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# IN THE DISTRICT COURT OF SHAWNEE COUNTY, KANSAS THIRD JUDICIAL DISTRICT

THE STATE OF KANSAS, *EX.REL*., DEREK SCHMIDT, ATTORNEY GENERAL

PLAINTIFF,

V.

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

DEFENDANTS.

Case No.

Jury Trial Demanded

## **PETITION**

(Filed Pursuant to K.S.A. Chapters 50 and 60)

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Comes now the Plaintiff, the State of Kansas, ex rel. Derek Schmidt, Attorney General, (the "State" or "Plaintiff"), and brings this action against Defendants Eli Lilly and Company; Novo Nordisk Inc.; Sanofi-Aventis U.S. LLC; Evernorth Health, Inc. (formerly Express Scripts Holding Company); Express Scripts, Inc.; Express Scripts Administrators, LLC; ESI Mail Pharmacy Service, Inc.; Express Scripts Pharmacy, Inc.; Medco Health Solutions, Inc; CVS Health Corporation; CVS Pharmacy, Inc; Caremark Rx, LLC; CaremarkPCS Health, LLC; Caremark, LLC; and OptumRx Inc. (collectively, "Defendants") for violations of the laws of the State of Kansas and alleges as follows:

#### I. INTRODUCTION

- 1. Diabetes is an epidemic and a public health crisis in Kansas. Kansas has a high prevalence of diabetes with approximately 10% of its adult population—or over 245,000 people—living with diabetes. An additional 800,000 Kansas residents have pre-diabetes, which is when a person's blood sugar level is higher than it should be and signifies that the person is at greater risk for developing diabetes.
- 2. Diabetes is the leading cause of blindness, kidney failure, and lower limb amputations and is the seventh leading cause of death in Kansas, despite the availability of effective treatment.
- 3. The economic impact of diabetes is staggering. The total estimated cost of diagnosed diabetes in Kansas is \$2.4 billion per year.
- 4. Over 50,000 diabetics in Kansas rely on daily insulin treatments to survive, and hundreds of thousands more use either oral medications, insulin, or a combination of both to control their diabetes.

- 5. Defendants Eli Lilly, Novo Nordisk, and Sanofi (collectively, "Manufacturer Defendants" or "Manufacturers") manufacture the vast majority of insulins and other diabetic medications available in Kansas.
- 6. Defendants CVS Caremark, Express Scripts, and OptumRx 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 (PBMs) in the United States and in Kansas (controlling approximately 80% of the PBM market) and (2) the largest pharmacies in the United States and in Kansas (making up 3 of the top 5 dispensing pharmacies in the U.S.). These Defendant corporate conglomerates sit at 4th (CVS Caremark), 5th (OptumRx), and 13th (Express Scripts) on the Fortune 500 list ranking largest corporations by revenue (collectively, "PBM Defendants" or "PBMs").
- 7. 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.
- 8. PBM Defendants understand that their standard formulary offerings drive drug utilization.
- 9. 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 Kansas's citizens.

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<sup>&</sup>lt;sup>1</sup> In the context of this Petition, the "at-issue drugs" are Humulin N, Humulin R, Humalog, Trulicity, Basaglar, Lantus, Toujeo, Apidra, Soliqua, Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic.

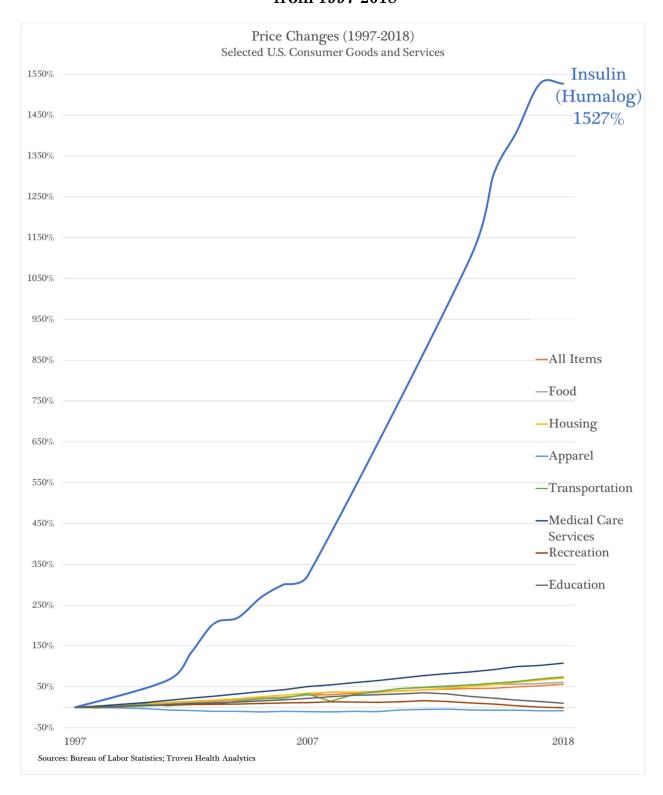
- 10. The Manufacturers likewise understand that the PBMs' standard formularies drive drug utilization—if Manufacturers want their drugs to be prescribed and paid for, they must obtain preferrable formulary position on the PBM Defendants' formularies.
- 11. Given the PBMs' market power and the crucial 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 in Kansas.
- 12. The unconscionable and deceptive scheme at the root of this Petition—the Insulin Pricing Scheme<sup>2</sup>—was born from this mutual understanding.
- 13. Over the course of the last fifteen years, and pursuant to the Insulin Pricing Scheme, Manufacturer Defendants have raised the prices of their respective diabetes drugs in an astounding manner, even though the cost to produce these drugs has decreased during that same time period.
- 14. Insulins, which today cost Manufacturer Defendants less than \$2 per drug to produce, and which were originally released at a list price of \$20 per drug in the late 1990s, now carry list prices that range between \$300 and \$700 per drug.
- 15. In the last decade alone, Manufacturer Defendants have increased the prices of their insulins up to 1,000%.

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<sup>&</sup>lt;sup>2</sup> The Insulin Pricing Scheme is further defined in paragraph 20 below.

16. Figure 1 illustrates the rate at 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



- 17. Remarkably, nothing about these medications has changed; today's \$350 insulin is the exact drug Defendants originally sold for \$20.
- 18. The current outrageously 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. Diabetics and payors bear the brunt of this increase.
- 19. Both Manufacturer and PBM Defendants play vital roles and profit immensely from the Insulin Pricing Scheme and the artificially inflated prices produced by it.
- 20. 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 an undisclosed portion of that price back to the PBMs. These Manufacturer Payments<sup>3</sup> are provided under a variety of labels, yet, however they are described, these

<sup>&</sup>lt;sup>3</sup> In the context of this Petition, 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 includes rebates, administrative fees, inflation fees, pharmacy supplemental discounts, volume discounts, price, or margin guarantees 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.

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

- 21. 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.
- 22. PBMs then grant preferred status on their standard formularies based upon the largest Manufacturer Payment and the highest inflated list price—which the PBMs know to be artificially inflated.
- 23. 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.
- 24. PBM Defendants profit from 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 prices 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.
- 25. Thus, while the PBM Defendants represent to diabetics and payors in Kansas 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.

- 26. Rather, the PBMs are intentionally driving up the price of the at-issue drugs. Indeed, the Manufacturer Payments that 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.
- 27. 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 Kansas who purchases these life-sustaining drugs.
- 28. The consequence to Kansas diabetics from the outrageous price increases caused by the Insulin Pricing Scheme cannot be overstated.
- 29. Kansas residents suffering from diabetes have been overcharged millions of dollars a year in out-of-pocket costs as a result of the Insulin Pricing Scheme.
- 30. For these Kansas residents with diabetes, 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 in Kansas 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.
- 31. In addition to the immeasurable human costs, the Insulin Pricing Scheme also adds substantial costs to the Kansas 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.

- 32. Kansas 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 that Kansas has spent on diabetes-related costs has steadily increased throughout the relevant time period and could grow exponentially given the high prevalence of pre-diabetes in Kansas.
- 33. Insulin rationing and the resulting otherwise-avoidable health complications caused by the Insulin Pricing Scheme leads to a loss in productivity and tax revenue, further damaging the State.
- 34. The State, through Derek Schmidt, Attorney General, brings this action on behalf of the State of Kansas and its residents to protect the health and economic well-being of the State as a whole and the heath and economic well-being of Kansas residents.
- 35. This action asserts causes for Defendants' violations of the Kansas Consumer Protection Act ("KCPA"), unjust enrichment, and civil conspiracy.
- 36. 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.
- 37. The relevant period for the claims alleged in this Petition is from 2003 continuing through the present.

#### II. PARTIES

#### A. Plaintiff

- 38. **Plaintiff, the State of Kansas**. The State of Kansas is the sole Plaintiff in this action, brought in its name on relation of the Attorney General Derek Schmidt. The Attorney General is the chief legal officer of the State and is charged with, among other things, enforcing and seeking redress for violations of Kansas consumer protection laws, including the KCPA. K.S.A. 50-628
- 39. The State is authorized to bring this action under the KCPA and in its parens patriae capacity, as Kansas has a quasi-sovereign interest in the health and well-being—physically and economically—of its citizens who have suffered because of Defendants' conduct in violation of the KCPA and the common law of the State of Kansas.

#### B. Manufacturer Defendants

- 40. **Defendant Eli Lilly and Company ("Eli Lilly")** is an Indiana corporation with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.
- 41. Eli Lilly is registered to do business in Kansas and may be served through its registered agent: National Registered Agents, Inc. of KS, 112 SW 7<sup>th</sup> Street, Suite 3C, Topeka, Kansas, 66603.
- 42. Eli Lilly holds four active Kansas Board of Pharmacy Licenses (License Nos. 5-00503, 5-31480, 5-00596, 5-02014).
- 43. These licenses allow Eli Lilly to manufacture, distribute, and sell its atissue drugs in Kansas.

- 44. In Kansas, Eli Lilly promotes and distributes several at-issue diabetes medications: Humulin N, Humulin R, Humalog, Trulicity, and Basaglar.
- 45. 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.
- 46. 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.
- 47. Eli Lilly transacts business in Kansas, targeting Kansas for its products, including the at-issue diabetes medications.
- 48. Eli Lilly employs sales representatives throughout Kansas to promote and sell Humulin N, Humulin R, Humalog, Trulicity, and Basaglar.
- 49. Eli Lilly also directs advertising and informational materials to Kansas physicians, pharmacies, payors, and diabetics for the specific purpose of selling more of the at-issue drugs in Kansas and profiting from the Insulin Pricing Scheme.
- 50. 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 Kansas with the express knowledge that payments by Kansas residents with diabetes would be based on those prices.
- 51. During the relevant time period, residents in Kansas with diabetes 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.

- 52. Kansas diabetics paid for all of the Eli Lilly diabetes medications related to the at-issue transactions in Kansas based on the specific inflated list prices Eli Lilly caused to be published in Kansas in furtherance of the Insulin Pricing Scheme.
- 53. **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.
- 54. Sanofi is registered to do business in Kansas and may be served through its registered agent: Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808.
- 55. Sanofi holds three active Kansas Board of Pharmacy Licenses (License Nos. 5-01739, 5-31031, 5-31127).
- 56. These licenses allow Sanofi to manufacture, distribute, and sell its atissue drugs in Kansas.
- 57. Sanofi promotes and distributes pharmaceutical drugs in Kansas, including several at-issue diabetes medications: Lantus, Toujeo, Soliqua, and Apidra.
- 58. Sanofi's global revenues in 2019 were \$3.50 billion from Lantus, \$1.03 billion from Toujeo, \$400 million from Apidra, and \$144 million from Soliqua.
- 59. 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.
- 60. Sanofi transacts business in Kansas and targets Kansas for its products, including the at-issue diabetes medications.

- 61. Sanofi employs sales representatives throughout Kansas to promote and sell Lantus, Toujeo, Soliqua, and Apidra.
- 62. Sanofi also directs advertising and informational materials to Kansas physicians, payors, pharmacies, and diabetics for the specific purpose of selling more of the at-issue drugs in Kansas and profiting from the Insulin Pricing Scheme.
- 63. 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 Kansas with the express knowledge that payment and reimbursement by Kansas diabetics would be based on these prices.
- 64. During the relevant time period, Kansas residents with diabetes spent millions of dollars per year out of pocket on Sanofi's at-issue drugs based on Sanofi's artificially inflated list prices.
- 65. Kansas diabetics paid for all of the Sanofi diabetes medications related to the at-issue transactions in Kansas based on the specific inflated prices Sanofi caused to be published in Kansas in furtherance of the Insulin Pricing Scheme.
- 66. **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.
- 67. Novo Nordisk is registered to do business in Kansas and may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

- 68. Novo Nordisk holds an active Kansas Board of Pharmacy License (License No. 4-1105080).
- 69. This license allows Novo Nordisk to manufacture, distribute, and sell its at-issue drugs in Kansas.
- 70. Novo Nordisk promotes and distributes pharmaceutical drugs in Kansas, including the at-issue diabetic medications: Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic.
- 71. 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, \$248.3 million from Novolin, and \$1.17 billion from Ozempic.
- 72. 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, \$284.5 million from Novolin, and \$185 million from Ozempic.
- 73. Novo Nordisk transacts business in Kansas, targeting Kansas for its products, including the at-issue diabetes medications.
- 74. Novo Nordisk employs sales representatives throughout Kansas to promote and sell Novolin R, Novolin N, Novolog, Levemir, Tresiba, Victoza, and Ozempic.
- 75. Novo Nordisk also directs advertising and informational materials to Kansas physicians, pharmacies, payors, and diabetics for the specific purpose of selling more of the at-issue drugs in Kansas and profiting from the Insulin Pricing Scheme.

- 76. 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 Kansas with the express knowledge that Kansas diabetics paid for the at-issue drugs based on these prices.
- 77. During the relevant time period, Kansas residents with diabetes spent millions of dollars per year out of pocket on Novo Nordisk's at-issue drugs based on Novo Nordisk's artificially inflated list prices.
- 78. Kansas diabetics paid for all of the Novo Nordisk diabetes medications related to the at-issue transactions in Kansas based on the specific inflated prices Novo Nordisk caused to be published in Kansas in furtherance of the Insulin Pricing Scheme.
- 79. Collectively, Defendants Eli Lilly, Novo Nordisk, and Sanofi are referred to as "Manufacturer Defendants" or "Manufacturers."

#### C. PBM Defendants

- 80. **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 Kansas.
- 81. CVS Health may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

- 82. CVS Health, through its executives and employees, is directly involved in the PBM services and formulary construction related to the Insulin Pricing Scheme that gave rise to the State's claims.
- 83. During the relevant time, CVS Health (or its predecessor)<sup>4</sup> has repeatedly, continuously, and explicitly stated that CVS Health:
  - a. "design[s] pharmacy benefit plans that minimize the costs to the client while prioritizing the welfare and safety of the clients' members and helping improve health outcomes;" 5
  - b. "negotiate[s] with pharmaceutical companies to obtain discounted acquisition costs for many of the products on [CVS Health's] drug lists, and these negotiated discounts enable [CVS Health] to offer reduced costs to clients;"6
  - c. "utilize[s] an independent panel of doctors, pharmacists, and other medical experts, referred to as its Pharmacy and Therapeutics Committee, to select drugs that meet the highest standards of safety and efficacy for inclusion on [CVS Health's] drug lists."
- 84. CVS Health publicly represents that CVS Health constructs programs that lower the costs of the at-issue diabetes medications. For example, in 2016, CVS Health announced a new program to "reduce overall spending in diabetes" that is available in all states, including Kansas, 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 decreased medical costs . . . [and that] participating clients could save between

<sup>&</sup>lt;sup>4</sup> 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."

<sup>&</sup>lt;sup>5</sup> CVS Caremark/CVS Health, Annual Reports (Form 10-K) (Dec. 31, 2009-2019).

<sup>&</sup>lt;sup>6</sup> CVS Caremark/CVS Health, Annual Reports (Form 10-K) (Dec. 31, 2009-2013).

<sup>&</sup>lt;sup>7</sup> CVS Caremark/CVS Health, Annual Reports (Form 10-K) (Dec. 31, 2009-2019).

\$3000 to \$5000 per year for each member who successfully improves control of their diabetes" (emphasis supplied).

- 85. 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 nearly 10 percent, CVS Health kept drug price growth at a minimal 0.2 percent."
- 86. 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.
- 87. 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."
- 88. 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:
  - a. In at least 2011, 2012, and 2016 the leaders of CVS Health and Novo Nordisk participated in executive exchange meetings, which appear to have included discussions 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.

- b. In at least 2012, the leaders of CVS Health and Eli Lilly participated in numerous executive meetings which appear to have included discussions 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.
- 89. **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.
- 90. CVS Pharmacy owns and operates dozens of pharmacies throughout Kansas that were directly involved in and profited from the Insulin Pricing Scheme.
- 91. CVS Pharmacy is the immediate and direct parent of Defendant Caremark Rx, LLC
- 92. CVS Pharmacy is registered to do business in Kansas and may be served through its registered agent: The Corporation Company, Inc., 112 SW 7<sup>th</sup> Street Suite 3C, Topeka, Kansas 66603.
- 93. During the relevant time period, CVS Pharmacy provided retail pharmacy services in Kansas that gave rise to the Insulin Pricing Scheme, which damaged Kansas diabetics.
- 94. **Defendant Caremark Rx, LLC** is a Delaware limited liability company and its principal place of business is at the same location as CVS Pharmacy and CVS Health.
- 95. Caremark Rx, LLC is a wholly-owned subsidiary of Defendant CVS Pharmacy.

- 96. Caremark Rx, LLC may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.
- 97. During the relevant time period, Caremark Rx, LLC provided PBM and mail order pharmacy services in Kansas that gave rise to the Insulin Pricing Scheme and damaged diabetics and payors in Kansas.
- 98. **Defendant Caremark, LLC** is a California limited liability company whose principal place of business is at the same location as CVS Health. Caremark, LLC is a wholly-owned subsidiary of Caremark Rx, LLC
- 99. Caremark, LLC is registered to do business in Kansas and may be served through its registered agent: The Corporation Company, Inc., 112 SW 7<sup>th</sup> Street, Suite 3C, Topeka, Kansas 66603.
- 100. Caremark, LLC is licensed with the Kansas Department of Insurance (License No. 902535).
- 101. During the relevant time period, Caremark, LLC provided PBM and mail order pharmacy services in Kansas that gave rise to the Insulin Pricing Scheme, which damaged diabetics and payors in Kansas.
- 102. **Defendant CaremarkPCS Health, LLC** is a Delaware limited liability company whose principal place of business is at the same location as CVS Health. CVS Health is the direct or indirect parent company of CaremarkPCS Health LLC.

- 103. CaremarkPCS Health, LLC provides pharmacy benefit management services.
- 104. CaremarkPCS Health, LLC is registered to do business in Kansas and may be served through its registered agent: The Corporation Company, Inc., 112 SW 7th Street, Suite 3C, Topeka, Kansas 66603.
- 105. CaremarkPCS Health, LLC is licensed with the Kansas Department of Insurance (License No. 902503).
- 106. During the relevant time period, CaremarkPCS Health, LLC provided PBM services in Kansas, which gave rise to the Insulin Pricing Scheme and damaged diabetics and payors in Kansas.
- 107. As a result of numerous interlocking directorships and shared executives, Caremark Rx, LLC, CVS Pharmacy, and CVS Health are directly involved in the conduct of and control of Caremark PCS Health, LLC and Caremark, LLC's operations, management, and business decisions related to the at-issue formulary construction, Manufacturer Payments, and mail order and retail pharmacy services to the ultimate detriment of diabetics and payors in Kansas. For example:
  - a. During the relevant time period, these parent and subsidiaries have had common officers and directors, including, but not limited to:
    - i. Thomas S. Moffatt was Vice President and Secretary of Caremark Rx, LLC, CaremarkPCS Health, LLC, and Caremark, LLC 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;
    - ii. Melanie K. Luker was the Assistant Secretary of CVS Pharmacy, Caremark Rx, LLC, Caremark PCS Health, LLC,

- and Caremark, LLC at the same time she was a Senior Manager of Corporate Services at CVS Health;
- iii. 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, LLC;
- iv. Daniel P. Davison was the President of CaremarkPCS Health, LLC at the same time he was a Senior Vice President at CVS Health; and
- v. Annie E. Klis was a Vice President at CVS Health at the same time she was CEO of Caremark, LLC.
- b. CVS Health directly or indirectly owns all the stock of CVS Pharmacy, Caremark Rx, LLC, Caremark, LLC and CaremarkPCS Health, LLC.
- c. All of the executives of CaremarkPCS Health, LLC, Caremark, LLC, Caremark Rx, LLC, and CVS Pharmacy ultimately report to the executives at CVS Health, including the President and CEO of CVS Health.
- d. 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, LLC, Caremark, LLC, and Caremark Rx, LLC as divisions or departments of one unified "diversified health services company" that "works together across our disciplines" to "create unmatched human connections to transform the health care experience." The day-to-day operations of this corporate family reflect these public statements. These entities are a single business enterprise and should be treated as such as to all legal obligations discussed in this Petition. 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.
- 108. Collectively, Defendants CVS Health, CVS Pharmacy, Caremark Rx, LLC, Caremark, LLC, and CaremarkPCS Health, LLC, including all predecessor and successor entities, are referred to as "CVS Caremark."

- 109. CVS Caremark is named as a Defendant in its capacities as a PBM, and retail and mail order pharmacy.
- 110. 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.
- 111. CVS Caremark has the largest PBM market share based on total prescription claims managed, representing approximately 40% of the national market. CVS Caremark's pharmacy services segment generated \$141.5 billion in total revenues last year.
- 112. At all times relevant hereto, CVS Caremark offered pharmacy benefit services to Kansas payors and their diabetic members, and derived substantial revenue therefrom. In doing so, CVS Caremark made the at-issue misrepresentations and utilized the artificially inflated prices generated by the Insulin Pricing Scheme to profit from Kansas diabetics and payors.
- 113. At all times relevant hereto, CVS Caremark constructed standard formularies that are used nationwide, including by CVS Caremark's payor clients in Kansas and that are relied on by residents in Kansas 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.
- 114. At all times relevant hereto, and contrary to all its express representations, CVS Caremark has knowingly insisted that its payor clients and

their diabetic members 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.

- 115. At all times relevant hereto, CVS Caremark has concealed its critical role in the generation of those artificially inflated list prices.
- 116. In its capacity as a mail order and retail pharmacy, CVS Caremark dispensed the at-issue drugs to Kansas diabetics and received payments from Kansas diabetics and payors based on the artificially inflated prices produced by the Insulin Pricing Scheme and, as a result, deceived and damaged Kansas diabetics and payors.
- 117. 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).
- 118. CVS Caremark purchases drugs produced by the Manufacturer Defendants, including the at-issue diabetes medications, for dispensing through its mail order and retail pharmacies.
- 119. 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 Kansas.

- 120. **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 63121.8
- 121. Evernorth may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.
- 122. 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.
- 123. Evernorth's conduct has had a direct effect in Kansas and damaged diabetics and payors in Kansas.
- 124. On a regular basis, Evernorth executives and employees communicate with and direct its subsidiaries related to the at-issue PBM services and formulary activities.

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<sup>&</sup>lt;sup>8</sup> Until 2021, Evernorth Health, Inc. conducted business under the name Express Scripts Holding Company. For the purposes of this Petition "Evernorth" refers to Evernorth Health, Inc. and Express Scripts Holding Company.

- 125. 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.
- 126. Manufacturers recognize that effectuating the Insulin Pricing Scheme requires "enhanced relationships at C Suite level" between the Manufacturers and Evernorth to "[i]mprove diabetes patient management through collaboration" and to "work synergistically within [Manufacturer Defendants] to maximize [Evernorth's] business opportunities."
- 127. 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 atissue drugs. Examples include:
  - a. In at least 2013, 2014, and 2015 the leaders of Evernorth and Eli Lilly participated in executive meetings which appear to have included discussions 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, among others.
  - b. In at least 2013 and 2014, the leaders of Evernorth and Novo Nordisk participated in executive meetings which appear to have included discussions in furtherance of the Insulin Pricing Scheme.
- 128. Evernorth is the immediate or indirect parent of pharmacy and PBM subsidiaries that operate throughout Kansas, which engaged in the activities that gave rise to this Petition.

- 129. In each annual report for at least the last decade, Evernorth has repeatedly, continuously, and explicitly stated:9
  - a. "[Evernorth] is one of the largest PBMs in North America . . . [and Evernorth] help[s] health benefit providers address access and affordability concerns resulting from rising drug costs while helping to improve healthcare outcomes."
  - b. "[Evernorth] manage[s] the cost of the drug benefit by . . . assists in controlling costs; evaluat[es] drugs for efficacy, value, and price to assist[ing] clients in selecting a cost-effective formulary; [and] offer[s] cost-effective home delivery pharmacy and specialty services that result in cost savings for plan sponsors [and better care for members] leveraging purchasing volume to deliver discounts to health benefit providers."
  - c. "[Evernorth] works with clients, manufacturers, pharmacists, and physicians to increase efficiency in the drug distribution chain, to manage costs in the pharmacy benefit chain and to improve members' health outcomes."
- 130. **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.
- 131. Express Scripts, Inc. is registered to do business in Kansas and may be served through its registered agent: C T Corporation System, 112 SW 7<sup>th</sup> Street, Suite 3C, Topeka, Kansas 66603.
- 132. Express Scripts, Inc. is licensed with the Kansas Department of Insurance (License No. 902232).

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<sup>&</sup>lt;sup>9</sup> Express Scripts Annual Reports (Form 10-K) (Dec. 31, 2009-2019).

- 133. Express Scripts, Inc. is the immediate or indirect parent of pharmacy and PBM subsidiaries that operate throughout Kansas that engaged in the conduct, which gave rise to this Petition.
- 134. During the relevant time period, Express Scripts Inc. was directly involved in the PBM and mail-order pharmacy services, which gave rise to the Insulin Pricing Scheme and damaged diabetics and payors in Kansas.
- 135. **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.
- 136. Express Scripts Administrators, LLC is registered to do business in Kansas and may be served through its registered agent: C T Corporation System, 112 SW 7th Street, Suite 3C, Topeka, Kansas 66603.
- 137. Express Scripts Administrators, LLC is licensed with the Kansas Department of Insurance (License No. 900298).
- 138. During the relevant time period, Express Scripts Administrators, LLC provided the PBM services in Kansas discussed in this Petition that gave rise to the Insulin Pricing Scheme that damaged diabetics and payors in Kansas.
- 139. **Defendant Medco Health Solutions, Inc. ("Medco")** is a Delaware Corporation with its principal place of business located at 100 Parsons Pond Road, Franklin Lakes, New Jersey, 07417.

- 140. Medco may be served through its registered agent: C T Corporation System, 112 SW 7<sup>th</sup> Street, Suite 3C, Topeka, Kansas 66603.
- 141. Prior to 2012, Medco provided the at-issue PBM and mail order services in Kansas, which gave rise to the Insulin Pricing Scheme and damaged diabetics and payors in Kansas.
  - 142. In 2012, Express Scripts merged with Medco in a \$29 billion deal.
- 143. Prior to the merger, Express Scripts and Medco were two of the largest PBMs in the United States and in Kansas.
- 144. Prior to the merger, Medco provided the at-issue PBM and mail-order services in Kansas, which gave rise to the Insulin Pricing Scheme and damaged diabetic Kansas residents and the State.
- 145. 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 customers becoming Express Scripts' customers. The combined company covered more than 155 million lives at the time of the merger.
- 146. 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."

- 147. 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."
- 148. **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.
- 149. ESI Mail Pharmacy Service, Inc. is registered to do business in Kansas and may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.
- 150. ESI Mail Pharmacy Service, Inc. is licensed with the Kansas Board of Pharmacy (License No. 22-02000).
- 151. During the relevant time period, ESI Mail Pharmacy Service, Inc. provided the mail order pharmacy services in Kansas discussed in this Petition, which gave rise to the Insulin Pricing Scheme and damaged diabetics and payors in Kansas.
- 152. **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.
- 153. Express Scripts Pharmacy, Inc. is registered to conduct business in Kansas and may be served through its registered agent: The Corporation Trust

Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

- 154. Express Scripts Pharmacy, Inc. holds two active Kansas Board of Pharmacy Licenses (License Nos. 22-44610, 22-16432).
- 155. During the relevant time period, Express Scripts Pharmacy, Inc. provided the mail order pharmacy services in Kansas discussed in this Petition, which gave rise to the Insulin Pricing Scheme and damaged diabetics and payors in Kansas.
- 156. As a result of numerous interlocking directorships and shared executives, Evernorth and Express Scripts, Inc. are directly involved in the conduct and control of 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 Kansas diabetics and payors. For example:
  - a. During the relevant time period, these parent and subsidiaries have had common officers and directors:
    - i. Officers and 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;
    - ii. Executives that have been shared between Express Scripts Administrators, LLC and Evernorth include Bradley Phillips, Chief Financial Officer; and Priscilla Duncan, Associate Secretary;
    - iii. Officers and 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;
- iv. Officers and 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
- v. Officers and 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.
- b. Evernorth directly or indirectly owns all the stock of Express Scripts Administrators, LLC, Medco Health Solutions, Inc., ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc., and Express Scripts, Inc.
- c. The Evernorth corporate family does not operate as separate entities. The public filings, documents, and statements of Evernorth 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 Petition. 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.
- d. 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.
- e. 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 State's claims in this Petition.
- 157. 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."
- 158. Express Scripts is named as a Defendant in its capacities as a PBM and mail-order pharmacy.
- 159. 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.
- 160. In 2019, Express Scripts was the largest independent PBM in the United States. During the relevant period of this Petition, Express Scripts controlled 30% of the PBM market in the United States.
  - 161. In 2017, annual revenue for Express Scripts was more than \$100 billion.
- 162. As of December 31, 2018, more than 68,000 retail pharmacies, representing more than 98% of all retail pharmacies in the nation, participated in one or more of Express Scripts' networks.
- 163. At all times relevant hereto, Express Scripts offered pharmacy benefit services, and derived substantial revenue therefrom, in Kansas and provided the atissue PBM services to numerous payors and diabetics in Kansas.

- 164. At all times relevant hereto, and contrary to all of their representations, Express Scripts has knowingly insisted that its payor clients and their diabetic members, including those in Kansas, use the artificially-inflated list prices produced by the Insulin Pricing Scheme as the basis for reimbursement of the at-issue drugs.
- 165. At all times relevant hereto, Express Scripts has concealed its critical role in the generation of those artificially inflated list prices.
- 166. At all times relevant hereto, Express Scripts constructed standard formularies that are used nationwide, including by Express Scripts' payors and diabetics in Kansas, and that are relied on by residents in Kansas 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.
- 167. 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).

- 168. In its capacity as a mail order pharmacy, Express Scripts dispensed the at-issue drugs to residents in Kansas with diabetes and received payments from Kansas diabetics and payors based on the artificially inflated prices produced by the Insulin Pricing Scheme and, as a result, damaged Kansas diabetics and payors.
- 169. At all times relevant hereto, Express Scripts derived substantial revenue providing mail-order pharmacy services in Kansas.
- 170. Express Scripts purchases drugs produced by the Manufacturer Defendants, including the at-issue diabetes medications, for dispensing through its mail order pharmacies.
- 171. 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 Kansas.
- 172. **Defendant OptumRx, Inc.** is a California corporation with its principal place of business at 2300 Main St., Irvine, California, 92614.
- 173. OptumRx, Inc. is registered to do business in Kansas and may be served through its registered agent: The Corporation Company, Inc., 112 SW 7<sup>th</sup> Street, Suite 3C, Topeka, Kansas 66603.

- 174. OptumRx, Inc. holds four active Kansas Board of Pharmacy Licenses (License Nos. 22-108120, 22-12911, 22-01845, 2-10031), and an active Kansas Department of Insurance License (License No. 901299).
- 175. During the relevant time period, OptumRx, Inc. provided the PBM and mail-order pharmacy services in Kansas that gave rise to the Insulin Pricing Scheme, which damaged diabetics and payors in Kansas.
- 176. Collectively, Defendant OptumRx, Inc., including all predecessor and successor entities, is referred to as "OptumRx."
- 177. On a regular basis throughout the relevant time period, executive teams from each Manufacturer Defendant—including at times their CEOs—met with executives from OptumRx to discuss their coordinated efforts in furtherance of the Insulin Pricing Scheme. Examples include:
  - a. In at least 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 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.
  - b. In at least October 2016, the CEO of OptumRx, Mark Thierer, and the CEO of UnitedHealth Group, Steve Hemsley, met the CEO of Eli Lilly, Dave Ricks, to discuss "strategic initiatives" between UHG/OptumRx and Eli Lilly.
- 178. OptumRx is named as a Defendant in its capacities as a PBM and mailorder pharmacy.

- 179. 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.
- 180. 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.
- 181. In 2019, OptumRx managed more than \$96 billion in pharmaceutical spending, with a revenue of \$74 billion.
- 182. 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, UnitedHealth Group bought Catamaran Corp in a deal worth \$12.8 billion and merged Catamaran with OptumRx.
- 183. Prior to merging with OptumRx, Catalyst Health Solutions, Inc. and Catamaran Corp. engaged in the at-issue PBM and mail-order activities in Kansas.
- 184. At all times relevant hereto, OptumRx derived substantial revenue providing pharmacy benefits in Kansas.
- 185. At all times relevant hereto, and contrary to all their express representations, OptumRx has knowingly insisted that payors and diabetics in

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

- 186. At all times relevant hereto, OptumRx has concealed its critical role in the generation of those artificially-inflated list prices.
- 187. At all times relevant hereto, OptumRx offered pharmacy benefit management services nationwide and constructed standard formularies that are used throughout Kansas by payors and diabetics, and that are relied on by residents in Kansas with diabetes as promoting diabetic health and lowering the price of the atissue drugs. During the relevant time period, these standard formularies included the at-issue diabetes medications.
- 188. In its capacity as a mail-order pharmacy, OptumRx dispensed the atissue drugs to Kansas diabetics and received payments from Kansas diabetics and payors based on the artificially inflated prices produced by the Insulin Pricing Scheme and, as a result, damaged Kansas diabetics and payors.
- 189. 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 Kansas through its mail-order pharmacies.
- 190. 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.

- 191. Collectively, CVS Caremark, OptumRx, and Express Scripts are referred to as "PBM Defendants" or "PBMs."
- 192. Collectively, the "PBM Defendants" and the "Manufacturer Defendants" are referred to as "Defendants."

### III. PUBLIC INTEREST

- 193. This action seeks, on behalf of the State of Kansas and its citizens, legal and equitable relief to redress injury and damage, as well as injunctive relief seeking an end to Defendants' misconduct. The State of Kansas has an interest in protecting the well-being of the hundreds of thousands of diabetic citizens of the State of Kansas who rely on the at-issue diabetic medications and have been damaged, and continue to be damaged, by the Insulin Pricing Scheme.
- an officer of the State of Kansas is a real party in interest in this action. Acting as an officer of the State of Kansas 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, the State's interests, and the integrity of its healthcare system. The Attorney General is authorized to bring this action under the provisions of the KCPA and in its *parens patriae* capacity as a representative of its citizens and chief legal officer, 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 Kansas laws.

## IV. JURISDICTION AND VENUE

195. This Court has jurisdiction and venue over this action under the KCPA, K.S.A. 50-623, *et seq*.

196. This Court has personal jurisdiction over Defendants pursuant to the KCPA, K.S.A. 50-638(a), because Defendants: (a) transact business and have engaged in a consumer transaction within Kansas; (b) maintain substantial contacts in Kansas; and (c) committed the violations of Kansas statutes and the common law at issue in this lawsuit in whole or in part within Kansas. 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 Kansas, and to the State. All of the at-issue transactions occurred in Kansas or involved Kansas residents or businesses.

197. Venue is proper in Shawnee County pursuant to the KCPA, K.S.A. 50-638(b), because Defendants are nonresidents of Kansas and have no principal place of business within this state. Additionally, Defendants transact business in Shawnee County and act or practice in violation of the KCPA in Shawnee County.

## V. FACTUAL ALLEGATIONS

# A. Diabetes and Insulin Therapy.

#### 1. Diabetes: A growing epidemic.

198. 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.

- 199. 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 medication in the form of a pill, in the long term most patients require insulin injections.
- 200. The other type of diabetes, known as 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, will die.
- 201. Insulin treatments are a necessary part of life for those who have diabetes. Interruptions to a diabetic's insulin regimen can have severe consequences. Missed or inadequate insulin therapy can trigger hyperglycemia and then diabetic ketoacidosis. Left untreated, diabetic ketoacidosis can lead to loss of consciousness and death within days.
- 202. 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 more than 10 million people. Fourteen (14) years later, the count tripled again. Now more than 30 million people—9.4% of the country—live with the disease.

- 203. Likewise, the prevalence of diabetes in Kansas has been steadily increasing as well. Over 200,000 Kansas adults now live with diabetes and another 800,000 have prediabetes.
- 204. The burden of diabetes is not equally distributed in Kansas. Diabetes is significantly more prevalent in impoverished regions; nearly one in four Kansas residents who earn less than \$25,000 a year have diabetes.

# 2. Insulin: A century old drug.

- 205. 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.
- 206. Unlike many high-burden diseases, treatment for diabetes has been available for almost a century.
- 207. In 1922, Frederick Banting and Charles Best, while working at the University of Toronto, pioneered a technique for removing insulin from an animal pancreas that could then be used to treat diabetes. After discovery, Banting and Best obtained a patent and then sold it to the University of Toronto for \$1 (equivalent to \$14 today), explaining "[w]hen the details of the method of preparation are published anyone would be free to prepare the extract, but no one could secure a profitable monopoly."
- 208. 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.

- 209. 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.
- 210. 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.
- 211. Over a decade later, Defendant Eli Lilly developed the first analog insulin, Humalog, in 1996.
- 212. 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.
- 213. 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.
- 214. Manufacturer Defendants introduced these rapid-acting and long-acting analog insulins between 1996 and 2007.

- 215. In 2015, Sanofi introduced Toujeo, another long-acting insulin also similar to Lantus, however Toujeo is highly concentrated, making injection volume smaller than Lantus.
- 216. In 2016, Eli Lilly introduced Basaglar, which is a long-acting insulin that is biologically similar to Sanofi's Lantus.
- 217. Even though insulin was first extracted nearly 100 years ago, only Defendants Eli Lilly, Novo Nordisk, and Sanofi manufacture insulin in the United States.
- 218. Many of the at-issue diabetes medications are now off patent. However, the Manufacturers have engaged in illicit tactics to maintain their complete market dominance.
- 219. 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.

- 220. 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.
- 221. 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.
- 222. 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.

223. 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.

- 224. All 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.
- 225. 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.

- 226. The production and research and development costs have also not increased. In fact, in the last 10 years, the production costs of insulin have decreased as manufacturers simplified and optimized processes. A September 2018 study published in BMJ Global Health calculated that, based on production costs, a reasonable price for a year's supply of human insulin is \$48 to \$71 per person and between \$78 and \$133 for analog insulins—which includes delivering a profit to manufacturers.
- 227. 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.

- 228. These figures stand in stark contrast to the \$5,705 that a diabetic spent, on average, for insulin in 2016.
- 229. Further, while research and development costs often make up a large percentage of the price of a drug, in the case of insulin the initial basic research—original drug discovery and patient trials—was performed 100 years ago.
- 230. Even the more recent costs, such as developing the recombinant DNA fermentation process and the creation of insulin analogs, were incurred decades ago by the Manufacturers.
- 231. 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.
- 232. Despite this decrease in production costs, and no new research and development, the reported price of insulins has risen astronomically over the last 15 years.

# 4. Insulin adjuncts: Type 2 medications.

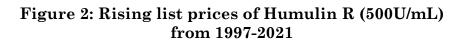
- 233. Over the past decade, Manufacturer Defendants have also released a number of non-insulin medications that help control the level of insulin in the bloodstream of Type 2 diabetics.
- 234. In 2010, Novo Nordisk released Victoza as an adjunct to insulin to improve glycemic control. In 2014, Eli Lilly released a similar drug, Trulicity. In 2016, Sanofi did the same with Soliqua, and in 2017, Novo Nordisk did the same with Ozempic.
- 235. Victoza, Trulicity, and Ozempic are all medications known as glucagonlike 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.
- 236. 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:

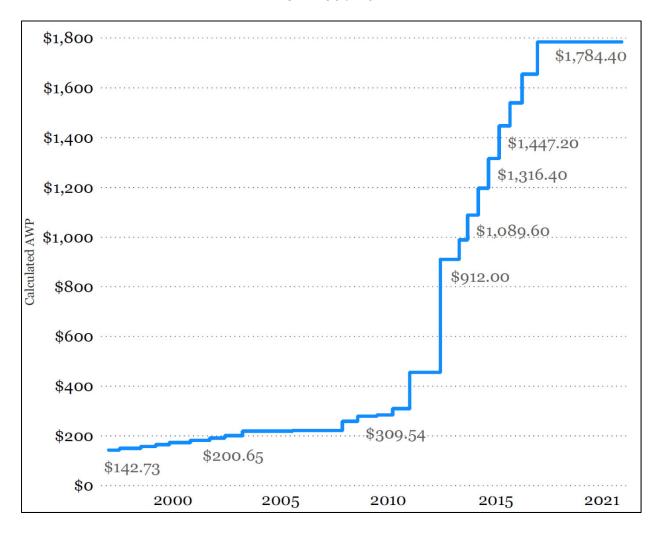
Table 1: Diabetes medications at issue in this case

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	\$ 340 (vial) \$510 (pens)
		Levemir	Novo Nordisk	2005	\$ 370 (vial) \$ 555 (pens)
		Basaglar (Kwikpen)	Eli Lilly	2016	\$392 (pens)
		Toujeo (Solostar)	Sanofi	2015	\$466 (pens) \$622 (max pens)
		Tresiba	Novo Nordisk	2015	\$407 (vial) \$610 (pens – 100u) \$732 (pens – 200u)
Type 2 Medications		Trulicity	Eli Lilly	2014	\$1,013 (pens)
		Victoza	Novo Nordisk	2010	\$813 (2 pens) \$1,220 (3 pens)
		Ozempic	Novo Nordisk	2017	\$1,022 (pens)
		Soliqua	Sanofi	2016	\$927.90 (pens)

## B. The Dramatic Rise in the Price of Diabetes Medications.

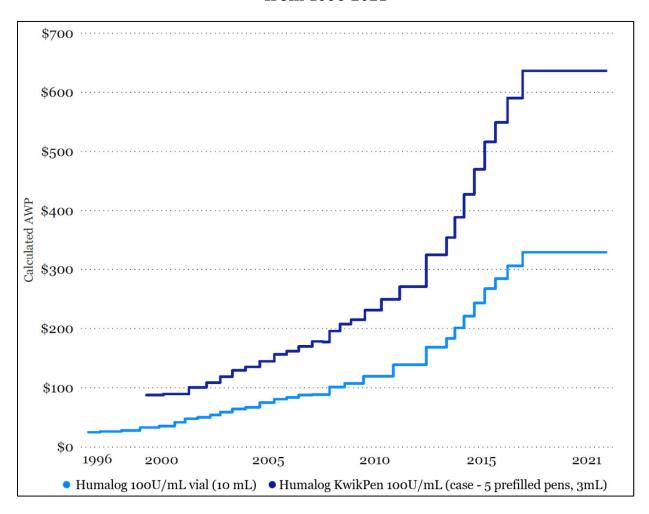
- 1. <u>Insulin price increases.</u>
- 237. In 2003, PBMs began their rise to power (which will be discussed in greater detail in the next section).
- 238. That same year, the price of insulin began its dramatic rise to its current exorbitant level.
- 239. Since 2003, the list price of certain insulins has increased in some cases by more than 1,000% an astounding increase especially when compared to a general inflation rate of 8.3% and a medical inflation rate of 46% in this same time period.
- 240. 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 is 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.
- 241. Since 1997, Defendant Eli Lilly has artificially inflated the list price of a vial of Humulin R (500U/ML) from \$165 to \$1,784 (See Figure 2).





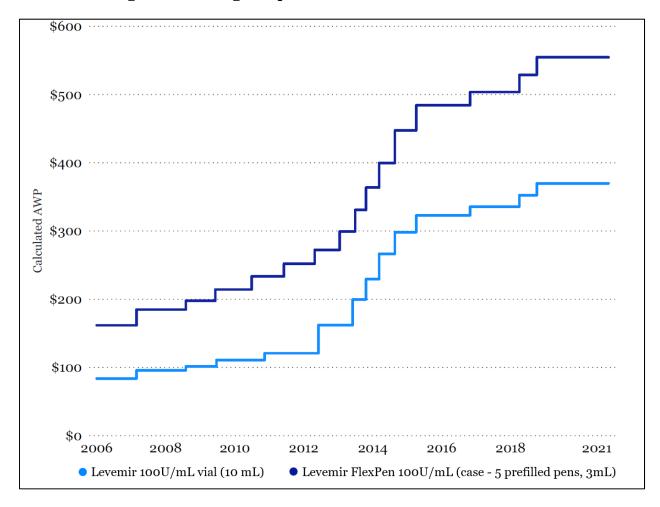
242. Since 1996, Defendant Eli Lilly has artificially inflated the list price for a package of pens of Humalog from less than \$100 to \$663, and from less than \$50 to \$342 per vial (*See* Figure 3).

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



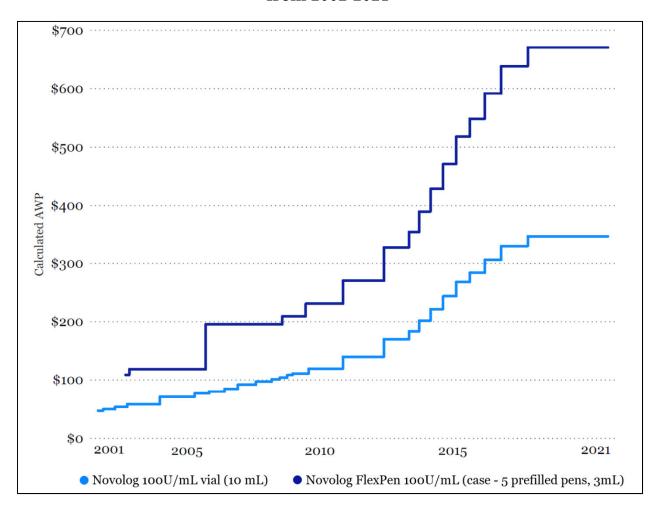
243. Novo Nordisk has also artificially inflated the list prices—from 2006 to 2020, Levemir rose from \$162 to \$555 for pens, and from under \$100 to \$370 per vial (See Figure 4).

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



244. 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 per vial (*See* Figure 5).

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



245. 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 more than \$500 in 2020 for a package of pens, and from less than \$50 to \$340 per vial (*See* Figure 6).

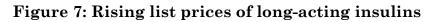
\$600
\$500
\$400
\$300
\$200
\$100
\$0
2001 2005 2010 2015 2021
• Lantus 100U/mL vial (10 mL)
• Lantus SoloStar 100U/mL (case - 5 prefilled pens, 3mL)

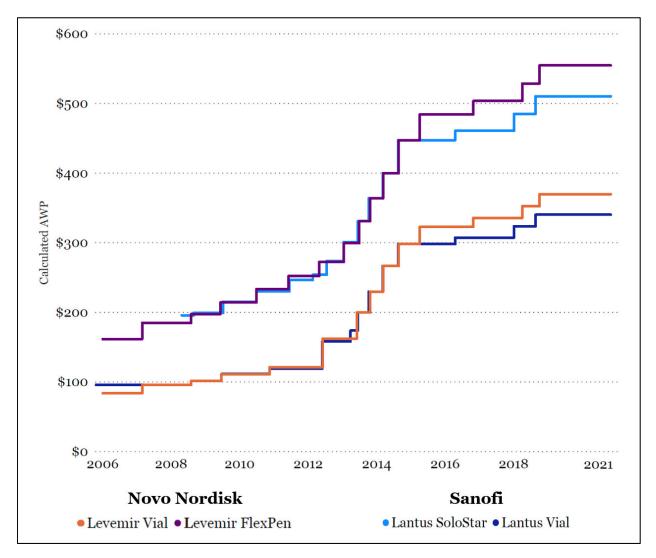
Figure 6: Rising list prices of Lantus vials and pens from 2001-2021

- 246. 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 by almost 50%.
- 247. Driven by these price hikes, payors' and diabetics' spending on diabetes medications has skyrocketed with totals in the tens of billions of dollars.

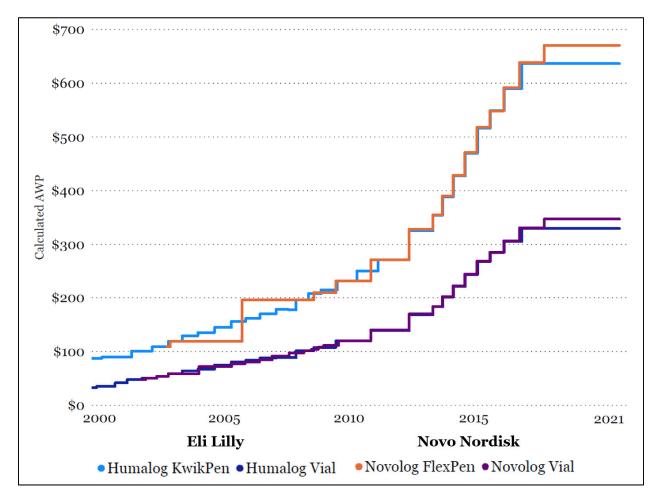
# 2. Manufacturers increased prices in lockstep.

- 248. The timing of the list price increases reveal that each Manufacturer Defendant has not only dramatically increased prices for the at-issue diabetes treatments, but they have also done so in perfect lockstep pursuant to the unconscionable and deceptive Insulin Pricing Scheme.
- 249. In 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 within a few days of each other.
- 250. 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 during 2016.
- 251. 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 this behavior with respect to Lantus and Levemir. Figure 8 demonstrates this behavior with respect to Humalog and Novolog.



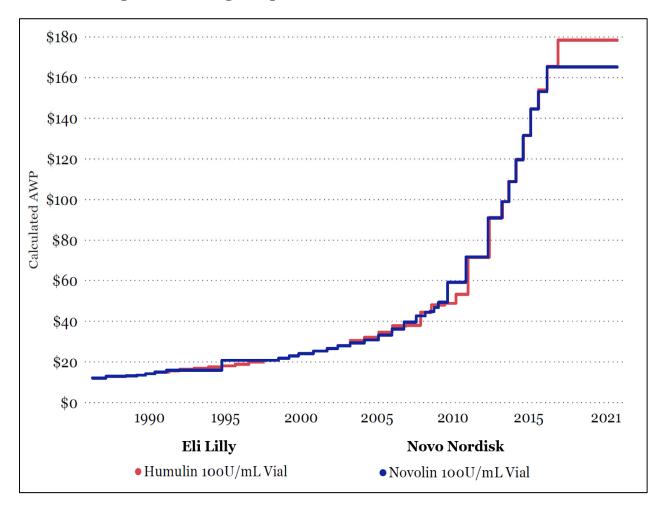






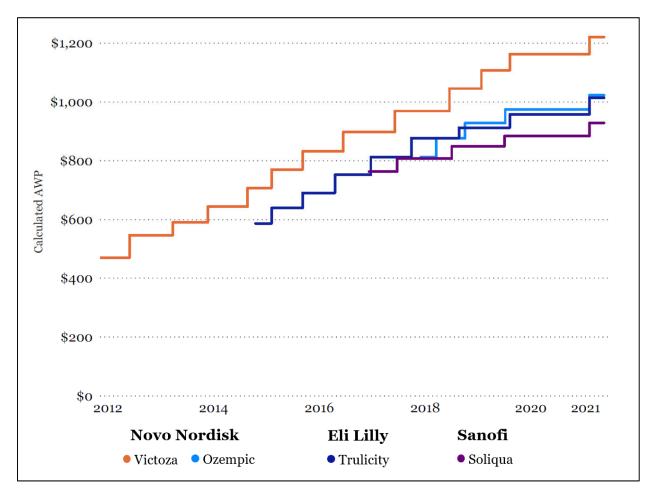
252. Figure 9 demonstrates this behavior with respect to the human insulins, Eli Lilly's Humulin and Novo Nordisk's Novolin.

Figure 9: Rising list price increases for human insulins



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

Figure 10: Rising list prices of Type 2 drugs



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

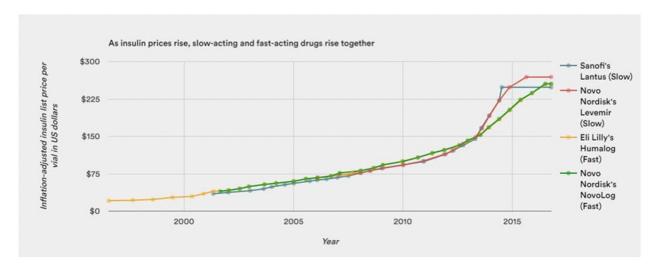


Figure 11: Lockstep insulin price increases

255. 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.

- 256. 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.
- 257. 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, and mail-order pharmacy to patient.

- 258. 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.
- 259. There is no transparency in this pricing system; typically, only a brand drug's list price—also known as its Average Wholesale Price (AWP) or the mathematically-related Wholesale Acquisition Cost (WAC)—is available. To note, "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.
- 260. 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.
- 261. 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.

262. Whether insured or not, all residents in Kansas with diabetes pay a substantial part of their diabetic drug costs based on the false and deceptive list prices generated by the Insulin Pricing Scheme.

- 263. Uninsured diabetics must pay the full, point-of-sale price (based on the artificial prices generated by the Insulin Pricing Scheme) every time they fill their prescription. In Kansas, 9.2% of the population—or 275,000 residents are uninsured. Approximately 18% of uninsured residents in Kansas are diabetic. As a direct result of the Insulin Pricing Scheme, the prices uninsured residents in Kansas pay for the at-issue life-sustaining drugs has skyrocketed over the last 15 years.
- 264. 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, or copayment requirements based on the artificially inflated list prices generated by the Insulin Pricing Scheme.
- 265. Thus, nearly all Kansas diabetics have been damaged by having to pay for diabetes medications out-of-pocket based upon the artificial prices generated by the Insulin Pricing Scheme. In many cases, diabetic residents in Kansas cannot afford these life-sustaining drugs.
- 266. The exorbitant out-of-pocket costs created by the Insulin Pricing Scheme make it more difficult, if not impossible, for patients to adhere to their doctor-prescribed medication regime. Often this results 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."

- 267. The overall economic impact from the loss of productivity and increased healthcare costs that result from diabetics underdosing on their insulin has been deeply damaging to the State.
  - 2. PBMs' role in the pharmaceutical payment chain.
- 268. PBMs are at the center of the convoluted pharmaceutical payment chain, as illustrated in Figure 12:

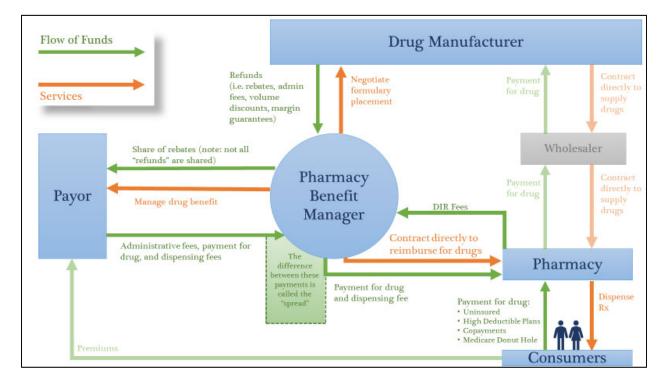


Figure 12: Insulin distribution and payment chain

269. 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.

- 270. 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.
- 271. 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.
- 272. Often—including for at-issue drugs—the PBM Defendants purchase drugs from the Manufacturers and dispense them to the patients.
- 273. Even where PBM Defendants' pharmacies purchase drugs from wholesalers, their costs are set by direct contracts with the Manufacturers.
- 274. In addition, and of particular significance here, PBM Defendants contract with pharmaceutical manufacturers, including Manufacturer Defendants.
- 275. These relationships allow PBMs to exert tremendous influence over what drugs are available throughout Kansas and at what prices.
- 276. Thus, PBMs are at the center of the flow of money in the pharmaceutical supply chain. In sum:
  - a. PBMs negotiate the price that payors pay for prescription drugs (for the at-issue drugs based on artificially-inflated prices generated by the Insulin Pricing Scheme);
  - b. PBMs separately negotiate a different (and often lower) price that pharmacies in their networks receive for that same drug;
  - c. PBMs set the amount in fees that the pharmacy pays back to the PBM for each drug sold (for the at-issue drugs based on artificially-inflated prices generated by the Insulin Pricing Scheme);

- d. PBMs 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
- e. PBMs 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).
- 277. Yet, for the majority of these transactions, only the PBMs are privy to the amount that any other entity in this supply chain is paying or receiving for the exact same drugs.
- 278. 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.
- 279. When they first came into existence in the 1960s, PBMs functioned largely as claims processors. Over time, however, they have taken on a larger role in the pharmaceutical industry. Today, PBMs wield significant control over the drug pricing system.
- 280. PBMs began negotiating with drug manufacturers ostensibly on behalf of payors.
  - 281. In the early 2000s, PBMs started buying pharmacies.
- 282. When a PBM combines with a pharmacy, it has an increased incentive to collude with Manufacturers to keep certain prices high.
- 283. These incentives still exist today with respect to both retail and mailorder pharmacies housed within the PBMs' corporate families.

- 284. More recently, further consolidation in the industry has afforded PBMs a disproportionate amount of market power.
- 285. In total, nearly 40 different PBM entities have merged or been absorbed into what are now the PBM Defendants.
- 286. After merging or acquiring all their competitors, PBM Defendants have taken over the market—controlling more than 80% of the market and managing pharmacy benefits for more than 270 million Americans.
- 287. PBM Defendants have near *complete* control over the Manufacturer Payment market. In addition to their own clients and their members, which represents 80% of the market, PBM Defendants or their controlled affiliate rebate aggregator companies contract with nearly all of the smaller pharmacy benefit managers, including the largest of those, Prime Therapeutics, to negotiate Manufacturer Payments on their behalf.
- 288. Business is booming for PBM Defendants. Together, they report more than \$300 billion in annual revenue.
- 289. 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 Advice and Vision for the Healthcare Ecosystem (ADVI) 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.
- 290. 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.
- 291. 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 to promote the Insulin Pricing Scheme.
- 292. David Ricks, CEO of Eli Lilly, Paul Hudson, CEO of Sanofi, and Douglas Langa, Executive Vice President of Novo Nordisk, are all part of the members of the PhRMA board of directors or part of the PhRMA executive leadership team.
- 293. PBM Defendants also routinely communicate through direct interaction with their competitors and the Manufacturers at PBM trade associations and industry conferences.
- 294. 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.
- 295. 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 Caremark. Past board members include John Prince, President and COO of Optum, Inc. (and former CEO of OptumRx), and Tim Wentworth, CEO of Evernorth.

- 296. 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.
- 297. The PCMA annual conferences appear to be at the center of the Insulin Pricing Scheme.
- 298. 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.
- 299. In fact, for at least the last six (6) years, all the Manufacturer Defendants have been "Presidential Sponsors" of these PBM conferences.
- 300. 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."
- 301. From at least 2010 to 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.
- 302. 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

- 303. 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.
- 304. 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. Mere days after the conference, on October 1, 2017, Sanofi increased Lantus's list price by 3% and Toujeo's list by 5.4%. Novo Nordisk also recommended that their company make a 4% list price increase on January 1, 2018, to match the Sanofi increase.
- 305. Likewise, on May 30, 2014, Novo Nordisk raised the list price of Levemir several hours after Sanofi made its list price increase on Lantus and this occurred only a few weeks after the 2014 PCMA spring conference in Washington, D.C. attended by representatives from all the PBM Defendants.
- 306. 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 as direct-to-consumer discounts.

## D. The Insulin Pricing Scheme.

- 307. 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.
- 308. 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.
- 309. But the PBMs do not want the prices for diabetes medications to go down because they make more money on higher prices, as do the Manufacturers.
- 310. As a result, Defendants have found a way to game the system for their mutual benefit—the Insulin Pricing Scheme.
- 311. 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.
- 312. Controlling the standard formularies gives PBM Defendants a crucial point of leverage over the system.

- 313. 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.
- 314. For example, Olivier Brandicourt, Sanofi's CEO, in a recent interview stressed the importance of the PBMs' standard formularies: "if you look at the way [CVS Caremark] is organized in the US . . . 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."
- 315. 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, in summarizing the internal documents produced by the Manufacturers, noted the following:

[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.

316. 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.

- 317. 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 15 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.
- 318. 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.

- 319. 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.
- 320. 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.
- 321. In exchange for the Manufacturers inflating their prices and paying the PBMs substantial amounts in Manufacturer Payments, PBM Defendants grant preferred status on their standard formularies to the Manufacturer Defendants' diabetes medications with the most elevated price and that are the most profitable to the PBMs.
- 322. Thus—and contrary to their public representations—the PBM Defendants' agreements with the Manufacturer Defendants (and the standard formularies that result from these agreements) are incentivizing and are responsible for the precipitous price increases for the at-issue diabetes medications.
- 323. 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 prices <sup>10</sup> as to constitute false and unlawful prices.

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 $<sup>^{10}</sup>$  "Net Price" refers to the Manufacturers' list price minus all Manufacturer Payments paid to the PBMs.

- 324. Despite this knowledge, PBMs include this false and deceptive 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.
- 325. 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 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."
- 326. The PBM Defendants also misrepresent the amount of "savings" they generate to their payor clients and prospective clients.
- 327. 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.
- 328. 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:
  - a. Manufacturers and PBMs are in constant communication and regularly meet and exchange information to construct and refine the

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

- b. Manufacturers and PBMs share confidential and proprietary information with each other in furtherance of the Insulin Pricing Scheme, such as market data gleaned from the PBMs' drug utilization tracking efforts and 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
- c. 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. 11 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."
- 329. Far from using their prodigious bargaining power to lower drug prices as they claim, Defendants use their dominant positions to work together to generate

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<sup>&</sup>lt;sup>11</sup> "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.

billions of dollars at the expense of Kansas diabetics and payors. Further, this scheme endangers the lives of diabetics and payors by inflating the prices of these life-saving drugs.

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

- 330. 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."
- 331. Representatives from all Defendants testified at the hearing and each acknowledged before Congress that the price for insulin has increased exponentially in the past 15 years.
- 332. Representatives from each Defendant explicitly admitted that the price that diabetics have to pay out-of-pocket for insulin is too high. For example:
  - a. Dr. Sumit Dutta, Chief Medical Officer of OptumRx stated, "A lack of meaningful competition allows the [M]anufacturers to set high [list] prices and continually increase them which is odd for a drug that is nearly 100 years old and which has seen no significant innovation in decades. These price increases have a real impact on consumers in the form of higher out-of-pocket costs."
  - b. Thomas Moriarty, Chief Policy and External Affairs Officer and General Counsel for CVS Health testified, "A real barrier in our country to achieving good health is cost, including the price of insulin products which are too expensive for too many Americans. Over the last several years, [list] prices for insulin have increased nearly 50 percent. And over the last ten years, [list] price of one product, Lantus, rose by 184 percent."
  - c. Mike Mason, Senior Vice President of Eli Lilly when discussing how much diabetics pay out-of-pocket for insulin stated "it's difficult for me to hear anyone in the diabetes community worry about the cost of

- insulin. Too many people today don't have affordable access to chronic medications . . ."
- d. Kathleen Tregoning, Executive Vice President External Affairs at Sanofi, testified, "Patients are rightfully angry about rising out-of-pocket costs and we all have a responsibility to address a system that is clearly failing too many people. . . we recognize the need to address the very real challenges of affordability . . . Since 2012, average out-of-pocket costs for Lantus have risen approximately 60 percent for patients . . ."
- e. Doug Langa, Executive Vice President of Novo Nordisk, stated, "On the issue of affordability . . . I will tell you that at Novo Nordisk we are accountable for the [list] prices of our medicines. We also know that [list] price matters to many, particularly those in high-deductible health plans and those that are uninsured."
- 333. Notably, none of the testifying Defendants claimed that the significant increase in the price of insulin was related to competitive factors such as increased production costs or improved clinical benefit.
- 334. 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.
- 335. 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.
- 336. 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).

337. 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].

338. 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.

- 339. 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.
- 340. 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 . . ."

- 341. 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.
- 342. 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.
- 343. 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 South California titled "The Association Between Drug Rebates and List Prices," found that an increase in the amount that the Manufacturers pay back to the PBMs is directly correlated to an increase in prices—on average, a \$1 increase in Manufacturer Payments is associated with a \$1.17 increase in price—and that reducing or eliminating Manufacturer Payments could result in lower prices and reduced out-of-pocket expenditures.
- 344. In addition, a recent report by the National Community Pharmacists Association estimated that Manufacturer Payments add nearly 30 cents per dollar to the price consumers pay for prescriptions.
- 345. 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 artificially increased. By way of

example, since 2003, Defendant Express Scripts has seen its profit per prescription increase more than 500% per adjusted prescription.

- 346. The Manufacturers, on the other hand, argued before Congress that the PBMs were to blame for high insulin prices because of the PBMs' demands for higher Manufacturer Payments in exchange for formulary placement.
- 347. 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.
  - 348. The January 2021 Senate Insulin Report concluded, inter alia:
    - a. Manufacturer Defendants are retaining more revenue from insulin than in the 2000s—for example, Eli Lilly has reported a steady increase in Humalog revenue for more than a decade—from \$1.5 billion in 2007 to \$3 billion in 2018;
    - b. Manufacturer Defendants have aggressively raised the list price of their insulin products absent significant advances in the efficacy of the drugs; and
    - c. Manufacturer Defendants only spend a fraction of their revenue related to the at-issue drugs on research and development—Eli Lilly spent \$395 million on R&D costs for Humalog, Humulin, and Basaglar between 2014-2018 during which time the company generated \$22.4 billion in revenue on these drugs. From 2016 to 2020, Novo Nordisk spent approximately \$29 billion on stock buybacks and shareholder

dividend payouts while only spending approximately \$12 billion on R&D costs.

349. 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 2021 Senate Insulin Report, summarizing Congress's findings from 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 From the Insulin Pricing Scheme.

- 1. Manufacturers Profit From the Insulin Pricing Scheme.
- 350. 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.
- 351. 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 From the Insulin Pricing Scheme.

- 352. 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 PBM and the pharmacy (i.e., Caremark-CVS pharmacy) these Defendants now capture an astonishing 40% 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.
- 353. PBM Defendants profit from the artificially inflated prices created by the Insulin Pricing Scheme in a myriad of 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 pharmacies

### 3. PBMs pocket most of the secret Manufacturer Payments.

- 354. The first way in which the PBMs profit from the Insulin Pricing Scheme is by keeping a significant portion of the secret Manufacturer Payments.
- 355. The amount that the Manufacturers pay back to the PBMs has accelerated to represent a large percentage of the list price of diabetes medications.

- 356. 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.
- 357. 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.
- 358. 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 move 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.
- 359. 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.
- 360. Notably, on June 17, 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.

- 361. In addition, the PBMs have come up with numerous ingenious methods to hide these renamed Manufacturer Payments in order keep them for themselves.
- 362. 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.
- 363. 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).
- 364. 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.
- 365. The PBMs set these "price protection guarantees" at a higher rate than the thresholds that trigger the Manufacturers' "inflation fees," usually around 12%-15%.

- 366. 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 the benefit of these price increases.
- 367. 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 Defendant Manufacturers, on behalf of a large group of pharmacy benefit managers (including the PBM Defendants) and different entities that contract for pharmaceutical drugs.
- 368. 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).
- 369. 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.
- 370. 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.

371. 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.

- 372. 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."
- 373. 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.

374. 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.

- 375. 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.
- 376. 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.

## 4. PBMs' profit from pharmacies.

377. A second way that PBM Defendants profit from 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 Kansas.

- 378. PBM Defendants decide which pharmacies are included in the PBM's network and how much they will reimburse these pharmacies for each drug dispensed.
- 379. 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).
- 380. PBMs do not disclose to their clients or network pharmacies how much the PBM is receiving from or paying to the other.
- 381. 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 Defendant Manufacturers inflate their prices, the more money the PBMs make off this spread.
- 382. PBMs also use the Insulin Pricing Scheme to generate additional profits from pharmacies by charging the pharmacies post-purchase fees, including DIR fees <sup>12</sup>, 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.

<sup>&</sup>lt;sup>12</sup> "DIR" fees are post-purchase concessions pharmacies pay back to the PBMs.

- 5. <u>Insulin Pricing Scheme increases PBM mail order and retail pharmacy profits.</u>
- 383. A third way PBMs profit from 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 residents in Kansas with diabetes and payors, to pay for diabetes medications, the higher the profits PBM Defendants realize through their mail order pharmacies.
- 384. During the relevant time period, the PBM Defendants' mail order and retail pharmacies dispensed the at-issue drugs to and were paid by residents in Kansas with diabetes based on the inflated list prices generated by the Insulin Pricing Scheme.
- 385. 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.
- 386. PBMs also charge the Manufacturer Defendants fees related to their mail order and retail pharmacies, such as pharmacy supplemental discount fees and indirect purchase fees, 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.
- 387. A third way PBMs profit from the false prices generated by the Insulin Pricing Scheme through their pharmacies 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.

388. 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. Defendants Deceived Kansas Diabetics.

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

## 1. <u>Manufacturer Defendants deceived Kansas Diabetics.</u>

- 390. At all times during the relevant time period, Manufacturer Defendants 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, Kansas diabetics and payors relied on the artificially inflated list prices by purchasing diabetic medications at such prices.
- 391. Manufacturer Defendants and PBM Defendants further knew that Kansas diabetics and payors expected and desired to pay the lowest fair-market price possible for the at-issue drugs.
- 392. Manufacturer Defendants 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.

- 393. 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.
- 394. Despite this knowledge, Manufacturer Defendants caused the artificially inflated list prices generated by the Insulin Pricing Scheme to be published throughout Kansas through publishing compendia and in various promotional and marketing materials distributed by entities downstream in the drug supply chain.
- 395. Manufacturer Defendants also published these prices to the PBMs and their pharmacies who then knowingly used the false prices to set the amount payors and diabetics pay for the at-issue drugs.
- 396. By publishing their prices throughout Kansas, the Manufacturer Defendants held these prices out as a reasonable price by which to base the prices diabetics and payors pay for the at-issue drugs.
- 397. 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.
- 398. Notably, during the relevant time period, the Manufacturer Defendants published prices in Kansas of \$300-\$400 for the same at-issue drugs they could have priced at less than \$2 and still been profitable.

- 399. 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 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 atissue price increases.
- 400. 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.
- 401. The Manufacturer Defendants' list prices were artificially inflated in furtherance of the Insulin Pricing Scheme to generate profits for the Manufacturer Defendants and PBM Defendants.
- 402. Manufacturer Defendants affirmatively withheld the truth from Kansas 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.

- 403. PBM Defendants ensured that the Manufacturer Defendants' artificially inflated list prices harmed diabetics and payors by selecting the highest price at-issue drugs for preferred formulary placement and by requiring that their contracts with both pharmacies and with payors include such prices as the basis for payment.
- 404. PBM Defendants perpetuate the use of the artificially inflated insulin prices because it allows them to obscure the actual price any entity in the drug pricing chain is paying for the at-issue drugs. This lack of transparency affords Defendants the opportunity to construct and perpetuate the Insulin Pricing Scheme, and to profit therefrom at the expense of Kansas residents with diabetes who need these live-saving drugs.

## 2. PBM Defendants deceived Kansas diabetics

- 405. PBM Defendants have deceived diabetics in Kansas.
- 406. Throughout the relevant time period, PBM Defendants have consistently and repeatedly represented publicly, in marketing and information sent direct to consumers and payors, 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.
- 407. PBM Defendants 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 and save lives.

- 408. 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.
- 409. 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:
  - a. In a public statement issued on May 11, 2010, CVS Caremark represented that it was focused on diabetes to "help us add value for our PBM clients and improve the health of plan members . . . a PBM client with 50,000 employees whose population has an average prevalence of diabetes could save approximately \$3.3 million a year in medical expenditures."
  - b. On June 22, 2010, Andrew Sussman, Chief Medical Officer of CVS Caremark stated on national television that "CVS is working to develop programs to hold down [diabetes] costs."
  - c. In a public statement issued in November 2012, CVS Caremark represented that formulary decisions related to insulin products "is one way the company helps manage costs for clients."
  - d. On August 31, 2016, Glen Stettin, Senior Vice President and Chief Innovation Officer at Express Scripts released a statement that stated "[d]iabetes is wreaking havoc on patients, and it is also a runaway driver of costs for payors . . . [Express Scripts] helps our clients and diabetes patients prevail over cost and care challenges created by this terrible disease."
    - i. Mr. Stettin continued on to represent that Express Scripts "broaden[s] insulin options for patients and bend[s] down the cost curve of what is currently the costliest class of traditional prescription drugs."

- e. In January 2017, Tim Wentworth, CEO of Express Scripts represented that "without PBMs, and specifically without Express Scripts, our clients would pay [many times] more for [insulin]."
  - i. Mr. Wentworth continued on to state Express Scripts is dedicated to controlling insulin prices because "we stand up for payers and patients."
- f. On June 1, 2018, Mark Merritt, President of the PCMA, in response to a question about PBMs' role in the insulin pricing system stated, "[Through their formulary construction], PBMs are putting pressure on drug companies to reduce insulin prices."
- g. CVS Caremark'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."
- h. 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."
- i. 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."
- 410. 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 of their intentional unconscionable and deceptive misrepresentations include:
  - a. Express Scripts' publicly available code of conduct states, "[a]t Express Scripts we're dedicated to keeping our promises to *patients* and clients . . . This commitment defines our culture, and all our collective efforts are focused on our mission to make the use of prescription drugs safer and more affordable." (Emphasis added).

- b. Amy Bricker, President at Express Scripts testified before Congress in April 2019, "At Express Scripts we negotiate lower drug prices with drug companies on behalf of our clients, *generating savings that are returned to patients* in the form of lower premiums and reduced out-of-pocket costs." (Emphasis added).
- c. Amy Bricker of Express Scripts also testified at the Congressional hearing that "Express Scripts remains committed to . . . patients with diabetes and creating affordable access to their medications." (Emphasis added).
- d. OptumRx's website has stated "[t]he services we provide help improve health outcomes for patients while making prescription drugs more affordable for plan sponsors and individuals, and more sustainable for the country . . . the reason is simple: drug manufacturers are responsible for the high cost of prescription drugs . . . OptumRx negotiates better prices with drug manufacturers for our customers and consumers . . . At OptumRx, our mission is helping people live healthier lives and to help make the health system work better for everyone." (Emphasis added).
- e. In its 2017 Drug Report, CVS Caremark stated that the goal of its pharmacy benefit plans is to ensure "that the cost of a drug is aligned with the value it delivers in terms of *patient* outcomes . . . in 2018, we are doing even more to help keep drugs affordable with our new Savings *Patients* Money initiative." (Emphasis added).
- f. The PCMA website states, "PBMs have kept average out-of-pocket (OOP) payments flat for beneficiaries with commercial insurance."
- 411. Not only have PBM Defendants intentionally misrepresented that they use their market power to save payors and diabetics money, but they have also specifically, knowingly, and falsely disavowed that their conduct drives the artificially inflated list prices higher. Examples of more of their falsehoods include:
  - a. On an Express Scripts' earnings call in February 2017, CEO Tim Wentworth stated, "Drugmakers set prices, and we exist to bring those prices down."
  - b. Larry Merlo, head of CVS Caremark sounded a similar refrain in February 2017, "Any suggestion that PBMs are causing prices to rise is simply erroneous."

- c. In 2017, Express Scripts' Wentworth went on CBS News to again argue that PBMs play no role in rising drug prices, stating that PBMs work to "negotiate with drug companies to get the prices down."
- d. During the April 2019 Congressional hearings, when asked if PBM-negotiated rebates and discounts were causing the insulin price to increase, OptumRx's Chief Medical Officer answered, "we can't see a correlation when rebates raise list prices."
- e. 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."
- 412. 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.
- 413. 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."
- 414. 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.
- 415. 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)

- 416. Throughout the relevant time period, the PBMs have made the foregoing misrepresentations consistently and directly to Kansas diabetics through member communications, formulary change notifications, and through extensive direct-to-consumer pull through efforts engaged in with the Manufacturers.
  - 417. The above stated PBM Defendants' representations are false.
- 418. Contrary to their representations that they lower the price of the at-issue drugs for diabetics and payors, PBM Defendants' 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.
- 419. 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.
- 420. In addition, diabetics that receive their medications from federal programs that do not utilize PBMs also pay significantly less. For example, in December 2020, the United States House of Representatives Committee on Oversight and Reform issued a Drug Pricing Investigation Report that found that federal health care programs that negotiate directly with the Manufacturers (such as the Department of Veterans Affairs), and thus are outside the PBM Defendants' scheme, paid \$16.7 billion less from 2011 through 2017 for the at-issue drugs than the Medicare Part D program which relies on the PBM Defendants to set their at-issue drug prices (and thus are victims of the PBMs' concerted efforts to drive up the list prices).

- 421. Contrary to PBM Defendants' representations that they work to promote the health of diabetics and as a direct result of the PBMs' conduct, 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.
- 422. Both PBM Defendants 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 Kansas diabetics. Both PBM Defendants and Manufacturer Defendants intended for Kansas residents with diabetes to rely on their misrepresentations.
- 423. Defendants concealed the falsity of these representations by closely guarding their pricing structures, agreements, and sales figures.
- 424. 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.
- 425. 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.

- 426. Each Defendant also conceals its unconscionable and deceptive conduct by signing confidentiality agreements with any entity in the supply chain who knows the actual prices of the at-issue drugs.
- 427. PBM Defendants have gone as far as suing governmental entities to block the release of details on their pricing agreements with Manufacturers and pharmacies.
- 428. Even when audited by payors, PBM Defendants often still refuse to disclose their agreements with Manufacturers and pharmacies, relying on overly broad confidentiality agreements, claims of trade secrets, and other broadly-claimed restrictions.
- 429. Each Defendant's effort to conceal its pricing structures for the at-issue drugs is evidence that each Defendant knows its conduct is unconscionable and deceptive.
- 430. To make matters worse, Kansas diabetics have no choice but to pay based on Defendants' artificially inflated list prices because they need these medications to live. Manufacturer Defendants make virtually all of the diabetes medications available in Kansas, and the PBM Defendants completely dominate the pharmacy pricing system and control nearly every Manufacturer Payment paid in the market.
- 431. 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 unconscionable and deceptive.

- 432. Kansas 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.
- 433. Kansas 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 unconscionable and deceptive.

## H. The Insulin Pricing Scheme Has Damaged Kansas Residents who Suffer from Diabetes.

- 434. PBM and Manufacturer Defendants have exploited the drug pricing and payment system to extract billions in profits at the expense of Kansas diabetics.
- 435. As discussed above, Kansas diabetics have been damaged by Defendants' Insulin Pricing Scheme by having to pay at least a portion of their at-issue purchases out-of-pocket based on Defendants' false prices generated by the Insulin Pricing Scheme.
- 436. If Defendants' prices were not falsely inflated as a result of the Insulin Pricing Scheme each of the above-described Kansas diabetics would have paid significantly less for the at-issue diabetes medications during the relevant time period.

Kansas Diabetics have been overcharged by millions of dollars as a result of the Insulin Pricing Scheme.

- 437. Whether insured or not, nearly all Kansas diabetics pay a substantial part of their diabetic drug costs based on Defendants' artificially inflated list prices and thus the Insulin Pricing Scheme has directly damaged residents in Kansas with diabetes.
- 438. In addition to financial losses, for many diabetics in Kansas, the Insulin Pricing Scheme has cost them their health and emotional well-being. Unable to afford Defendants' price increases, many diabetics in Kansas 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 Kansas healthcare system as a whole by burdening its resources and the Kansas economy by requiring additional millions of dollars of additional revenues to be spent.
- 439. 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.

- 440. 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.
- 441. The Insulin Pricing Scheme has pushed, and will continue to push, access to these lifesaving drugs out of reach for many diabetes patients in Kansas.
- 442. Because Kansas 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.

## I. Defendants' Recent Efforts in Response to Rising Insulin Prices.

- 443. In reaction to the mounting political and public pressure, Defendants recently have taken action, both on Capitol Hill and in the insulin marketplace.
- 444. 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.
- 445. Eli Lilly and Sanofi have directed millions of dollars through their PACs as well in recent years.
- 446. Likewise, the PBM Defendants have steadily increased their political spending for the past five years as public outcry has grown against them.
- 447. Defendants have also recently begun introducing programs ostensibly aimed at lowering the cost of insulins.

- 448. 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.
- 449. 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."
- 450. However, in the months after Eli Lilly's announcement, reports raised questions about the availability of "Insulin Lispro" in local pharmacies.
- 451. 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.
- 452. 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."
- 453. 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.

- 454. 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.
- 455. Thus, Defendants' "lower priced" insulin campaigns have not addressed the problem. Kansas diabetics and the State continue to suffer great harm as a result of the Insulin Pricing Scheme.

### VI. CLAIMS FOR RELIEF

#### FIRST CAUSE OF ACTION

# Kansas Consumer Protection Act, K.S.A. 50-623, et seq. (Against All Defendants)

- 456. The State re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.
- 457. The State brings this Kansas Consumer Protection Act (KCPA) claim against all Defendants on behalf of Kansas diabetics.
- 458. Defendants are "persons" and "suppliers" within the meaning of, and subject to, the provisions of the KCPA, K.S.A 50-624.
- 459. Kansas diabetics are "consumers" as defined in the KCPA, K.S.A 50-624(b).
- 460. The sale, pricing, and promotion of the at-issue drugs constitutes "consumer transaction" as defined under K.S.A 50-624(c).

- 461. By engaging in the Insulin Pricing Scheme, as described herein, Defendants have engaged in deceptive acts and practices as prohibited by the provisions of the KCPA, K.S.A 50-626(a) & (b), affecting and causing harm to Kansas diabetics, including but not limited to:
  - Knowingly making false representations as to the characteristics and benefits of goods and services. K.S.A 50-626(b)(1)(A) & (F).
    - A characteristic of every commodity in Kansas's economy is its price, which is represented by every seller to every buyer that the product being sold is being sold at a legal, competitive, and fair market value.
    - At no point did Defendants 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.
    - o 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 (research and developments costs) behind their artificially inflated prices.
    - 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.
    - o By granting the at-issue diabetes medications with the highest list prices preferred formulary positions, PBM Defendants ensured that prices generated by the Insulin Pricing Scheme would harm diabetics.
    - o PBM Defendants also made false representations that their formularies and the Manufacturer Payments they receive have the benefit and characteristic of lowering the price of the at-issue drugs and promoting the health of diabetics.

- Willfully using oral and written representations of exaggeration, falsehood, innuendo and ambiguity as to a material fact, K.S.A 50-626(b)(2).
- Willfully failing to state a material fact and concealing, suppressing, and omitting material facts, K.S.A 50-626(b)(3).
  - Manufacturer Defendants conceal the fact that their published prices were untethered from the actual, net prices they were paid for the atissue drugs.
  - PBM Defendants conceal the fact that their formularies and the Manufacturer Payments they receive are aimed at raising the price of the at-issue drugs and, as a result, damage the health of diabetics.
  - O Defendants conceal, suppress, and omit these material facts with the intent that diabetics and payors rely on these concealments, suppressions, and omissions in purchasing the at-issue drugs and utilizing the at-issue formularies.
- Making false or misleading representations, knowingly or with reason to know, of fact concerning the reason for, existence of or amounts of price reductions, or the price in comparison to prices of competitors or one's own price at a past or future time, K.S.A 50-626(b)(7).
  - o The PBM Defendants misrepresented that the false, inflated prices generated by the Insulin Pricing Scheme were the actual bona fide prices in order to make a deceptive comparison in representing the substantial "savings" that the PBMs generated for Kansas diabetics, payors and the Kansas healthcare system.
  - Defendants misrepresented that the Manufacturer Payments exchanged between them lowered the actual price of the at-issue drugs.
- Falsely stating, knowingly or with reason to know, the reasons for offering or supplying property and services at sale or discount prices, K.S.A 50-626(b)(10).
- Defendants continue to make these misrepresentations and publish prices generated by the Insulin Pricing Scheme; diabetics continue to purchase diabetes medications at Defendants' prices as a result of the ongoing Insulin Pricing Scheme.

- 462. Defendants made these misrepresentations with the intent to deceive Kansas diabetics.
- 463. Defendants' representations are false, and at all relevant times Defendants knew they were false.
- 464. 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 their expectation was to pay a legal, competitive and fair market price that resulted from transparent market forces.
- 465. Defendants' also engaged in conduct that constituted unconscionable practices within the meaning of K.S.A 50-627(a) & (b), including but not limited to:
  - Defendants knowingly "took advantage of the inability of the consumer reasonably to protect the consumer's interests because of the consumer's physical infirmit[ies]." K.S.A 50-627(b)(1). In particular, Defendants knew that Kansas diabetics needed the at-issue drugs to stay alive, and because the Manufacturers make nearly all of the products available in the diabetes market, and because the PBM Defendants dominate the at-issue drug pricing market, Kansas diabetics had no choice but to purchase the at-issue drugs at the egregiously inflated prices.
  - Defendants knew "at the time the consumer transaction was entered into, the price grossly exceeded the price at which similar property or services were readily obtainable in similar transactions by similar consumers" in other markets. K.S.A 50-627(b)(2). In particular, Kansas diabetics pay far more for the at-issue drugs at prices based on the false, inflated list prices generated by the Insulin Pricing Scheme than Kansas diabetics in federal programs that negotiate directly with the Manufacturers, (such as the Department of Veterans Affairs) or diabetics in Canada or Europe.

"[T]he transaction [Defendants] induced [Kansas diabetics] to enter into was excessively one-sided in favor of [Defendants]." K.S.A 50-627(b)(5). Defendants knew Kansas diabetics needed the at-issue drugs to stay

- alive. Defendants also knew Kansas diabetics had no choice but to purchase the at-issue drugs at the egregiously inflated prices because the Manufacturers make nearly all of the products available in the diabetes market, and because the PBM Defendants dominate the at-issue drug pricing market.
- Defendants, acting as suppliers, "made a misleading statement of opinion," by representing the price for at-issue drugs as the legitimate price or a good value. Kansas consumers were "likely to rely" on Defendants' statements "to the consumer's detriment." K.S.A 50-627(b)(6).
- 466. Defendants acted knowingly and in a willful, wanton or reckless disregard for the safety of others in committing the violations of the KCPA.
- 467. Each at-issue purchase Kansas diabetics made for diabetes medications at the prices generated by the Insulin Pricing Scheme constitutes a separate violation of the KCPA.
- 468. Defendants' acts or practices caused injuries to consumers in the State of Kansas.
- 469. In addition, the imposition of an injunction against Defendants prohibiting the conduct set forth herein is in the public interest, and the State is seeking the entry of an injunction prohibiting Defendants' conduct in violation of the KCPA.
- 470. As a 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, and penalties for which recovery is sought herein.

471. The State seeks an injunction against Defendants to prevent future unconscionable and deceptive practices under the KCPA.

# SECOND CAUSE OF ACTION Unjust Enrichment (Against All Defendants)

- 472. The State re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.
- 473. Defendants knowingly, willfully, and intentionally deceived Kansas diabetics and have received a financial windfall from the Insulin Pricing Scheme at the expense of Kansas diabetics.
- 474. The elements of an unjust enrichment claim are: (1) a benefit conferred upon the defendant by the plaintiff; (2) an appreciation or knowledge of the benefit by the defendant; and (3) the acceptance or retention by the defendant of the benefit under such circumstances as to make it inequitable for the defendant to retain the benefit without payment of its value. *Haz-Mat Response, Inc. v. Certified Waste Services Ltd.*, 259 Kan. 166, 177, 910 P.2d 839 (1996).
- 475. Defendants wrongfully secured and retained unjust benefits—with knowledge and appreciation of the benefits—from Kansas 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.
- 476. It is inequitable and unconscionable for Defendants to retain these benefits.
- 477. Defendants knowingly accepted the unjust benefits of their unconscionable and deceptive conduct.

- 478. Defendants have been enriched by revenue resulting from the Insulin Pricing Scheme while Kansas diabetics have been impoverished by Defendants' misconduct. Defendants' enrichment directly caused Kansas diabetics' impoverishment.
- 479. Accordingly, Defendants should not be permitted to retain the proceeds from the benefits conferred upon them by the Insulin Pricing Scheme. The State seeks disgorgement of Defendants' unjustly acquired profits and other monetary benefits resulting from their unlawful conduct and seeks restitution and recission, in an equitable and efficient fashion to be determined by the Court.
- 480. There is no express contract governing the dispute at-issue. PBMs do not contract with Kansas diabetics on an individual drug basis. The State's claims do not arise out of a written contract, but rather are based on the larger unconscionable and deceptive Scheme that drove up the at-issue artificially inflated list prices for all Kansas diabetics.
- 481. As a direct and proximate cause of Defendants' unjust enrichment, as referenced above, Kansas diabetics suffered, and continue to suffer, ascertainable losses and damages as specified herein in an amount to be determined at trial.

## THIRD CAUSE OF ACTION

# Civil Conspiracy (Against All Defendants)

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

- 483. Defendants' conduct described herein constitutes a civil conspiracy and aiding and abetting each other to violate the KCPA and to commit unjust enrichment.
- 484. The elements of a civil conspiracy are: (1) two or more persons; (2) an object to be accomplished; (3) a meeting of the minds in the object or cause of action; (4) one or more unlawful overt acts; and (5) damages as the proximate result thereof. Stoldt v. City of Toronto, 234 Kan. 957, Syl. ¶ 5, 678 P.2d 153 (1984).
- 485. As demonstrated above, the PBMs and Manufacturers, with the object of increasing the profits they each made from the at-issue drugs, agreed to participate in the unfair, deceptive, and unconscionable Insulin Pricing Scheme. Kansas diabetics were harmed as the proximate result thereof.
- 486. 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 Manufacturer Defendants 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.
- 487. As a direct result of the overt acts taken in furtherance of Defendants' conspiracy, residents in Kansas with diabetes 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 State respectfully requests a trial by jury on all issues so triable.

#### VIII. PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, the State of Kansas, *ex rel*. Derek Schmidt, Attorney General, respectfully requests that this Honorable Court enter an Order:

- A. Adjudging and decreeing that Defendants have engaged in acts or practices complained of herein, and that such constitute unconscionable acts or practices in violation of the Kansas Consumer Protection Act, that Defendants were unjustly enriched at the expense of Kansas diabetics, Defendants' misconduct damaged the State, and that Defendants engaged in a civil conspiracy;
- B. Issuing an injunction prohibiting Defendants, their agents, servants, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in deceptive and unconscionable trade practices;
- C. Ordering Defendants to make such financial payments as are authorized by law, including but not limited to damages and restitution that may be owed to Kansas diabetics and the State;
- D. Imposing civil penalties to be paid to the State by Defendants in an amount of up to \$10,000 for each violation of the KCPA;
- E. Ordering Defendants to pay all costs and attorney's fees for the prosecution and investigation of this action;

- F. Awarding punitive damages pursuant to K.S.A 60-3701 because Defendants acted knowingly, willfully, intentionally, and with actual malice toward the State and its citizens, harming the health, wellbeing and financial interests of diabetic Kansans and the State;
- G. Awarding pre-and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of the Petition; and
- H. Awarding such other, further, and different relief as the case may require and the Court may deem just and proper under the circumstances.

Respectfully submitted,

OFFICE OF ATTORNEY GENERAL DEREK SCHMIDT

B<sub>v</sub>.

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