of these entities are a single business enterprise and should be treated as such as to all legal obligations detailed in this Complaint. The Evernorth enterprise and each of these entities, both individually and collectively, engaged in the at-issue conduct that gave rise to the Insulin Pricing Scheme.

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

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

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

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

167. Prior to merging with Cigna in 2019, Express Scripts was the largest independent PBM in the United States. During the relevant period of this Complaint, Express Scripts controlled between 23% and 30% of the PBM market in the United States.

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

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

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

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

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

173. At all times relevant hereto, Express Scripts constructed standard formularies that are used nationwide, including by Express Scripts' payor clients in Kentucky, and that are relied on by residents in Kentucky with diabetes as promoting diabetic health and lowering the price of the at-issue drugs. During the

relevant time period, these standard formularies included the at-issue diabetes medications.

174. During certain years when some of the largest at-issue price increases occurred, including in 2013 and 2014, Express Scripts worked directly with OptumRx to negotiate Manufacturer Payments on behalf of OptumRx and its clients in exchange for preferred formulary placement. For example, in a February 2014 email released by the U.S. Senate in conjunction with its January 2021 report titled “Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug” (“January 2021 Senate Insulin Report”), Eli Lilly describes a “Russian nested doll situation” in which Express Scripts was negotiating rebates on behalf of OptumRx related to the at-issue drugs for Cigna (who later would become part of Express Scripts).

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

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

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

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

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

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

181. UnitedHealth Group, Inc. is a diversified managed healthcare company. In 2015, UnitedHealth Group listed revenue in excess of \$257 billion, and the company is currently ranked fifth on the Fortune 500 list. UnitedHealth Group, Inc. offers a spectrum of products and services including health insurance plans and pharmacy benefits through its wholly-owned subsidiaries.

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

183. UnitedHealth Group, through its executives and employees, is directly involved in the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs and related to the Insulin

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

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

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

- In at least in 2010, 2016, 2017, and 2018, executives from UnitedHealth Group, including its CEOs, the Executive Vice President of Corporate Affairs, Senior Directors of Diabetes Alliance, CEOs of OptumRx, and the Executive Vice President of OptumRx, met and/or engaged in discussions with executives at Eli Lilly, including CEO Dave Ricks, that included discussions in furtherance of the Insulin Pricing Scheme.
- In 2014, the CEO and Senior Vice President of UnitedHealth Group met with executives at Novo Nordisk and engaged in discussions in furtherance of the Insulin Pricing Scheme.
- In at least 2014 and 2018, executives at UnitedHealth Group, including CEOs, met with executives at Sanofi, including CEO of Sanofi to engage in discussions in furtherance of the Insulin Pricing Scheme. Sanofi’s

stated objective for these meetings was to “[l]everage the entire Sanofi portfolio of assets to set the stage for future business development with UHG, along with establishing a stronger executive level strategic relationship with UHG.”

- In April 2015, the Executive Vice President at UnitedHealth Group, the Chief Commercial Officer at Optum Analytics, the Vice President of OptumRx, the Vice President of OptumInsight, among other executives met with Novo Nordisk’s Vice President of Market Access and the Executive Vice President of Strategic Accounts, among other executives from Novo Nordisk, at UnitedHealth Group’s corporate headquarters to discuss their strategic overview and prioritized opportunities in diabetes in furtherance of the Insulin Pricing Scheme.

186. In 2011, UnitedHealth Group invested significantly in building out OptumRx’s capabilities, including unifying all UnitedHealth Group-related formularies, including OptumRx, with the goal of aligning their formularies/PDLs across all their segments (Medicare, commercial and managed care) and moving to one P&T committee in 2012. This effort also included tasking OptumRx with negotiating rebates and manufacturer contracts for all UnitedHealth Group enterprise-wide formularies.

187. UnitedHealth Group’s conduct had a direct effect in Kentucky and damaged diabetics and payors in Kentucky.

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

189. OptumInsight, Inc. is registered to do business in Kentucky and may be served through its registered agent: CT Corporation System, 306 West Main Street, Suite 512, Frankfort, Kentucky 40601.

190. OptumInsight, Inc. holds 1 active license with the Board of Insurance in Kentucky.

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

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

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

194. The Manufacturers utilized their relationships with OptumInsight to deepen their ties to the overall UnitedHealth Group corporate family and to secure formulary wins for their diabetes medications. During the relevant time period OptumInsight provided data to the Manufacturer Defendants in order to increase sales of the at-issue drugs.

195. Each Manufacturer Defendant had dedicated executives assigned to OptumInsight to collaborate the UnitedHealth Group corporate family and to coordinate with OptumInsight for data acquisition and utilization.

196. These collaborations between the UnitedHealth Group family (including OptumInsight) and the Manufacturer Defendants included providing data to the Manufacturers following formulary “wins” to help the Manufacturers promote their preferred formulary status (referred to as “pull through” efforts).

197. These collaborations between the UnitedHealth Group family (including OptumInsight) and the Manufacturer Defendants included in person meetings.

198. These meetings between the UnitedHealth Group family (including OptumInsight) and the Manufacturer Defendants occurred throughout the relevant time period.

199. Data exchanges between the UnitedHealth Group family (including OptumInsight) and the Manufacturer Defendants also occurred throughout the relevant time period.

200. Each Manufacturer Defendant also contracted with OptumInsight during the relevant time period.

201. The Manufacturer Defendants’ strategic plans included partnering with OptumInsight to identify challenges and growth opportunities.

202. During the relevant time period, OptumInsight also worked with OptumRx to offer the at-issue pharmacy benefit and data and cost analysis services that gave rise to the Insulin Pricing Scheme to Kentucky diabetics and payors.

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

204. OptumRx is registered to do business in Kentucky and may be served through its registered agent: CT Corporation System, 306 West Main Street, Suite 512, Frankfort, Kentucky 40601.

205. OptumRx holds 1 active license with the Board of Pharmacy in Kentucky and 2 active licenses with the Board of Insurance in Kentucky.

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

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

- These parent and subsidiaries have common officers and directors, including:
 - Sir Andrew Witty is president of UnitedHealth Group and CEO of Optum, Inc.;
 - Dan Schumacher is president of Optum, Inc, the Chief Strategy and Growth Officer at UnitedHealth Group, Inc. and oversees OptumInsight;
 - Terry Clark is a senior vice president and chief marketing officer at UnitedHealth Group and also oversees the branding, marketing, and advertising for UnitedHealth Group and Optum, Inc.;
 - Tom Roos serves as chief accounting officer for UnitedHealth Group and Optum, Inc.;

- Heather Lang is Deputy General Counsel, Subsidiary Governance at UnitedHealth Group, Inc. and also Assistant Secretary at OptumRx, Inc.;
 - Peter Gill is Vice President at UnitedHealth Group, Inc. and also Treasurer at OptumRx, Inc.;
 - John Santelli leads Optum Technology, the leading technology division of Optum, Inc serving the broad customer base of Optum and UnitedHealthcare and also serves as UnitedHealth Group's chief information officer;
 - Eric Murphy is the Chief Growth and Commercial Officer for Optum, Inc. and has also led OptumInsight, Inc.; and
 - Timothy Wicks, CFO and Executive Vice President of Industry and Network relations for OptumRx, Inc. also held “executive management positions” with UnitedHealth Group “including operations product management and business development roles at UnitedHealthcare, OptumInsight and most recently, Optum Shared Services.”
- UnitedHealth Group directly or indirectly owns all the stock of OptumRx, Inc. and OptumInsight, Inc.
 - The UnitedHealth Group corporate family does not operate as separate entities. The public filings, documents, and statements of UnitedHealth Group presents its subsidiaries, including OptumRx, Inc. and OptumInsight as divisions or departments of a single company that is “a diversified family of businesses” that “leverages core competencies” to “help[] people live healthier lives and helping make the health system work better for everyone.” The day-to-day operations of this corporate family reflect these public statements. These entities are a single business enterprise and should be treated as such as to all legal obligations detailed in this Complaint. Indeed, UHG and OptumRx represent directly to their clients and potential clients in Kentucky that the “Optum family of companies—OptumRx, OptumHealth and OptumInsight—each wholly owned subsidiaries of UnitedHealth Group” work as a cohesive unit to offer the at-issue services related to the Insulin Pricing Scheme in Kentucky.
 - The UnitedHealth Group enterprise and each of these entities, both individually and collectively, engaged in the at-issue conduct that gave rise to the Insulin Pricing Scheme.

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

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

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

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

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

212. In its capacity as a PBM, OptumRx coordinates with Novo Nordisk, Eli Lilly, and Sanofi regarding the artificially inflated list prices for the at-issue diabetes medications, as well as for the placement of these firms' diabetes medications on OptumRx's drug formularies.

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

214. In 2018, OptumRx managed more than \$96 billion in pharmaceutical spending, with a revenue of \$74 billion.

215. Prior to 2011, OptumRx was known as Prescription Solutions. In addition, as illustrated in Figure 13, OptumRx rose to power through numerous mergers with other PBMs. For example, in 2012, a large PBM, SXC Health Solutions bought one of its largest rivals, Catalyst Health Solutions Inc. in a roughly \$4.14 billion deal. Shortly thereafter, SXC Health Solutions Corp. renamed the company Catamaran Corp. Following this OptumRx's parent company, UnitedHealth Group, bought Catamaran Corp in a deal worth \$12.8 billion and combined Catamaran with OptumRx.

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

217. At all times relevant hereto, OptumRx derived substantial revenue providing pharmacy benefits in Kentucky.

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

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

220. At all times relevant hereto, OptumRx offered pharmacy benefit management services nationwide and constructed standard formularies that are used throughout Kentucky by payors and diabetics, and that are relied on by residents in

Kentucky with diabetes as promoting diabetic health and lowering the price of the at-issue drugs. During the relevant time period, these standard formularies included the at-issue diabetes medications.

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

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

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

224. Collectively, CVS Caremark, OptumRx, and Express Scripts are referred to as "PBM Defendants" or "PBMs."

225. Collectively, the "PBM Defendants" and the "Manufacturer Defendants" are referred to as "Defendants."

III. PUBLIC INTEREST

226. The Kentucky Attorney General believes this action to be in the public interest of the citizens of the Commonwealth of Kentucky and brings this action pursuant to the Kentucky Consumer Protection Act, Kentucky False Advertising Statute, and the Kentucky common law.

227. This action seeks, on behalf of the Commonwealth of Kentucky and its citizens, legal and equitable relief to redress injury and damage, as well as injunctive relief seeking an end to Defendants' misconduct. The Commonwealth of Kentucky has both a sovereign and a quasi-sovereign interest in protecting the well-being of the millions of diabetic citizens of the Commonwealth of Kentucky who rely on the at-issue diabetic medications and have been damaged, and continue to be damaged, by the Insulin Pricing Scheme.

228. The Commonwealth of Kentucky is a real party in interest in this action. Acting as a constitutional officer of the Commonwealth of Kentucky possessing all the power and authority under the common law and statute, the Attorney General institutes this action to protect the health and economic interests of its residents, its own interests and the integrity of its healthcare system. The Attorney General is authorized to bring this action on behalf of the Commonwealth to recover damages, punitive damages, restitution, penalties, disgorgement, injunctive relief and to remediate all harm arising out of—and provide full relief for—violations of Kentucky laws.

IV. JURISDICTION AND VENUE

229. This Court has subject matter jurisdiction pursuant to KRS 23A.010 and KRS 367.190 as the claims enumerated herein arise exclusively under Kentucky statutory and common law and from *parens patriae* authority of the Attorney General to protect the health and welfare of its citizens under the common law. The Commonwealth's claims are in excess of any minimum dollar amount necessary to establish the jurisdiction of this Court.

230. This Court has personal jurisdiction pursuant to KRS 454.210 because each Defendant: (a) transacts business and/or is admitted to do business within Kentucky, (b) maintains substantial contacts in Kentucky, and (c) committed the violations of Kentucky statutes and the common law at issue in this lawsuit in whole or part within Kentucky. The Insulin Pricing Scheme has been directed at, and has had the foreseeable and intended effect of, causing injury to persons residing in, located in, or doing business in Kentucky, and to the Commonwealth.

231. All of the at-issue transactions occurred in Kentucky and/or involved Kentucky residents.

232. Venue for this action properly lies in Franklin County pursuant to KRS 452.450 and 452.460 because Defendants transact business in Franklin County and the causes of action arose in whole or in part in Franklin County and pursuant to KRS 367.190(1) because Defendants' unlawful methods, acts, and/or practices were committed in Franklin County.

V. FACTUAL ALLEGATIONS

A. Diabetes and Insulin Therapy

1. Diabetes: A growing epidemic

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

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

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

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

237. 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 (10) million. Fourteen (14) years later, the count tripled again. Now over thirty (30) million people—9.4% of the country—live with the disease.

238. Likewise, the prevalence of diabetes in Kentucky has been steadily increasing as well, approximately 450,000 Kentucky adults now live with diabetes and another 1,200,000 have prediabetes.

239. The burden of diabetes is not equally distributed in Kentucky. Diabetes is more common among individuals with less education – adults not completing high school are, in fact, more than twice as likely to suffer from diabetes compared to those with a college education. That distinction is reflected in the earnings data for Kentucky diabetics – over 44% of adult diabetics in Kentucky reportedly earn less than \$25,000 per year.

2. Insulin: A century old drug

240. 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.

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

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

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

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

245. While effective, animal-derived insulin created the risk of allergic reaction. This risk was lessened in 1982 when synthetic insulin, known as human insulin, was developed by Defendant Eli Lilly. Eli Lilly marketed this insulin as Humulin. The development of human insulin benefited heavily from government and non-profit funding through the National Institute of Health and the American Cancer Society.

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

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

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

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

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

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

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

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

3. Current insulin landscape

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

255. 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.

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

257. 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.

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

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

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

260. Nor have the production or research and development costs increased. In fact, in the last ten (10) years, the production costs of insulin have decreased as manufacturers simplified and optimized processes. A September 2018 study published in *BMJ Global Health* calculated that, based on production costs, a reasonable price for a year's supply of human insulin is \$48 to \$71 per person and between \$78 and \$133 for analog insulins—which includes delivering a profit to manufacturers. Indeed, over the past 3 years, each manufacturer has conducted billions of dollars in stock buybacks, for example, in 2021 Eli Lilly was authorized to conduct \$5 billion in stock buybacks over the course of 2 years.

261. Another recent study noted anecdotal evidence that the Manufacturers could be *profitable 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:

If we are wrong on [the \$2.50 cost estimate] it would be by *overestimating* them. In short, [while we calculate] costs are likely around \$2.50 pen/vial . . . in discussion with Biocon (a foreign insulin manufacturer) we were told insulin price in India was ~\$2/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 national tenders.

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

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

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

265. 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.

266. Despite this decrease in production costs and no new research and development, the reported price of insulins has risen astronomically over the last fifteen (15) years.

4. Insulin adjuncts: Type 2 medications

267. Over the past decade, Manufacturer Defendants have also released a number of non-insulin medications that help control the level of insulin in the bloodstream of Type 2 diabetics.

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

269. Victoza, Trulicity, and Ozempic are all medications known as glucagon-like peptide-1 receptor agonists (“GLP-1”) and are similar to the GLP-1 hormone that is already produced in the body. Soliqua is a combination long-acting insulin and GLP-1 drug. Each of these drugs can be used in conjunction with insulins to control diabetes.

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

Table 1: Diabetes medications at issue in this case

Insulin Type	Action	Name	Company	FDA Approval	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	\$350 (vial) \$525 (pens)
		Levemir	Novo Nordisk	2005	\$370 (vial) \$555 (pens)
		Basaglar (Kwikpen)	Eli Lilly	2016	\$392 (pens)
		Toujeo (Solostar)	Sanofi	2015	\$489 (pens) \$653 (max pens)
	Tresiba	Novo Nordisk	2015	\$407 (vial) \$610 (pens – 100u) \$732 (pens – 200u)	
Type 2 Medications		Trulicity	Eli Lilly	2014	\$1,117 (pens)
		Victoza	Novo Nordisk	2010	\$893 (2 pens) \$1,340 (3 pens)
		Ozempic	Novo Nordisk	2017	\$1,122 (pens)
		Soliqua	Sanofi	2016	\$1,018 (pens)

B. The Dramatic Rise in the Price of Diabetes Medications

1. Insulin price increases

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

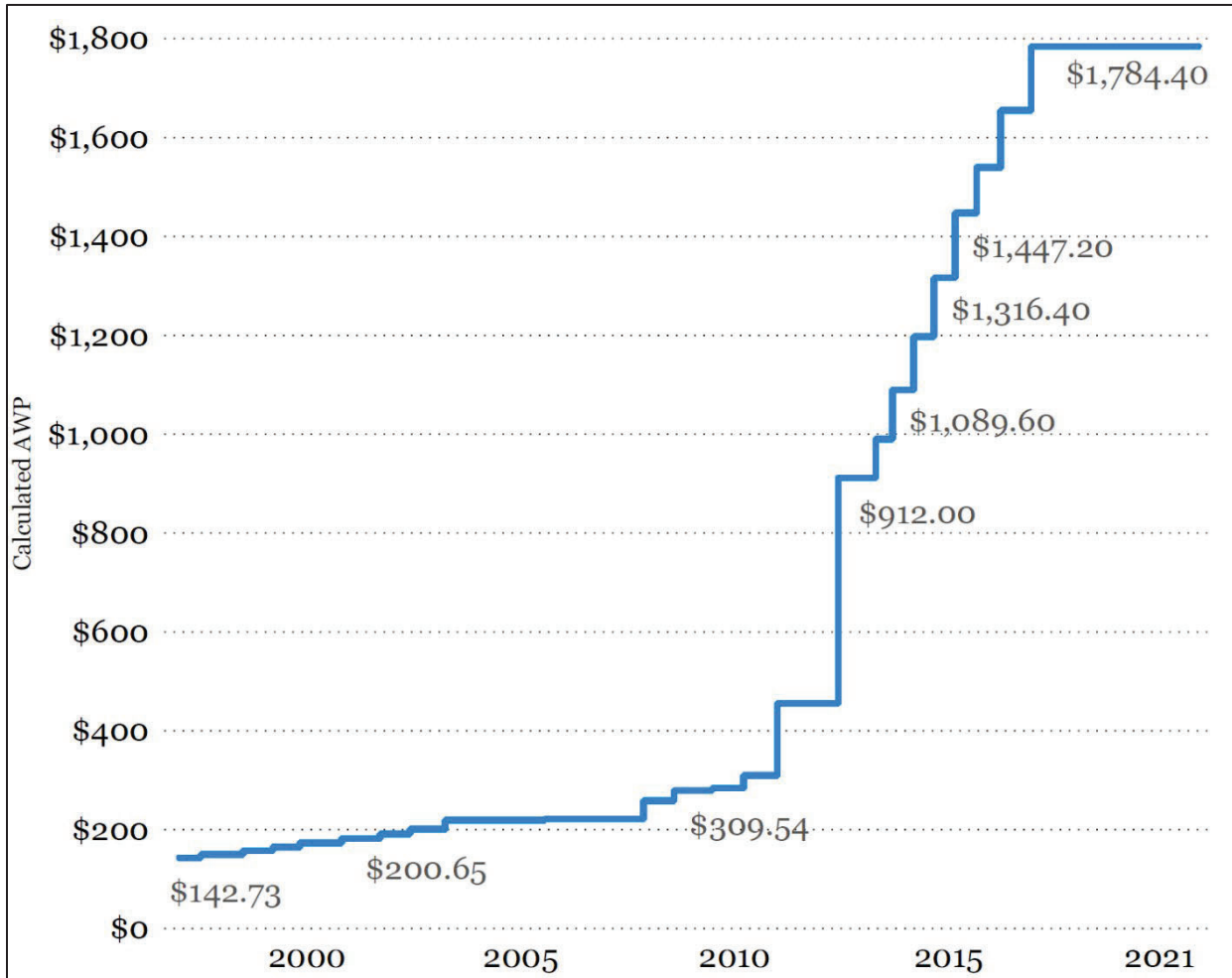
272. That same year, the price of insulin began its dramatic rise to its current exorbitant level.

273. Since 2003, the list price of certain insulins has increased in some cases by more than 1000%; an astounding increase especially when compared to a general inflation rate of 8.3% and a medical inflation rate of 46% in this time period.

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

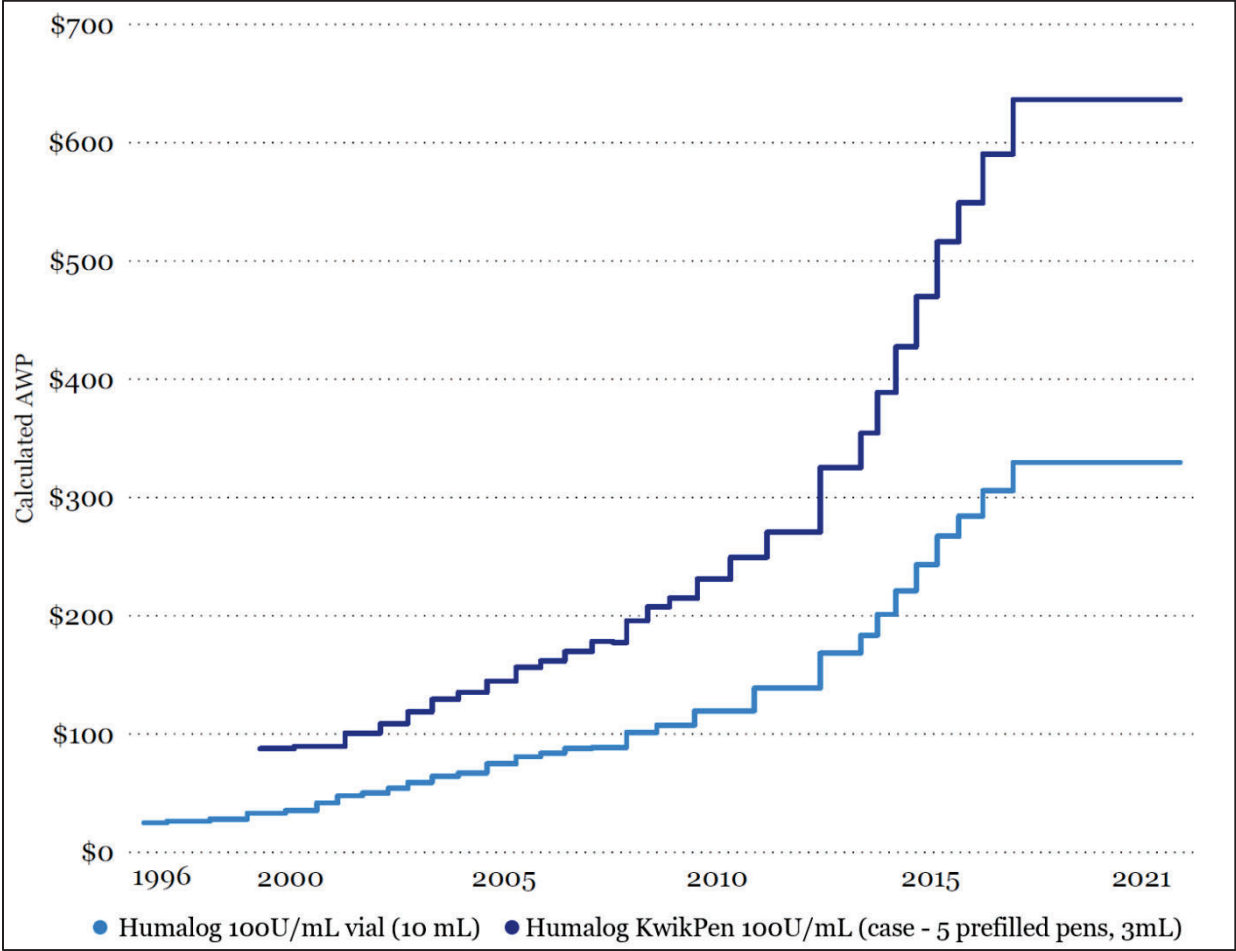
275. Since 1997, Defendant Eli Lilly has artificially inflated the list price of a vial of Humulin R (500U/ML) from \$165 to \$1784 (*See Figure 2*).

**Figure 2: Rising list prices of Humulin R (500U/mL)
from 1997-2021**



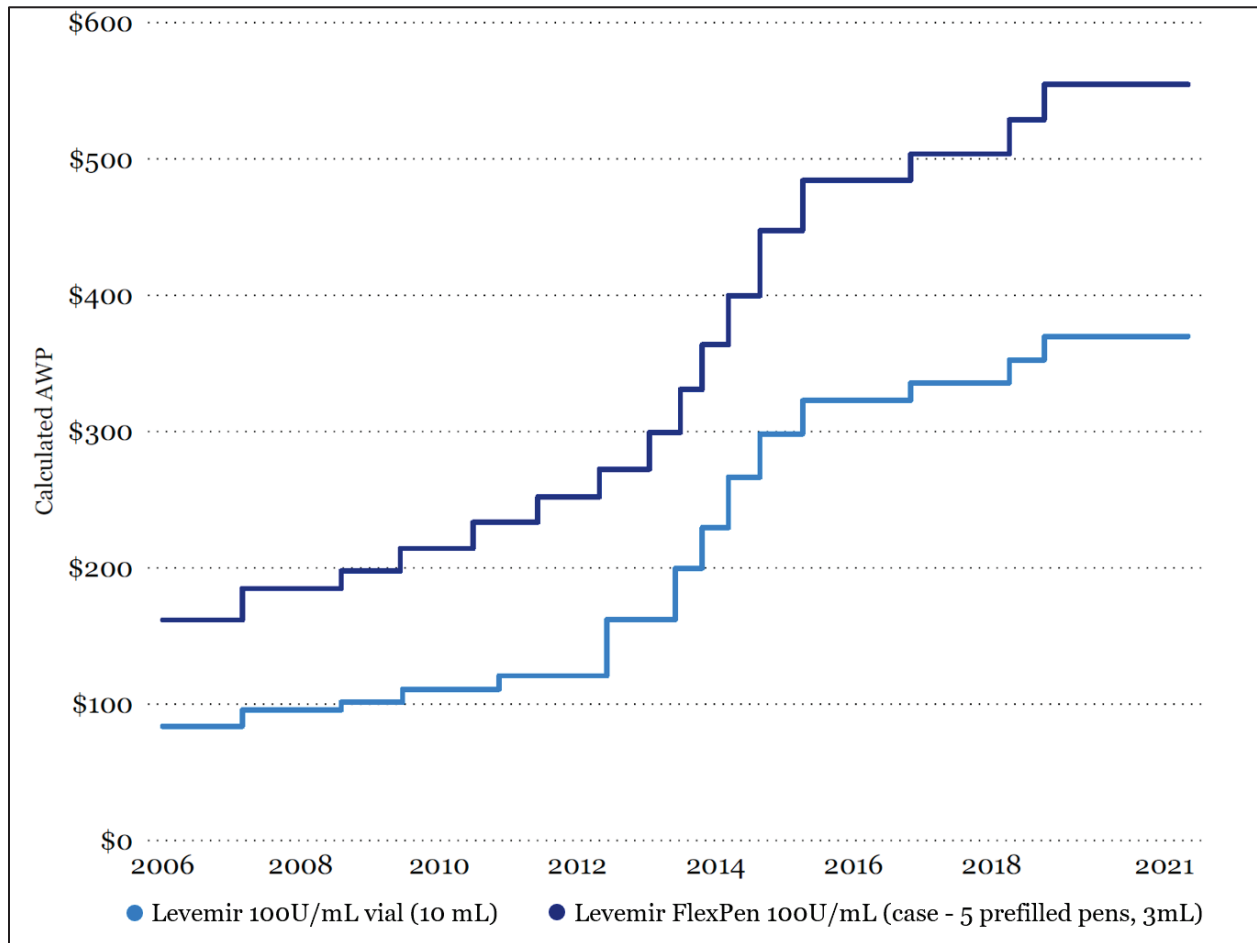
276. Since 1996, Defendant Eli Lilly has artificially inflated the list price for a package of pens of Humalog from less than \$100 to \$663 and from less than \$50 for a vial to \$342 (See Figure 3).

Figure 3: Rising list prices of Humalog vials and pens from 1996-2021



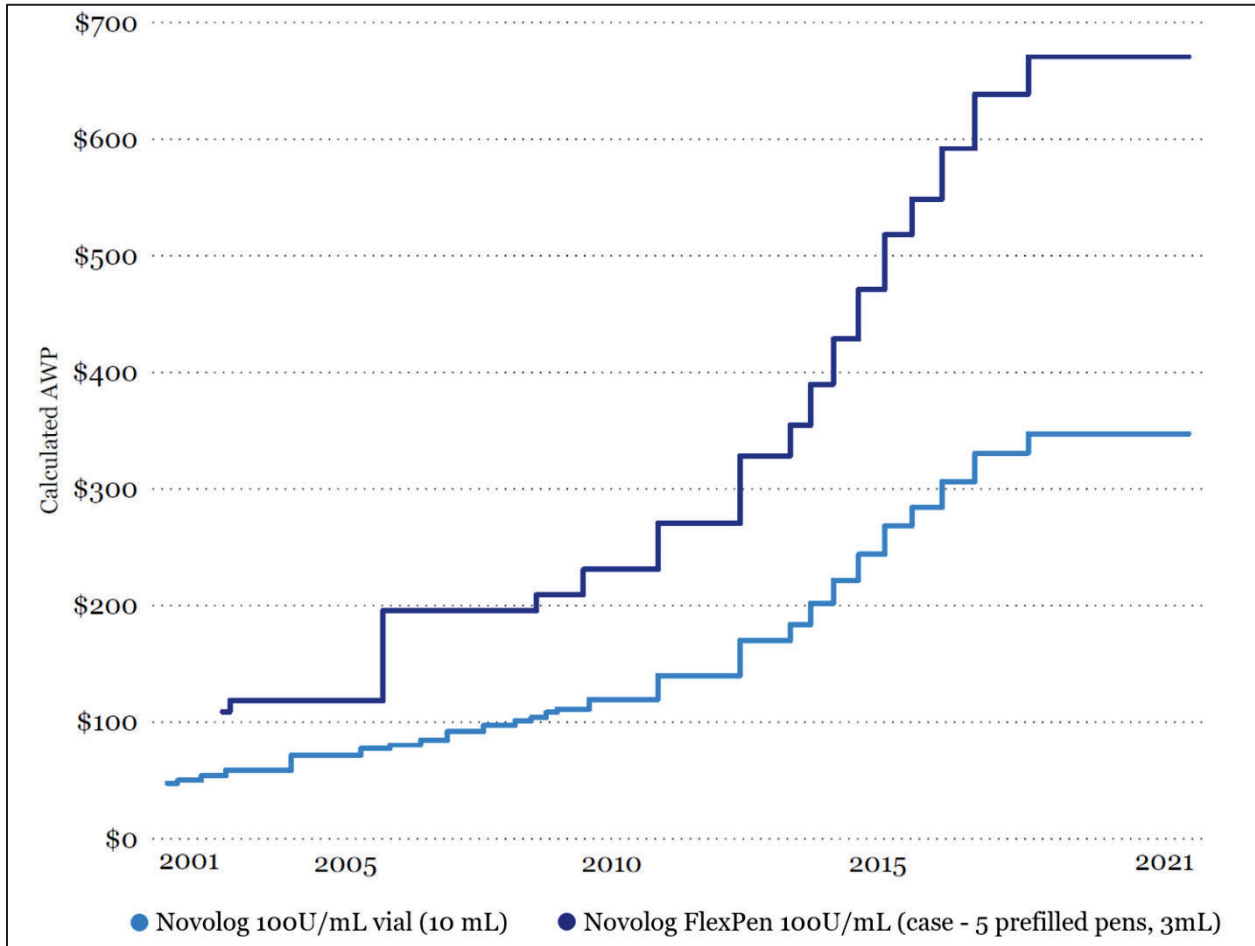
277. Novo Nordisk has also artificially inflated the list prices—from 2006 to 2020, Levemir rose from \$162 to \$555 for pens and from under \$100 to \$370 per vial (See Figure 4).

Figure 4: Rising list prices of Levemir from 2006-2021



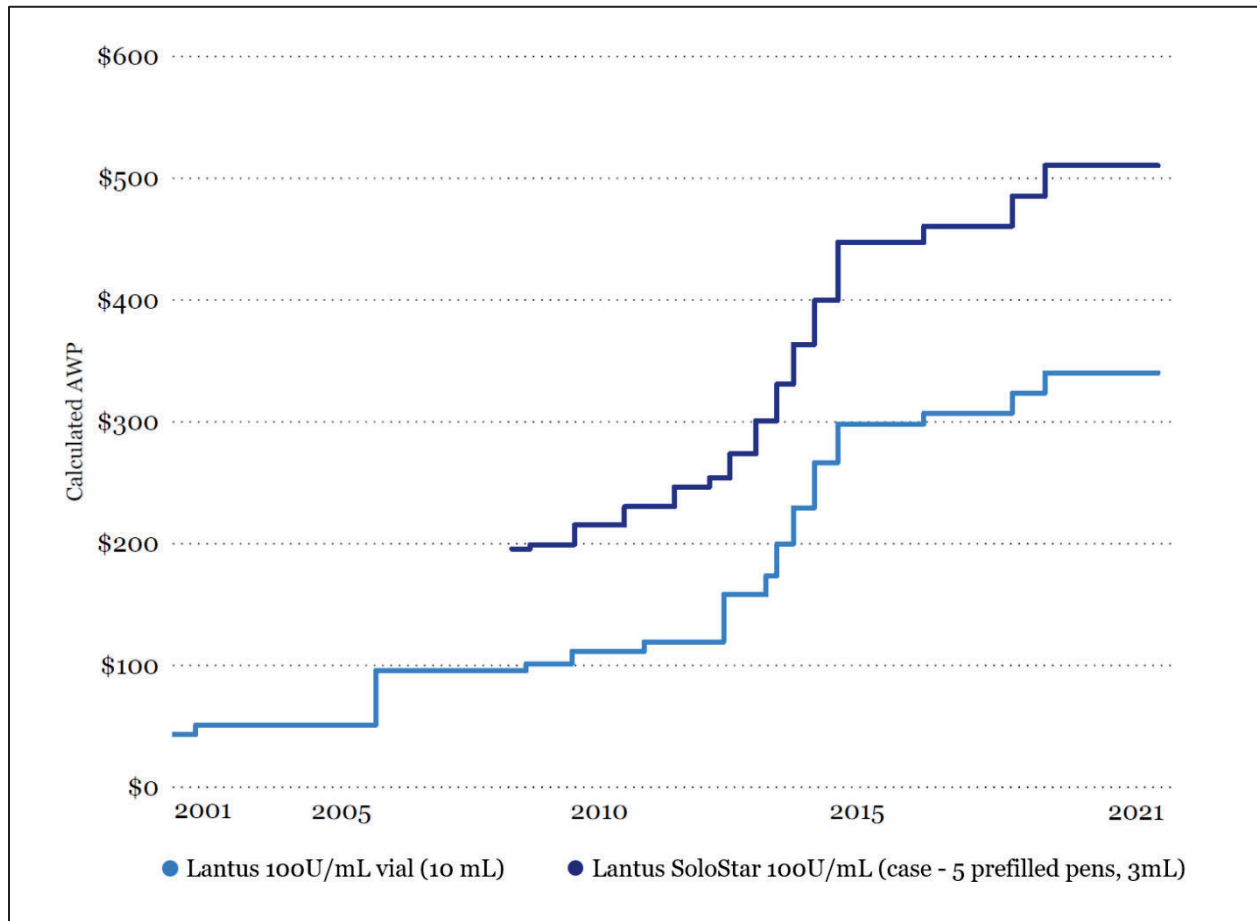
278. From 2002 to 2020, Novo Nordisk has artificially inflated the list price of Novolog from \$108 to \$671 for a package of pens and from less than \$50 to \$347 for a vial (See Figure 5).

Figure 5: Rising list prices of Novolog vials and pens from 2002-2021



279. Defendant Sanofi has kept pace as well, artificially inflating the list price for Lantus, the top-selling analog insulin, from less than \$200 in 2006, to over \$500 in 2020 for a package of pens and from less than \$50 to \$340 for a vial (See Figure 6).

Figure 6: Rising list prices of Lantus vials and pens from 2001-2021



280. Manufacturer Defendants’ non-insulin diabetes medications have experienced similar recent price increases. For example, since 2015 Eli Lilly has artificially inflated the list price of Trulicity almost 50%.

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

2. Manufacturers increased prices in lockstep

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

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

284. 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.”

285. 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.

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

Figure 7: Rising list prices of long-acting insulins

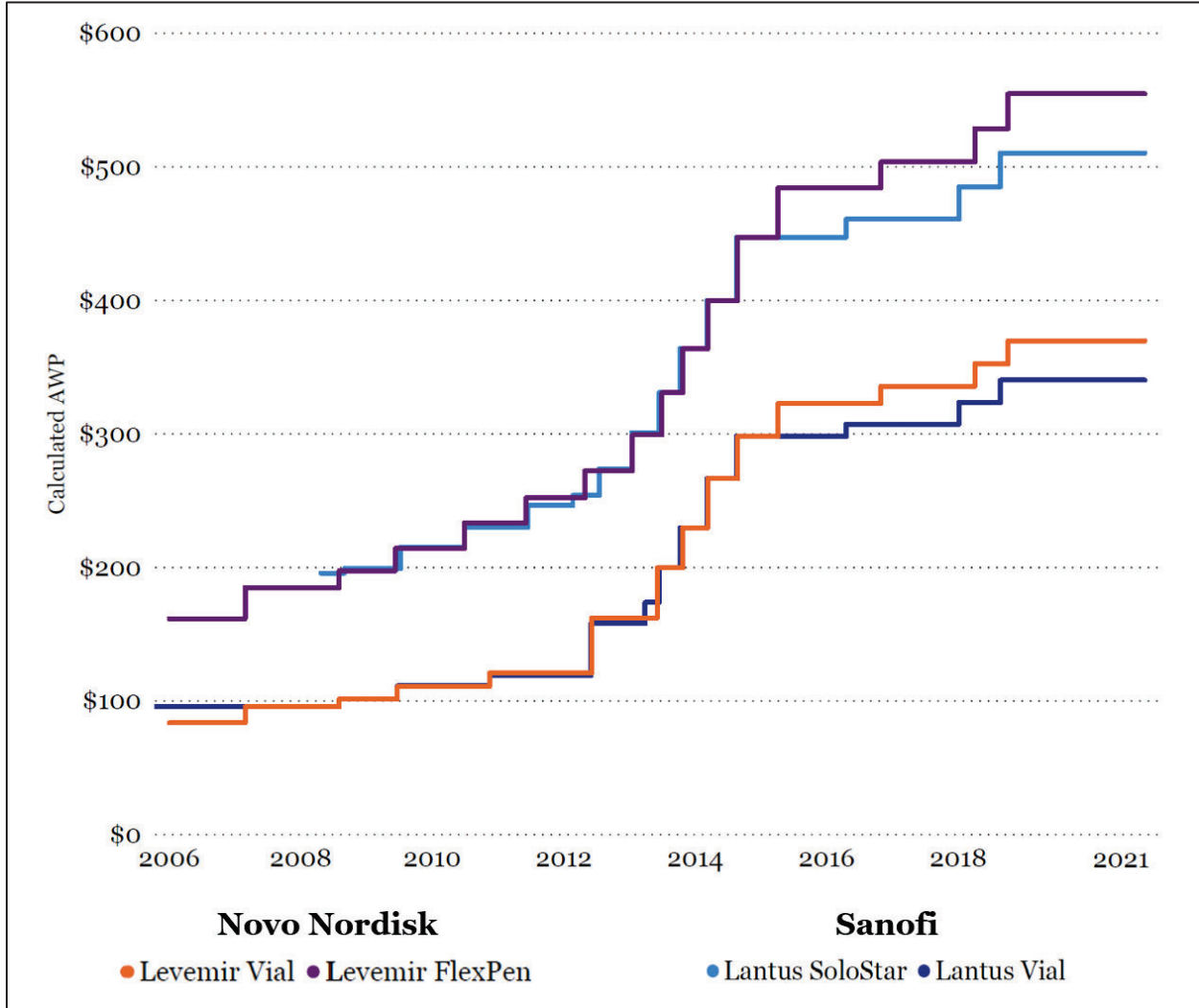
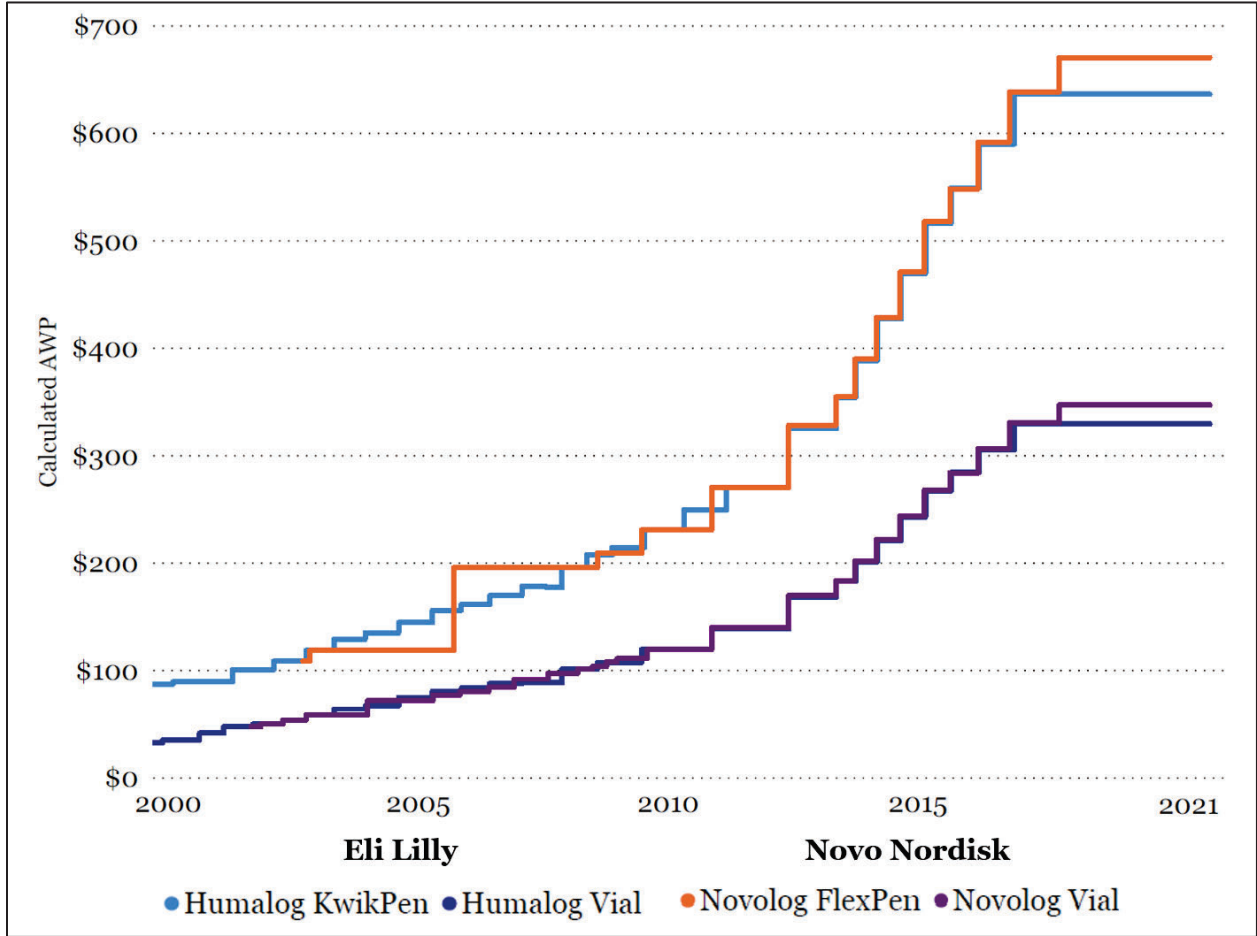
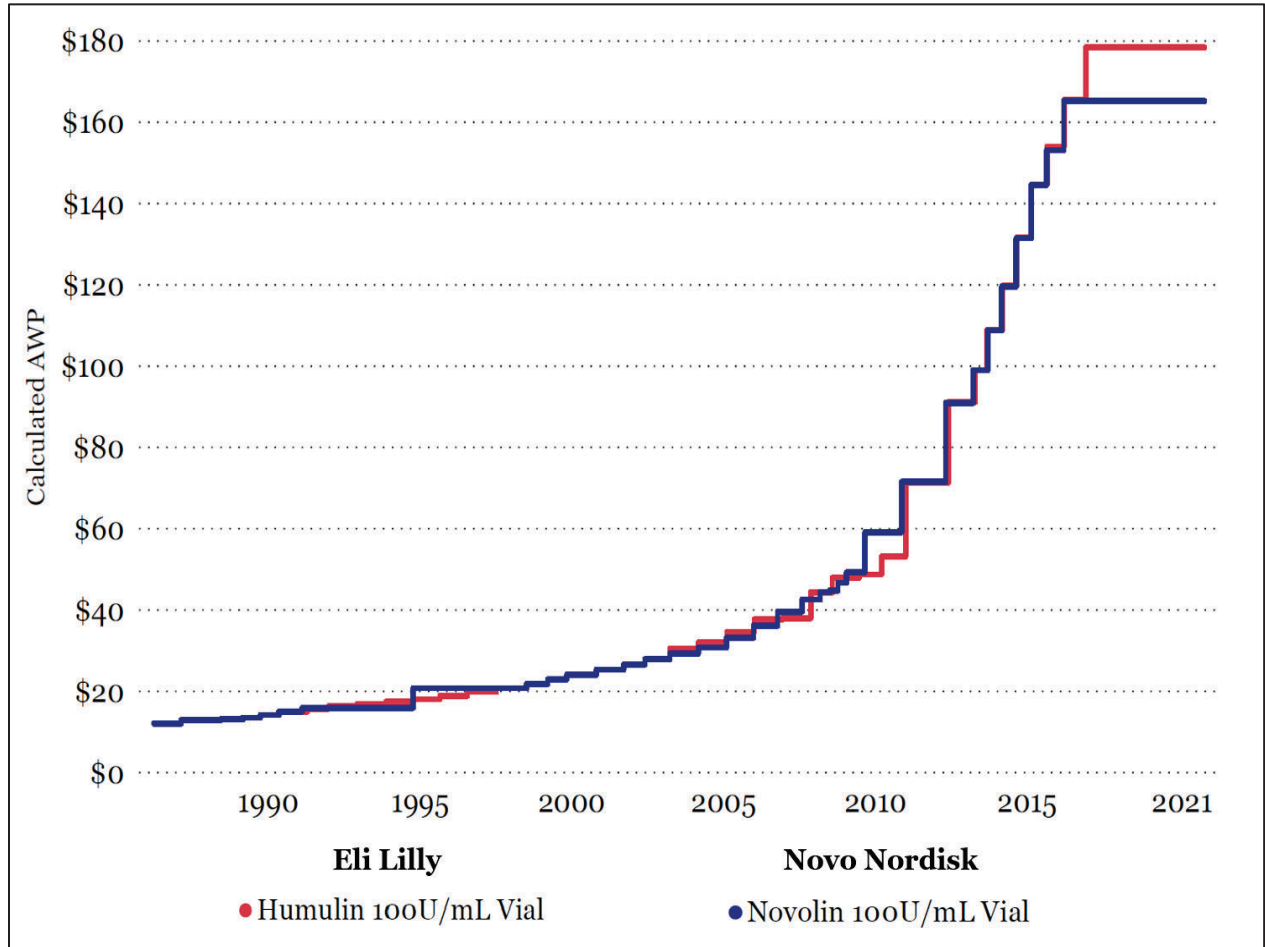


Figure 8: Rising list prices of rapid-acting insulins



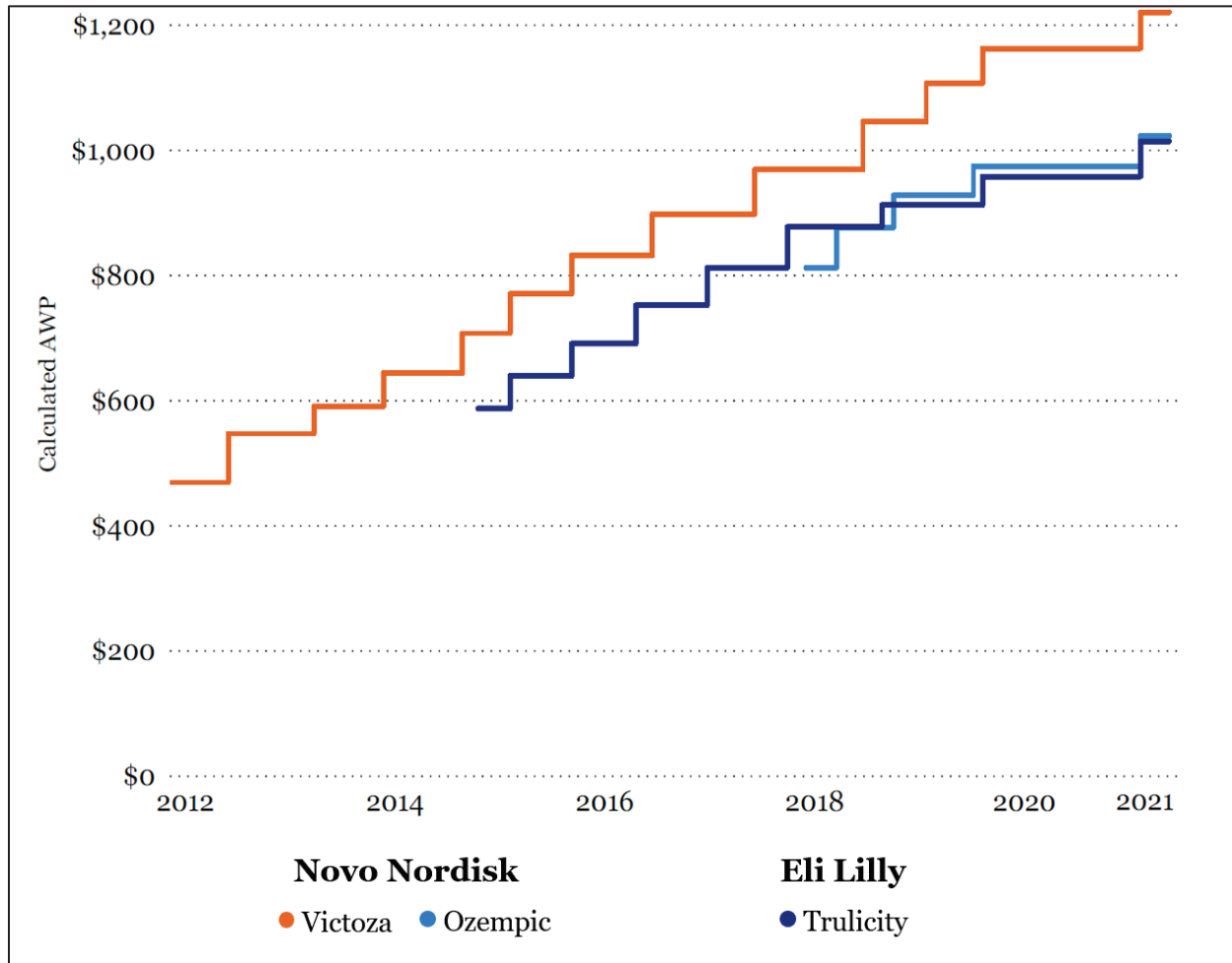
287. Figure 9 demonstrates this behavior with respect to the human insulins, Eli Lilly's Humulin and Novo Nordisk's Novolin.

Figure 9: Rising list price increases for human insulins



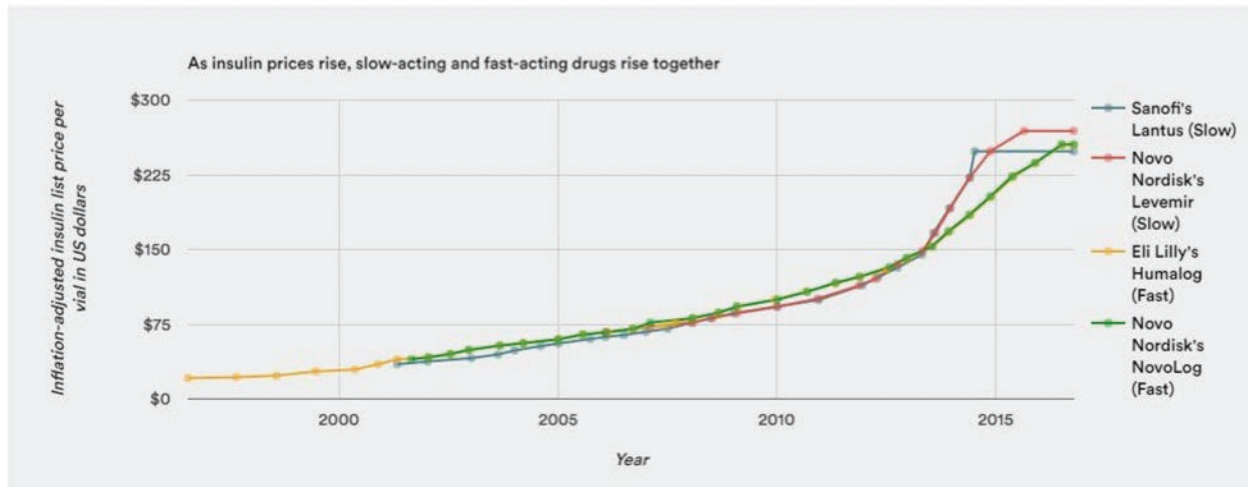
288. Figure 10 demonstrates Defendants' lockstep price increases for their Type 2 drugs, Trulicity, Victoza and Ozempic.

Figure 10: Rising list prices of Type 2 drugs



289. Figure 11 shows how, collectively, Manufacturer Defendants have exponentially raised the prices of insulin products in near perfect unison.

Figure 11: Lockstep insulin price increases



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

C. Pharmaceutical Payment and Supply Chain

291. The prescription drug industry consists of a deliberately opaque network of entities engaged in multiple distribution and payment structures. These entities include drug manufacturers, wholesalers, pharmacies, health plans/third party payors, pharmacy benefit managers, and patients.

292. 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.

293. The pharmaceutical industry, however, is unique in that the pricing chain is distinct from the distribution chain. The prices for the drugs distributed in the pharmaceutical chain are different for each participating entity: different actors pay different prices set by different entities for the same drugs. The unifying factor is that the price that each entity in the pharmaceutical chain pays for a drug is directly tied to the manufacturer's list price.

294. There is no transparency in this pricing system; typically, only a brand drug's list price—also known as its Wholesale Acquisition Cost (WAC) or the mathematically-related Average Wholesale Price (AWP)—is available. To note, “Wholesale Acquisition Cost” 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.

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

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

1. Drug Costs for Diabetics.

297. Whether insured or not, all Kentucky diabetics pay a substantial part of their diabetic drug costs based on the false list prices generated by the Insulin Pricing Scheme.

298. Uninsured diabetics must pay the full, point-of-sale prices (based on the artificial prices generated by the Insulin Pricing Scheme) every time they fill their prescriptions. In Kentucky, 10.1% of the population—or 700,000 Kentucky residents are uninsured. Approximately 18% of uninsured Kentucky residents are diabetic. As a direct result of the Insulin Pricing Scheme, the prices uninsured Kentucky residents pay for the at-issue life-sustaining drugs has skyrocketed over the last fifteen years.

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

300. Thus, nearly all Kentucky diabetics have been damaged by having to pay for diabetes medications out-of-pocket based upon the specific artificial prices generated by the Insulin Pricing Scheme. In many cases, the Kentucky diabetics have been priced out of being able to afford these life-sustaining drugs.

301. In addition, these exorbitant indefensible out-of-pocket costs created by the Insulin Pricing Scheme make it more difficult for patients to adhere to their medications, resulting in avoidable complications and higher overall healthcare costs. An American Diabetes Association working group recently noted that “people with high cost-sharing are less adherent to recommended dosing, which results in short- and long-term harm to their health.”

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

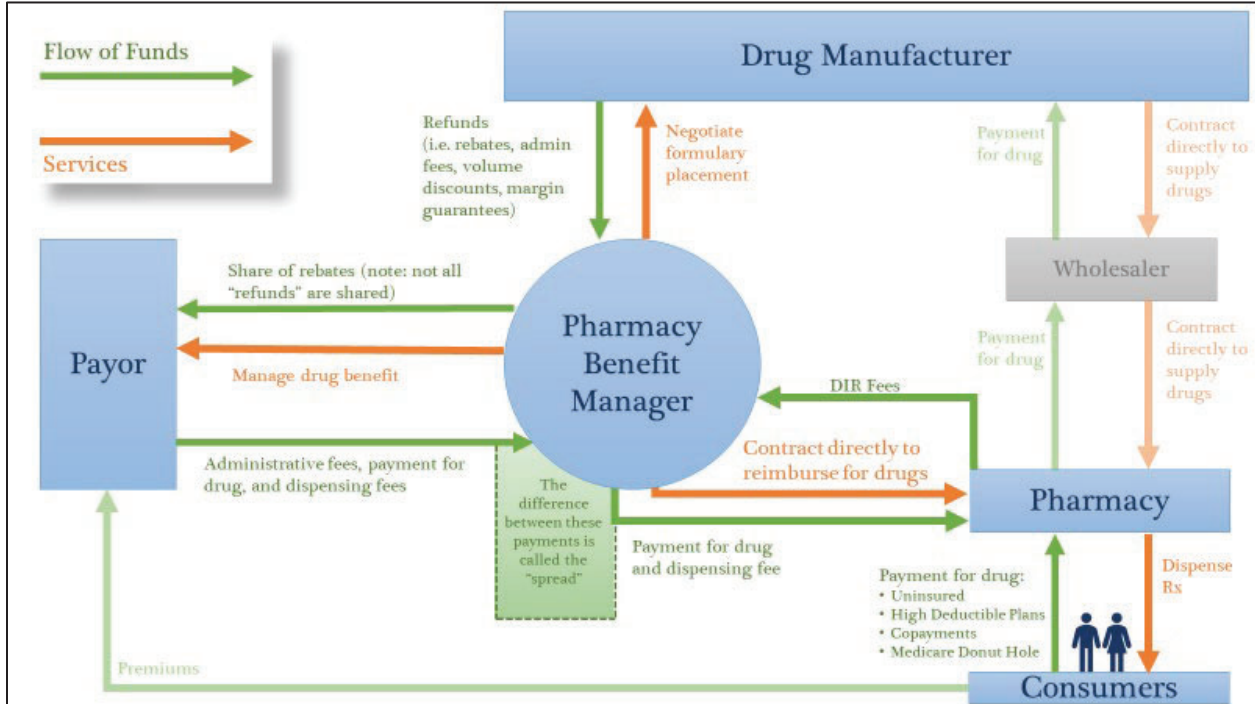
303. President of CVS Caremark, David Joyner stated in his opening statement at the 2023 Senate Insulin Hearing, “When people can afford their medications, like insulin, they are more likely to adhere to prescribed therapies. Adherence means better outcomes; better outcomes mean the health care system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

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

2. PBMs’ role in the pharmaceutical payment chain

305. PBMs are at the center of the convoluted pharmaceutical payment chain, as illustrated in Figure 12:

Figure 12: Insulin distribution and payment chain



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

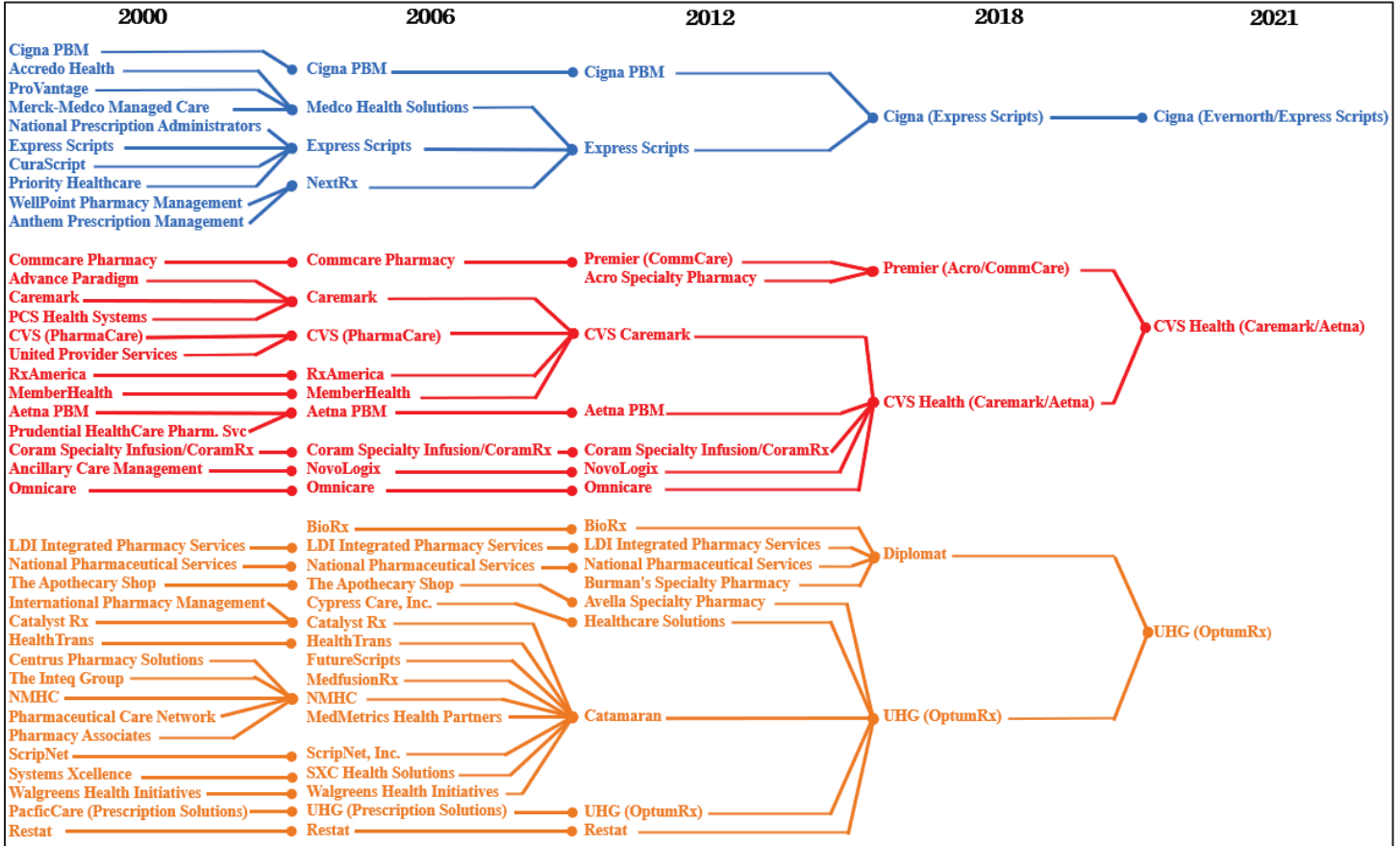
320. These perverse incentives still exist today with respect to both retail and mail order pharmacies housed within the PBMs' corporate families.

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

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

323. Figure 13 depicts this consolidation within the PBM market.

Figure 13: PBM consolidation



324. After merging or acquiring all their competitors and now backed by multi-billion-dollar corporations, PBM Defendants have taken over the market in the past decade—controlling over 80% of the market and managing pharmacy benefits for over 270 million Americans.

325. Importantly, PBM Defendants have near *complete* control over the Manufacturer Payment market, given that in addition to their own clients (which represent 80% of the market), most smaller pharmacy benefit managers—including the largest pharmacy benefit manager in the United States outside the PBM Defendants, Prime Therapeutics—contract with the PBM Defendants (or their

controlled affiliate rebate aggregator companies) to negotiate Manufacturer Payments on their behalf.

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

327. 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.”

4. Insular nature of the pharmaceutical industry

328. The insular nature of the PBM and pharmaceutical industry has provided PBM Defendants with ample opportunity for contact and communication amongst themselves, as well as with Manufacturer Defendants, in order to devise and agree to the Insulin Pricing Scheme.

329. 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.

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

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

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

333. The current board of the PCMA includes Amy Bricker, President of Express Scripts, Heather Cianfrocco, CEO of OptumRx, and Alan Lotvin, Executive Vice President of CVS Health and President of CVS Caremark. Past board members include John Prince, President and COO of Optum, Inc. (and former CEO of OptumRx); Mark Thierer, CEO of OptumRx; Jonathan Roberts, Executive Vice President of CVS Health; and Tim Wentworth, CEO of Evernorth.

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

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

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

337. In fact, for at least the last six (6) years, all of the Manufacturer Defendants have been “Presidential Sponsors” of these PBM conferences.

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

339. From at least 2010-2019, representatives from each Manufacturer Defendant met privately with representatives from each PBM Defendant during both the Annual Meetings and Business Forum conferences that the PCMA held each year.

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

341. In addition, all PCMA members, affiliates and registered attendees of these conferences are invited to join PCMA-Connect, “an invitation-only LinkedIn

Group and online networking community.” As PCMA members, PCMA-Connect provides PBM and Manufacturer Defendants with a year-round, non-public online forum to engage in private discussions in furtherance of the Insulin Pricing Scheme.

342. Notably, key at-issue lockstep price increases occurred shortly after the Defendants met at PCMA meetings. For example, on September 26 and 27, 2017 the PCMA held its annual meeting where each of the Manufacturer Defendants hosted private rooms and executives from each Defendant engaged in several meetings throughout the conference. Several days after the conference, 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 on January 1, 2018 to match the Sanofi increase, which was approved Nov 3, 2017.

343. Likewise, on May 30, 2014, Novo Nordisk raised the list price of Levemir several hours after Sanofi took its list price increase on Lantus and this occurred only a few weeks after a PCMA spring conference in Washington DC attended by representatives from all the PBM Defendants.

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

D. The Insulin Pricing Scheme

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

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

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

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

349. PBM Defendants' formularies are at the center of the Insulin Pricing Scheme. Given the asymmetry of information and disparity in market power between payors and PBM Defendants and the costs associated with making formulary changes, most payors accept the standard formularies offered by the PBMs.

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

351. For example, Olivier Brandicourt, Sanofi's Chief Executive Officer, in a recent interview stressed the importance of the PBMs' standard formularies: "if you look at the way [CVS Caremark] is organized in the U.S . . . 15 million [lives] are part

of [CVS Caremark’s standard] formulary and that’s very strict, all right. So, [if we were not included in CVS Caremark’s standard formulary] we wouldn’t have access to those 15 million lives.”

352. Manufacturer Defendants also recognize that the PBM Defendants profits are directly tied to the Manufacturers’ list prices. For example, the January 2021 Senate Insulin Report noted this in summarizing the internal documents produced by the Manufacturers:

[B]oth Eli Lilly and Novo Nordisk executives, when considering lower list prices, were sensitive to the fact that PBMs largely make their money on rebates and fees that are based on a percentage of a drug’s list price . . . In other words, the drug makers were aware that higher list prices meant higher revenue for PBMs.

353. The documents released by the Senate contemporaneous with the January 2021 Senate Insulin Report further corroborate the degree to which the Manufacturers’ pricing strategy is focused on the PBMs’ profitability. In an internal August 6, 2015 email, Novo Nordisk executives debated delaying increasing the price of an at-issue drug in order to make the increase more profitable for CVS Caremark, stating:

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

354. Because the Manufacturer Defendants know that—contrary to their public representations—PBM Defendants make more money from *increasing* prices,

over the course of the last fifteen years and working in coordination with the PBMs, the Manufacturers have artificially inflated their list prices for the at-issue drugs exponentially, while largely maintaining their net prices by paying larger and larger amounts of Manufacturer Payments back to the PBMs.

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

In July 2013, Sanofi offered rebates between 2% and 4% for preferred placement on CVS Caremark's commercial formulary. Five years later, in 2018, Sanofi rebates were as high as 56% for preferred formulary placement. Similarly, rebates to Express Scripts and OptumRx increased dramatically between 2013 and 2019 for long-acting insulins. For example, in 2019, Sanofi offered OptumRx rebates up to 79.75% for Lantus for preferred formulary placement on their client's commercial formulary, compared to just 42% in 2015. Similarly, Novo Nordisk offered Express Scripts rebates up to 47% for Levemir for preferred formulary placement on their client's commercial formulary, compared to 25% in 2014.

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

357. The value of these rebates and administrative fees to the PBMs was highlighted during the 2023 Senate Insulin Hearing where the executives for all three Manufacturers testified that \$0.75 to \$0.84 of every dollar spent on the list price of insulin goes directly to the Rebate Aggregators that are affiliates of the PBMs—despite the rising out-of-pocket costs to diabetics.

358. A recent study by the Pew Charitable Trust estimated that, between 2012 and 2016, the amount of administrative and other fees that the PBMs requested and received from the Manufacturers tripled, reaching more than \$16 billion.

359. In exchange for the Manufacturers inflating these prices and paying the PBMs substantial amounts in Manufacturer Payments, PBM Defendants grant Manufacturer Defendants' diabetes medications with the most elevated price (while at the same time excluding lower priced insulins) and that are the most profitable to the PBMs preferred status on their standard formularies.

360. At all times relevant hereto the PBM Defendants have known that the list prices for the at-issue drugs are grossly inflated. Indeed, the Manufacturers' list prices have become so untethered from the Manufacturers' net prices⁷ as to constitute false and unlawful prices.

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

362. Moreover, the PBMs also use this false price to misrepresent the amount of “savings” they generate for diabetics, payors and the healthcare system. For example, in January 2016, Express Scripts' president Tim Wentworth stated at the 34th annual JP Morgan Healthcare Conference that Express Scripts “saved our clients more than \$3 billion through the Express Scripts National Preferred Formulary.” Likewise, in April 2019, CVS Caremark President and Executive Vice President of

⁷ “Net Price” refers to the Manufacturers' list price minus all Manufacturer Payments paid to the PBMs.

CVS Health Corp. Derica Rice stated, “Over the last three years . . . CVS Caremark has helped our clients save more than \$141 billion by blunting drug price inflation, prioritizing the use of effective, lower-cost drugs and reducing the member’s out-of-pocket spend.”

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

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

365. Importantly, the Insulin Pricing Scheme is a coordinated effort between the Manufacturer and PBM Defendants, that each agreed to and participated in and that created enormous profits for all of Defendants. For example:

- Manufacturers and PBMs are in constant communication and regularly meet and exchange information to construct and refine the PBM formularies that fuel the scheme. As part of these communications, the Manufacturers are directly involved in determining not only where their own diabetes medications are placed on the PBMs’ formularies and with what restrictions, but also determining the same for competing products;
- Manufacturers and PBMs share confidential and proprietary information with each other in furtherance of the Insulin Pricing Scheme, such as market data gleaned from the PBMs’ drug utilization tracking efforts and mail order pharmacy claims, internal medical efficacy studies and financial data. Defendants then use this information in coordination to set the false prices for the at-issue medications and construct their formularies in the manner that is most profitable for both sets of Defendants. The data that is used to further this coordinated scheme is compiled, analyzed and shared either by departments directly housed within the PBM or by subsidiaries of the PBM, as is the case with OptumRx which utilizes OptumInsight and Optum Analytics; and

- Manufacturers and PBMs engage in coordinated outreach programs directly to patients, pharmacies and prescribing physicians to convince them to switch to the diabetes medications that are more profitable for the PBMs and Manufacturers, even drafting and editing letters in tandem to send out to diabetes patients on behalf of the PBMs' clients. For example, the January 2021 Senate Insulin Report released an email where Eli Lilly discussed paying Defendant UnitedHealth Group and OptumRx additional rebates for every client that was converted to formularies that exclusively preferred Eli Lilly's at-issue drugs, including Humalog. The email continued: "United's leadership committee made one ask of Lilly – that we are highly engaged in the communication/pull through plan.⁸ I of course indicated we fully expect to support this massive patient transition [to Eli Lilly's at-issue drugs favored by United] and provider education with the full breadth of Lilly resources. UHC also proactively thanked Lilly for our responsiveness, solution generation and DBU execution."

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

E. Defendants Admit That They Have Engaged in the Insulin Pricing Scheme

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

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

⁸ "Pull through" is an industry term that refers to an integrated process between PBMs and Manufacturers aimed at moving market share and increasing sales for a certain product following the PBM granting that product preferred placement on its formulary.

369. Representatives from each Defendant 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 [M]anufacturers to set high [list] prices and continually increase them which is odd for a drug that is nearly 100 years old and which has seen no significant innovation in decades. These price increases have a real impact on consumers in the form of higher out-of-pocket costs.”
- Thomas Moriarty, Chief Policy and External Affairs Officer and General Counsel for CVS Health testified, “A real barrier in our country to achieving good health is cost, including the price of insulin products which are too expensive for too many Americans. Over the last several years, [list] prices for insulin have increased nearly 50 percent. And over the last ten years, [list] price of one product, Lantus, rose by 184 percent.”
- Mike Mason, Senior Vice President of Eli Lilly when discussing how much diabetics pay out-of-pocket for insulin stated “it’s difficult for me to hear anyone in the diabetes community worry about the cost of insulin. Too many people today don’t have affordable access to chronic medications . . .”
- Kathleen Tregoning, Executive Vice President External Affairs at Sanofi, testified, “Patients are rightfully angry about rising out-of-pocket costs and we all have a responsibility to address a system that is clearly failing too many people. . . we recognize the need to address the very real challenges of affordability . . . Since 2012, average out-of-pocket costs for Lantus have risen approximately 60 percent for patients . . .”
- Doug Langa, Executive Vice President of Novo Nordisk, stated, “On the issue of affordability . . . I will tell you that at Novo Nordisk we are accountable for the [list] prices of our medicines. We also know that [list] price matters to many, particularly those in high-deductible health plans and those that are uninsured.”

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

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

372. 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.

373. For example, at the April 2019 Congressional hearing Novo Nordisk's President, Doug Langa, explained Novo Nordisk's and PBM Defendants' role in perpetuating the “perverse incentives” of the Insulin Pricing Scheme:

[T]here is this perverse incentive and misaligned incentives (in the insulin pricing system) and this encouragement to keep [list] prices high. And *we've been participating in that system* because the higher the [list] price, the higher the rebate . . . There is a significant demand for rebates. We spend almost \$18 billion in rebates in 2018 . . . [I]f we eliminate all the rebates . . . we would be in jeopardy of losing [our formulary] positions. (Emphasis added).

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

Seventy-five percent of our [list] price is paid for rebates and discounts to secure [formulary position] . . . \$210 of a vial of Humalog is paid for discounts and rebates. . . We have to provide rebates [to PBMs] in order to provide and compete for [formulary position].

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

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

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

377. Amy Bricker, President of Express Scripts, when asked to explain why Express Scripts did not grant an insulin with a lower list price preferred formulary status, answered, “Manufacturers do give higher [payments] for exclusive [formulary] position . . .”

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

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

380. This statement is objectively false. The Manufacturers’ coordinated, lockstep price increases are a direct reflection of the PBMs’ coordinated requests for larger Manufacturer Payments. A February 2020 study by the Leonard D. Schaeffer Center for Health Policy & Economics at the University of Southern California titled “The Association Between Drug Rebates and List Prices,” found that an increase in the amount that the Manufacturers pay back to the PBMs is directly correlated to an

increase in prices—on average, a \$1 increase in Manufacturer Payments is associated with a \$1.17 increase in price—and that reducing or eliminating Manufacturer Payments could result in lower prices and reduced out-of-pocket expenditures.

381. In addition, in a 2019 report the National Community Pharmacists Association estimated that Manufacturer Payments add nearly 30 cents per dollar to the price consumers pay for prescriptions.

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

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

384. However, that also is not true. For example, a 2020 study from the Institute of New Economic Thinking titled, “Profits, Innovation and Financialization in the Insulin Industry,” demonstrates that Manufacturer Defendants are still making substantial profits from the sale of 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 Manufacturers’ shareholders in the form of cash dividends and share repurchases totaled *\$122 billion*.

In fact, during this time period the Manufacturers spent a significantly lower proportion of profits on research and development compared to shareholder payouts.

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

- Manufacturer Defendants are retaining more revenue from insulin than in the 2000s—for example, Eli Lilly has reported a steady increase in Humalog revenue for more than a decade—from \$1.5 billion in 2007 to \$3 billion in 2018;
- 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—Eli Lilly spent \$395 million on R&D costs for Humalog, Humulin and Basaglar between 2014-2018 during which time the company generated \$22.4 billion in revenue on these drugs. From 2016 to 2020, Novo Nordisk spent approximately \$29 billion on stock buybacks and shareholder dividend payouts while only spending approximately \$12 billion on R&D costs.

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

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

F. Defendants Profit Off the Insulin Pricing Scheme

1. Manufacturers Profit Off Insulin Pricing Scheme

387. For Manufacturer Defendants, the Insulin Pricing Scheme affords them the ability to pay the PBM Defendants significant, yet undisclosed, Manufacturer Payments in exchange for formulary placement—which garners Manufacturer Defendants greater revenues from sales—without decreasing their profit margins. During the relevant time period, PBM Defendants granted preferred formulary position to each at-issue drug in exchange for large Manufacturer Payments and inflated prices.

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

2. PBMs Profit Off Insulin Pricing Scheme

389. Because of the increased list prices, and related Manufacturer Payments, PBMs' profit per prescription has grown exponentially during the relevant time period. A recent study published in the Journal of the American Medical Association titled, "Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies and Health Plans from 2014 to 2018" concluded that the amount of money that goes to the PBM Defendants for each insulin prescription increased over 150% from 2014 to 2018. In fact, for transactions where the PBM Defendants control the insurer, the PBM and the pharmacy (i.e. Aetna-CVS Health/Caremark-CVS pharmacy) these Defendants now capture an astonishing 50% of the money spent on each insulin prescription (up

from only 25% in 2014), despite the fact that they do not contribute to the development, manufacture, innovation or production of the product.

390. PBM Defendants profit off the artificially inflated prices created by the Insulin Pricing Scheme in myriad ways, including (1) retaining a significant—yet undisclosed—percentage of the Manufacturers Payments, (2) using the inflated price to generate profits from pharmacies in their networks and (3) relying on the inflated price to drive up the PBMs’ profits through their own mail order and retail pharmacies.

a) PBMs pocket most of the secret Manufacturer Payments

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

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

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

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

395. In this regard, PBM and Manufacturer Defendants have created a “hide-the-ball” system where the consideration exchanged between them (and not shared with payors) is labeled and relabeled. As more payors moved to contracts that require

PBMs to pass a majority of the manufacturer “rebates” through to the payor, PBMs have begun renaming the Manufacturer Payments in order to keep a larger portion of this money. Payments once known as “rebates” are now called administrative fees, volume discounts, service fees, inflation fees or other industry jargon terms designed to obfuscate and distract from the substantial sums being secretly exchanged.

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

397. Notably, on June 7, 2022, the Federal Trade Commission (“FTC”) voted 5-0 to issue a policy statement expressing its intent to closely scrutinize such PBM Defendant practices related to Manufacturer Payments to determine if these practices constitute unfair and deceptive practices. In its policy statement, the FTC cited specifically to the effect that Manufacturer Payments have in the context of the exorbitant insulin prices and the devastating impact such practices have on the lives of diabetics.

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

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

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

401. For many of their clients, the PBMs have separate “price protection guarantees” that state that if the overall drug prices for that payor increase by more than a set amount, then the PBMs will revert a portion of that amount back to these clients.

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

403. If the Manufacturers increase their list prices more than the 6% (or 8%) inflation fee rate but less than the 10%-15% client price protection guarantee rate, then the PBMs can keep 100% of these “inflation fee” payments. This is a win-win for the Manufacturers and PBMs—they get to mutually retain and share all of the benefit of these price increases.

404. Another method that the PBMs have devised to hide the renamed Manufacturer Payments is through the use of “rebate aggregators.” Rebate aggregators, sometimes referred to as rebate group purchasing organizations (“GPOs”), are entities that negotiate for and collect payments from drug

manufacturers, including the Manufacturers, on behalf of a large group of pharmacy benefit managers (including the PBM Defendants) and different entities that contract for pharmaceutical drugs.

405. These rebate aggregators are often owned and controlled by the PBM Defendants, such as Ascent Health Services (Express Scripts), Coalition for Advanced Pharmacy Services and Emisar Pharma Services (OptumRx), and Zinc (CVS Caremark). Since their formation the PBMs have shifted the Manufacturer Payment aspect of the Insulin Pricing Scheme over to these entities in order to extract new fees and to retain a larger share of existing Manufacturer Payments that they should pass through to their clients.

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

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

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

passed through to its client payor because OptumRx would not allow the auditor access to its rebate contracts. The audit report explained:

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

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

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

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

[I]t is noteworthy that industry observers have suggested that the recent partnership between Express Scripts and Prime Therapeutics may serve as a vehicle to avoid increasing legislative and regulatory scrutiny related to administrative fees by channeling such fees through a Swiss-

based group purchasing organization (GPO), Ascent Health. While there are several regulatory and legislative efforts underway to prohibit manufacturers from paying administrative fees to PBMs, there is no such effort to change the GPO safe harbor rules. New arrangements used by PBMs to collect fees should be an area of continued investigative interest for Congress.

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

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

b) PBMs profit off pharmacies

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

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

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

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

418. This spread pricing, like the secret Manufacturer Payment negotiation, happens behind closed doors. There is no transparency, no commitment from PBM Defendants to take into account the cost effectiveness of a drug, and no communication to either the payor or the pharmacy to let them know if they are getting a fair deal. The higher the Manufacturers inflate their prices, the more money the PBMs make off this spread.

419. PBMs also use the Insulin Pricing Scheme to generate additional profits from pharmacies by charging the pharmacies post-purchase fees, including DIR fees⁹, based on the artificially inflated prices generated by the Scheme—and again, the higher the list price for each diabetes medication sold, the more the PBMs generate in these pharmacy fees.

c) Insulin Pricing Scheme increases PBM mail order and retail pharmacy profits

420. A third way PBMs profit off the Insulin Pricing Scheme is through the PBM Defendants' own mail order and retail pharmacies. The higher the price that PBM Defendants are able to get their customers, such as Kentucky diabetics and payors, to pay for diabetes medications, the higher the profits PBM Defendants realize through their mail order and retail pharmacies.

⁹ "DIR" fees are post-purchase concessions pharmacies pay back to the PBMs.

421. Because the PBMs base the price they charge for the at-issue diabetes medications on the list price, the more the Manufacturers inflate these prices, the more money the PBMs make.

422. PBMs also charge the Manufacturer Defendants fees related to their mail order pharmacies, such as pharmacy supplemental discount fees, indirect purchase fees and rebates, that are directly tied to the false prices generated by the Insulin Pricing Scheme. Thus, once again, the higher the price is, the more money the PBMs make on these fees.

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

424. In sum, every way that the PBMs make money on diabetes medications is directly tied to the artificially inflated list prices generated by the Insulin Pricing Scheme. PBMs are not lowering the price of diabetes medications as they publicly represent—rather they are making billions of dollars by fueling these skyrocketing prices.

G. Kentucky Diabetics Purchase the At-Issue Drugs from Defendants

425. During the relevant time period, the PBM Defendants' mail order and retail pharmacies dispensed the at-issue drugs to and were paid by Kentucky diabetics based on the inflated list prices generated by the Insulin Pricing Scheme.

H. Defendants Deceived Kentucky Diabetics

426. At no time have either Defendant group disclosed the Insulin Pricing Scheme or the artificially inflated list prices produced by it.

1. Manufacturer Defendants deceived Kentucky diabetics

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

428. Manufacturer and PBM Defendants further knew that Kentucky diabetics and payors expected and desired to pay the lowest fair-market price possible for the at-issue drugs.

429. Manufacturer and PBM Defendants knew that the artificially inflated list prices generated by the Insulin Pricing Scheme were false and completely untethered from the net prices that the Manufacturer Defendants were paid for the drugs.

430. 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.

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

432. Manufacturer Defendants also published these prices to the PBMs and their pharmacies who then knowingly use the false prices to set the amount payors and diabetics pay for the at-issue drugs.

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

434. These representations are false. Manufacturer Defendants knew that their artificially inflated list prices were not remotely related to the net price they received for the at-issue drugs and were not based on transparent or competitive factors such as cost of production or research and development.

435. Notably, during the relevant time period, the Manufacturers published prices in Kentucky of \$300-\$400 for the same at-issue drugs they could have priced at less than \$2 and still been profitable.

436. Manufacturer Defendants have also publicly represented that they price the at-issue drugs according to each drug's value to the health care system and the

need to fund innovation. For example, briefing materials prepared for Chief Executive Officer (CEO) Dave Ricks as a panelist at the 2017 Forbes Healthcare Summit included “Reactive Key Messages” on pricing that emphasized the significant research and development costs for insulin. During the relevant time period, executives from Sanofi and Novo Nordisk also represented that research and development costs were key factors driving the at-issue price increases.

437. These statements are also false. Between 2005 and 2018, Eli Lilly only spent \$680 million on R&D costs related to Humalog while earning \$31.35 billion in *net* sales during that same time period. In other words, Eli Lilly made more than 46 times its reported R&D costs on Humalog during this portion of the relevant time period. And Novo Nordisk has spent triple the amount it spends on R&D on stock buyouts and shareholder dividend payouts in recent years.

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

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

440. PBM Defendants ensured that the Manufacturers’ artificially inflated list prices harmed diabetics and payors by requiring that their contracts with both pharmacies and with payors include such prices as the basis for payment.

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

2. PBM Defendants deceived Kentucky diabetics

442. PBM Defendants have deceived diabetics and payors in Kentucky.

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

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

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

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

- In a public statement issued on May 11, 2010, CVS Caremark represented that it was focused on diabetes to “help us add value for our PBM clients and improve the health of plan members . . . a PBM client with 50,000 employees whose population has an average prevalence of diabetes could save approximately \$3.3 million a year in medical expenditures.”
- On June 22, 2010, Andrew Sussman, Chief Medical Officer of CVS Caremark stated on national television that “CVS is working to develop programs to hold down [diabetes] costs.”
- In a public statement issued in November 2012, CVS Caremark represented that formulary decisions related to insulin products “is one way the company helps manage costs for clients.”
- On August 31, 2016, Glen Stettin, Senior Vice President and Chief Innovation Officer at Express Scripts released a statement that stated “[d]iabetes is wreaking havoc on patients, and it is also a runaway driver of costs for payors . . . [Express Scripts] helps our clients and diabetes patients prevail over cost and care challenges created by this terrible disease.”
 - Mr. Stettin continued on to represent that Express Scripts “broaden[s] insulin options for patients and bend[s] down the cost curve of what is currently the costliest class of traditional prescription drugs.”
- In January 2017, Tim Wentworth, CEO of Express Scripts represented that “without PBMs, and specifically without Express Scripts, our clients would pay [many times] more for [insulin].”
 - Mr. Wentworth continued on to state Express Scripts is dedicated to controlling insulin prices because “we stand up for payers and patients.”
- On June 1, 2018, Mark Merritt, President of the PCMA, in response to a question about PBMs’ role in the insulin pricing system stated, “[Through their formulary construction], PBMs are putting pressure on drug companies to reduce insulin prices.”
- On April 4, 2019, Steve Miller Express Scripts’ chief medical officer stated that Express Scripts “give[s] people who rely on insulin greater affordability and cost predictability so they can focus on what matters most: their well-being.

- CVS Health’s Chief Policy and External Affairs Officer testified during the April 2019 hearings that, CVS Caremark “has taken a number of steps to address the impact of insulin price increases. We negotiate the best possible discounts off the manufacturers’ price on behalf of employers, unions, government programs, and beneficiaries that we serve.”
- Chief Medical Officer of OptumRx, testified before the U.S. Congress in the April 2019 hearing that for “insulin products . . . we negotiate with brand manufacturers to obtain significant discounts off list prices on behalf of our customers.”
- The PCMA website contains the following misrepresentations, “the insulin market is consolidated, hindering competition and limiting alternatives, leading to higher list prices on new and existing brand insulins. PBMs work hard to drive down costs using formulary management and rebates.”

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

- Express Scripts’ publicly available code of conduct states, “[a]t Express Scripts we’re dedicated to keeping our promises to *patients and clients* . . . This commitment defines our culture, and all our collective efforts are focused on our mission to make the use of prescription drugs safer and more affordable.” (Emphasis added).
- Amy Bricker, President at Express Scripts testified before Congress in April 2019, “At Express Scripts we negotiate lower drug prices with drug companies on behalf of our clients, *generating savings that are returned to patients* in the form of lower premiums and reduced out-of-pocket costs.” (Emphasis added).
- Amy Bricker of Express Scripts also testified at the Congressional hearing that “Express Scripts remains committed to . . . *patients* with diabetes and creating affordable access to their medications.” (Emphasis added).
- OptumRx’s website has stated “[t]he services we provide help *improve health outcomes for patients* while making prescription drugs more affordable for plan sponsors and *individuals*, and more sustainable for the country . . . the reason is simple: drug manufacturers are responsible

for the high cost of prescription drugs . . . OptumRx negotiates better prices with drug manufacturers for our customers *and consumers* . . . At OptumRx, *our mission is helping people live healthier lives and to help make the health system work better for everyone.*” (Emphasis added).

- In its 2017 Drug Report, CVS Caremark stated that the goal of its pharmacy benefit plans is to ensure “that the cost of a drug is aligned with the value it delivers in terms of *patient* outcomes . . . in 2018, we are doing even more to help keep drugs affordable with our new Savings *Patients Money* initiative.” (Emphasis added).
- The PCMA website states, “PBMs have kept average out-of-pocket (OOP) payments flat for beneficiaries with commercial insurance.”
- On March 12, 2019, OptumRx represented, “OptumRx is uniquely able to deploy the broadest range of tools to rein in high drug prices, [which] demonstrates our commitment to delivering better prices for consumers.”

448. Not only have PBM Defendants intentionally misrepresented that they use their market power to save payors and diabetics money, they have specifically, knowingly, and falsely disavowed that their conduct drives the artificially inflated list prices higher. Examples include:

- On an Express Scripts’ earnings call in February 2017, CEO Tim Wentworth stated, “Drugmakers set prices, and we exist to bring those prices down.”
- Larry Merlo, head of CVS Caremark sounded a similar refrain in February 2017, “Any suggestion that PBMs are causing prices to rise is simply erroneous.”
- In 2017, Express Scripts’ Wentworth went on CBS News to again argue that PBMs play no role in rising drug prices, stating that PBMs work to “negotiate with drug companies to get the prices down.”
- During the April 2019 Congressional hearings, when asked if PBM-negotiated rebates and discounts were causing the insulin price to increase, OptumRx’s Chief Medical Officer answered, “we can’t see a correlation when rebates raise list prices.”
- In 2019, when testifying under oath before Congress on the rising price of insulins, Senior Vice President Amy Bricker of Express Scripts

testified, “I have no idea why the prices [for insulin] are so high, none of it is the fault of rebates.”

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

450. Despite this, in 2011, OptumRx’s President stated: “We want our clients to fully understand our pricing structure . . . [e]veryday we strive to show our commitment to our clients, and one element of that commitment is to be open and honest about our pricing structure.”

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

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

Ms. Bricker. The rebate system is 100 percent transparent to the plan sponsors and the customers that we service. To the people that hire us, employers of America, the government, health plans, what we negotiate for them is transparent to them. . . [However] the reason I’m able to get the discounts that I can from the manufacturer is because it’s confidential [to the public].

Mr. Sarbanes. What about if we made it completely transparent? Who would be for that?

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

Mr. Sarbanes. I don't buy it.

Ms. Bricker – prices will be held high.

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

453. Throughout the relevant time period, the PBMs have made the foregoing misrepresentations consistently and directly to Kentucky diabetics through member communications, formulary change notifications, and through extensive direct-to-consumer pull through efforts engaged in with the Manufacturers.

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

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

455. The above stated PBM Defendants' representations are false.

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

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

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

459. Contrary to their representations that they work to promote the health of diabetics, as a result of the Insulin Pricing Scheme many diabetics have been priced out of these life-sustaining medications. As a result, many of these diabetics are forced

to either ration their insulin or to skip doses. This behavior is dangerous to a diabetic's health and can lead to a variety of complications and even death.

460. Both PBM and Manufacturer Defendants knew that these representations were false when they made them and affirmatively withheld the truth regarding the artificially inflated list prices, formulary construction, and Manufacturer Payments from the Kentucky diabetics. Both PBM Defendants and Manufacturer Defendants intended for Kentucky residents with diabetes to rely on their misrepresentations.

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

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

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

464. Each Defendant also conceals its unfair and deceptive conduct by signing confidentiality agreements with any entity in the supply chain with whom it contracts.

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

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

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

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

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

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

471. Kentucky diabetics did not know, because the Defendants affirmatively concealed, that (i) the list prices were artificially inflated; (ii) the list prices were manipulated to satisfy Defendants' profit demands; (iii) the list prices bore no relationship to the net prices paid for the at-issue drugs to the Manufacturers; and (iv) that the entire insulin pricing structure Defendants created was deceptive and unfair.

I. The Insulin Pricing Scheme Has Damaged Diabetics

1. Defendants' misconduct has caused increased healthcare costs

472. As discussed below, the rising price for the at-issue drugs has had a devastating effect on the health of diabetics. It has also caused a staggering increase in healthcare costs.

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

474. One national model projected that improved adherence to diabetes medication would avert 699,000 emergency department visits and 341,000 hospitalizations annually, for a savings of \$4.7 billion. The model further found that eliminating the loss of adherence would lead to another \$3.6 billion in savings, for a combined potential savings of \$8.3 billion.

475. Much of the increased healthcare costs caused by the Insulin Pricing Scheme are shouldered by the Commonwealth. As a result of the Insulin Pricing Scheme, the amount Kentucky spends each year on diabetes-related healthcare costs

has risen dramatically during the relevant time period, now totaling in the billions of dollars per year.

476. Lack of adherence to diabetes medications also has a significant adverse effect on labor productivity in terms of absenteeism (missing work due to health-related reasons), presenteeism (being present at work but not productive), and disability (inability to perform necessary physical tasks at work).

2. The Insulin Pricing Scheme has damaged Kentucky Diabetics

477. Whether insured or not, all Kentucky diabetics pay a substantial part of their diabetic drug costs based on Defendants' artificially inflated list prices generated and thus the Insulin Pricing Scheme has directly damaged Kentucky diabetics.

478. In addition to financial losses, for many diabetics in Kentucky, the Insulin Pricing Scheme has cost them their health and emotional well-being. Unable to afford Defendants' price increases, many diabetics in Kentucky 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 even two meals a day. These practices—which ineffectively control blood sugar levels—can lead to serious complications such as kidney disease and failure, heart disease and heart attacks, infection, amputation, and blindness, which harm not only the individual persons affected, but also harm the Kentucky healthcare system as a whole by burdening its resources and the Kentucky economy by requiring additional millions of dollars of additional revenues to be spent.

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

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

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

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

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

483. In reaction to the mounting political and public pressure, Defendants recently have taken action, both on Capitol Hill and in the insulin marketplace.

484. In recent years, Novo Nordisk’s political action committee (“PAC”) has doubled its spending on federal campaign donations and on lobbying efforts. In 2017 alone, Novo Nordisk spent \$3.2 million lobbying Congress and federal agencies, its biggest ever investment in directly influencing U.S. policymakers.

485. Eli Lilly and Sanofi have directed millions of dollars through their PACs as well in recent years.

486. Likewise, the PBM Defendants have steadily increased their political spending for the past five years as public outcry has grown against them.

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

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

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

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

491. Following this, a Congressional staff report was issued examining the availability of this drug. The investigative report, *Inaccessible Insulin: The Broken Promise of Eli Lilly's Authorized Generic*, concluded that Eli Lilly's lower-priced, authorized generic insulin is widely unavailable in pharmacies across the country, and that the company has not taken meaningful steps to increase insulin accessibility and affordability.

492. The conclusion of the report was that: “Eli Lilly has failed to deliver on its promise to put a more-affordable insulin product on the shelves. Instead of giving

patients access to its generic alternative, this pharmaceutical behemoth is still charging astronomical prices for a drug people require daily and cannot live without.”

493. In 2019, Novo Nordisk partnered with Walmart to offer ReliOn brand insulins for a discounted price at Walmart. However, experts have warned that the Walmart/Novo Nordisk insulins are not substitutes for most diabetics’ regular insulins and should only be used in an emergency or when traveling. In particular, for many diabetics, especially Type 1 diabetics, these insulins can be dangerous.

494. In fact, in August 2019, a Type 1 diabetic who could no longer afford his \$1,200 a month insulin prescription died months after switching to ReliOn brand insulin due to complications from the disease.

495. Thus, Defendants’ “lower priced” insulin campaigns have not addressed the problem. Kentucky diabetics continue to suffer great harm as a result of the Insulin Pricing Scheme.

VI. TOLLING OF STATUTE OF LIMITATIONS

496. None of the statute of limitations associated with the causes of action asserted in this Complaint apply to the Commonwealth.

497. Even assuming, *arguendo*, that the Commonwealth was subject to applicable statutes of limitations, the Commonwealth asserts that it diligently pursued and investigated the claims asserted in this Complaint. Through no fault of its own, neither the Commonwealth, nor any Kentucky diabetics, received inquiry notice or learned of the factual basis for its claims in this Complaint and the injuries suffered therefrom until recently. Consequently, the following tolling doctrines apply.

A. Discovery Rule Tolling

498. The Commonwealth and Kentucky diabetics had no way of knowing about the Insulin Pricing Scheme.

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

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

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

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

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

B. Fraudulent Concealment Tolling

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

C. Estoppel

505. Defendants were under a continuous duty to disclose to the Commonwealth or Kentucky diabetics the true character, quality and nature of the prices upon which payments for diabetes medications were based, and the true nature of the services being provided.

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

D. Continuing Violations

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

VI. CLAIMS FOR RELIEF

COUNT I

Kentucky Consumer Protection Act, KRS 367.110, *et. seq.* ("KCPA") (Against All Defendants)

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

509. KRS 367.170(1) provides that: “Unfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.”

510. By engaging in the Insulin Pricing Scheme, as described herein, Defendants have committed unfair, false, misleading, and deceptive trade acts affecting the conduct of any trade or commerce within Kentucky as prohibited by the broad provisions of the KCPA, , including but not limited to:

- Representing that goods or services have characteristics and/or benefits that they do not have. In particular:
 - A characteristic of every commodity in Kentucky’s economy is its price, and sellers are prohibited from making false statements about prices.
 - Defendants did not reveal that the prices associated with the lifesaving diabetic treatments at issue herein were not legal, competitive or at fair market value and were completely untethered from the actual, net prices realized by Defendants.
 - At no point did Defendants disclose that the prices associated with the at-issue drugs were generated by the Insulin Pricing Scheme.
 - In furtherance of the Insulin Pricing Scheme, at least once a year for each year during the relevant time period, Defendants reported and published artificially inflated prices for each at-issue drug and in doing so represented that the reported prices were reasonably related to the net prices for the at-issue drugs.
 - Defendants also made false statements related to the reason behind their artificially inflated prices (ie research and developments costs).
 - Despite knowing these prices were false and artificially inflated, PBM Defendants ensured that the Manufacturers’ list prices harmed diabetics by requiring that their contracts with both pharmacies and with payors include such prices as the basis for payment.

- By granting the at-issue diabetes medications with the highest list prices preferred formulary positions and excluding lower priced insulins, PBM Defendants ensured that prices generated by the Insulin Pricing Scheme would harm diabetics.
- PBM Defendants also misrepresent that their formularies and the Manufacturer Payments that they receive have the benefit, characteristic, and quality of lowering the price of the at-issue drugs and promoting the health of diabetics.
- All of these representations are false.
- Making false or misleading statements of fact concerning the reason for, existence of, or amount of price reductions. In particular:
 - PBM Defendants made false representations that the Manufacturer Payments lower the price of the at-issue drugs, when in truth they are responsible for the precipitous price increases.
 - PBM Defendants also knowingly used the artificially inflated price generated by the Insulin Pricing Scheme to misrepresent the amount of “savings” they generate for diabetics, payors, and the healthcare system.
 - In making these representations, Defendants fail to disclose that the amount of “savings” they have generated is calculated based on the false list price, which is not paid by any entity in the pharmaceutical pricing chain and which the PBMs are directly responsible for artificially inflating.

511. Defendants continue to make these misrepresentations and publish prices generated by the Insulin Pricing Scheme; Kentucky diabetics continue to purchase diabetes medications at Defendants’ prices as a result of the ongoing Insulin Pricing Scheme.

512. Defendants made these misrepresentations with the intent to deceive Kentucky diabetics.

513. Defendants' representations are false, and at all relevant times Defendants knew they were false.

514. At all times relevant hereto, Defendants affirmatively withheld this truth from diabetics, even though Defendants knew that diabetics intention was to pay the lowest possible fair market price for diabetes medications and expectation was to pay a legal, competitive and fair market price that resulted from transparent market forces.

515. Defendants' conduct and practices are also unfair and unconscionable under the KCPA, because they are likely to cause substantial injury, offend public policy, are unethical, and the conduct cannot be reasonably avoided. Furthermore, there are no countervailing benefits to consumers that result from Defendants egregiously driving up the price of the at-issue drugs. In particular:

- Diabetics in Kentucky need these diabetes medications to survive.
- Manufacturer Defendants make nearly every single vial of insulin available in Kentucky.
- PBM Defendants dominate the pharmacy benefit services market and control nearly every Manufacturer Payment paid in this market.
- The price increases for the at-issue drugs are egregious, excessive, and bear no relation to manufacturing or production cost increases or changes in supply and demand conditions.
- In fact, the prices have become so untethered from production costs, that insulins, which the Manufacturer Defendants could *profitably price at less than \$2 a vial*, are now priced at up to \$400 a vial or more.
- Given this market dominance and the fact that diabetics' lives depend on access to these drugs, diabetics have little alternative except to submit to the Insulin Pricing Scheme.

- Defendants use their market dominance and superior resources/bargaining power to enforce grossly unfair terms and conditions on Kentucky diabetics.
- There are no conceivable benefits to diabetics or payors in Kentucky to being forced to pay these egregious prices for medicines they need to stay alive. In fact, the opposite is true—as a direct result of Defendants’ egregious price increases Kentucky diabetics’ health and wellbeing have been severely and detrimentally impacted and they have overpaid millions of dollars for the at-issue drugs.
- Defendants’ misconduct offends public policy and have caused a substantial injury to Kentucky diabetics.

516. Defendants acted knowingly and in a willful, wanton or reckless disregard for the safety of others in committing the violations of the KCPA.

517. Each at-issue purchase Kentucky diabetics made for diabetes medications at the prices generated by the Insulin Pricing Scheme constitutes a separate violation of the KCPA.

518. In addition, the imposition of an injunction against Defendants prohibiting the conduct set forth herein is in the public interest, and the Commonwealth is seeking the entry of an injunction prohibiting Defendants’ conduct in violation of the KCPA.

519. As a direct and proximate result of Defendants’ conduct in committing the above and foregoing violations of the KCPA, Defendants are directly and jointly and severally liable for all equitable relief, restitution, damages, punitive damages, penalties and disgorgement for which recovery is sought herein.

520. The Commonwealth seeks a permanent injunction against Defendants to prevent future deceptive and unfair trade practices under the KCPA.

COUNT II

Violation of the Kentucky False Advertising Statute (KRS 517.030) Through KRS 446.070 (Against All Defendants)

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

522. KRS 517.030 provides that: “A person is guilty of false advertising when, in connection with the promotion of the sale of or to increase the consumption of property or services he knowingly makes or causes to be made a false or misleading statement in any advertisement address to the public or to a substantial number of persons.”

523. KRS 446.070 provides that “[a] person injured by the violation of any statute may recover from the offender such damages as he sustained by reason of the violation, although a penalty or forfeiture is imposed for such violation.”

524. By engaging in the conduct described above, Manufacturer Defendants have violated KRS 517.030, by knowingly and willfully reporting false, misleading, and inflated prices on their diabetes medications to national reporting services, while at the same time concealing actual pricing information. The reporting services in turn published Defendants’ price information to substantial numbers of persons, including, but not limited to, wholesalers, pharmacies, and people with diabetes in the Commonwealth in connection with promotion of the sale, or to increase the consumption, of Manufacturer Defendants’ diabetes medications.

525. By engaging in the conduct described above, PBM Defendants have violated KRS 517.030, by knowingly and willfully misrepresenting that their

formularies and the Manufacturer Payments they receive lower the price of diabetes medications and promote diabetic health to a substantial numbers of persons, including, but not limited to, Kentucky diabetics, payors, and the Commonwealth in connection with increasing the consumption of Manufacturer Defendants' diabetes medications.

526. As a direct result of Defendants' violations of KRS 517.030, Defendants have caused damages to consumers in the Commonwealth, through payment of grossly excessive prices for diabetes medications.

COUNT III

Unjust Enrichment (Against All Defendants)

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

528. Defendants deceived Kentucky diabetics, and have received a financial windfall from the Insulin Pricing Scheme at the expense of Kentucky diabetics. Defendants concealed their deceptive conduct, and thus Kentucky consumers were not aware that Defendants' deceptively priced their diabetes medications and received no benefit from Defendants' transgressions.

529. Defendants wrongfully secured and retained unjust benefits from Kentucky diabetics, in the form of amounts paid for diabetes medications and fees and payments collected based on the artificially inflated prices generated by the Insulin Pricing Scheme.

530. It is inequitable and unfair for Defendants to retain these benefits.

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

532. Defendants have been enriched by revenue resulting from the Insulin Pricing Scheme while Kentucky diabetics have been impoverished by Defendants' misconduct. Defendants' enrichment and Kentucky diabetics' impoverishment are connected.

533. Accordingly, Defendants should not be permitted to retain the proceeds from the benefits conferred upon them by the Insulin Pricing Scheme. The Commonwealth seeks disgorgement of Defendants' unjustly acquired profits and other monetary benefits resulting from their unlawful conduct and seeks restitution and/or rescission, in an equitable and efficient fashion to be determined by the Court.

534. There is no express contract governing the dispute at-issue. The Commonwealth's claims do not arise out of a contract, but rather are based on the larger unfair and deceptive Scheme that drove up the at-issue artificially inflated list prices for all Kentucky diabetics.

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

COUNT IV

Civil Conspiracy (Against All Defendants)

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

537. Defendants' conduct described herein constitutes a civil conspiracy and aiding and abetting each other to violate the KCPA, KFAS, and to commit unjust enrichment.

538. In addition to the direct agreements between the Manufacturers and PBMs, as well as the agreements between the PBMs (including through their controlled rebate aggregator entities), the following circumstantial evidence demonstrates the Defendants' concerted activity:

- Key lockstep price increases occurred shortly after PCMA conferences, which included private exchanges and meetings that appear to be focused on developing and maintaining the Insulin Pricing Scheme, which all Manufacturers and PBM Defendants attended;
- Defendants' refusal to disclose the details of their pricing structures, agreements and sales figures in order maintain the secrecy of their Scheme;
- Numerous ongoing government investigations, hearings and inquiries have targeted the collusion between Defendants related to the at-issue drugs, including:
 - In 2016, the U.S. Attorney's Office for the Southern District of New York issued a CID for information related to the Defendants' conduct involving insulin prices;
 - In 2016, Defendants received civil investigative demands from the State of Washington, in conjunction with the Attorney Generals for California, Florida and Minnesota, related to their role in increasing insulin prices;
 - In 2017, Manufacturers received civil investigation demands from the States of Minnesota, California and Florida related to the pricing of their insulin products and their relationships with the PBMs;
 - In April 2019, U.S Congress held a hearing on the Insulin Pricing Scheme before the Senate Financing Committee in which each Defendant testified;

- The Senate Finance Committee’s recent two-year probe into the Insulin Pricing Scheme that resulted in the January 2021 Senate Insulin Report;
- A December 10, 2021 Congressional Report prepared by the House Committee on Oversight and Reform Minority Staff titled “A View from Congress: Role of Pharmacy Benefit Managers in Pharmaceutical Markets” that concluded:
 - Manufacturers raise their prices due to PBMs;
 - PBMs’ retail and mail order pharmacies create conflicts of interest, hurt competition and distort the market;
 - PBMs’ practices impact patient health; and
 - PBMs use their market leverage to increase their profits, not reduce costs for consumers.
- The astronomical rise in the price of the at-issue drugs coincides with PBM Defendants’ rise to power within the pharmaceutical pricing system in 2003 and increased in parallel with the PBMs’ increased market power

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

VII. JURY DEMAND

The Commonwealth respectfully requests a trial by jury on all issues so triable.

VIII. PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, the Commonwealth of Kentucky, *ex rel.* Daniel Cameron, Attorney General, prays for entry of judgment against the Defendants, individually, and jointly and severally, for all the relief requested herein

and to which the Commonwealth may otherwise be entitled, specifically, but without limitation, to-wit:

- A. Declaring that Defendants committed repeated willful violations of KRS 367.170;
- B. Declaring pursuant to KRS 446.070 that Defendants committed repeated violations of KRS 517.030;
- C. Declaring that Defendants were unjustly enriched by their conduct;
- D. Declaring that Defendants conspired to commit all of the above stated violations;
- E. Permanently enjoining Defendants and their employees, officers, directors, agents, successors, assigns, affiliates, merged or acquired predecessors, parent or controlling entities, subsidiaries, and any and all persons acting in concert or participation with Defendants from continuing their unlawful conduct, acts, and practices;
- F. Awarding civil penalties of \$2,000 for each willful violation of the Kentucky Consumer Protection Act pursuant to KRS 367.990(2);
- G. Awarding civil penalties of \$10,000 for each violation of the Kentucky Consumer Protection Act pursuant to KRS 367.990(2), where Defendants' conduct was directed at a person aged sixty (60) years of age or older;
- H. Disgorging Defendants' unjust profits pursuant to KRS 367.200;

- I. Awarding punitive damages against Defendants pursuant to KRS 411.184;
- J. Awarding the Commonwealth of Kentucky its costs and attorneys' fees;
- K. Awarding the Commonwealth of Kentucky prejudgment interest as permitted by law; and
- L. Awarding any other relief to which the Commonwealth of Kentucky is entitled or the Court deems appropriate and just.

Plaintiff demands trial by jury on all issues so triable.

RESPECTFULLY SUBMITTED this the 1st day of August 2023.

Office of the Attorney General
Commonwealth of Kentucky

By: /s/ Jonathan E. Farmer
Matthew C. Cocanougher
Assistant Attorney General
Jonathan E. Farmer
Deputy Executive Director
J. Christian Lewis
Commissioner of Consumer Protection
Office of Consumer Protection
Office of Attorney General
1024 Capital Center Drive, Suite 200
Frankfort, Kentucky 40601
Matthew.Cocanougher@ky.gov
Jonathan.Farmer@ky.gov
Christian.Lewis@ky.gov
Counsel for the Commonwealth