# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: INSULIN PRICING LITIGATION

CLARK COUNTY,

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; EXPRESS SCRIPTS PHARMACY, INC.: MEDCO HEALTH SOLUTIONS, INC.; THE CIGNA **GROUP; CVS HEALTH** CORPORATION; CVS PHARMACY, INC; CAREMARK RX, L.L.C.; CAREMARKPCS HEALTH, L.L.C.; CAREMARK, L.L.C.; UNITEDHEALTH GROUP, INC.; OPTUM, INC.; OPTUMRX INC.,

Defendants.

Case No. 2:23-md-03080 (BRM)(RLS) MDL No. 3080

JUDGE BRIAN R. MARTINOTTI JUDGE RUKHSANAH L. SINGH

DIRECT-FILED COMPLAINT PURSUANT TO CASE MANAGEMENT ORDER NO. 9

Civil Action No.

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Pursuant to this Court's Case Management Order No. 9, the "Designated Forum"—the federal district court in which Plaintiff would have filed its case in the absence of direct filing—is the United States District Court for the Western District of Washington. Plaintiff Clark County, by and through its undersigned attorneys, brings this action against Defendants Novo Nordisk Inc. ("Novo Nordisk"); Eli Lilly and Company ("Eli Lilly"); Sanofi-Aventis U.S. LLC ("Sanofi"); CVS Health Corporation; CVS Pharmacy, Inc.; Caremark Rx, L.L.C.; CaremarkPCS Health, L.L.C.; Caremark Rx, Inc. (together with CVS Health Corporation, CVS Pharmacy Inc., CaremarkPCS Health, L.L.C., and Caremark Rx, L.L.C., "CVS Caremark"); Express Scripts, Inc.; Express Scripts Administrators, LLC; Express Scripts Pharmacy, Inc.; Evernorth Health, Inc. (formerly Express Scripts Holding Company); Medco Health Solutions, Inc.: The Cigna Group (together with Express Scripts, Inc., Express Scripts Administrators, LLC, Express Scripts Pharmacy, Inc., Evernorth Health, Inc., and Medco Health Solutions, Inc., "Express Scripts"); UnitedHealth Group, Inc.; Optum, Inc.; OptumRx, Inc., (together with UnitedHealth Group, Inc. and Optum, Inc., "OptumRx"), and allege as set forth below.

#### I. INTRODUCTION

1. The three largest pharmacy benefit managers in the United States—

CVS Health, Express Scripts, and OptumRx (the "PBM Defendants")—engage in

unfair and deceptive conduct designed to artificially inflate the list price of insulin and other diabetes medications and extract ever-larger portions of rebates and other payments from the three largest insulin manufacturers—Eli Lilly, Novo Nordisk, and Sanofi (the "Manufacturers" or the "Manufacturer Defendants"). The Manufacturer Defendants, seeking to secure preferential or exclusionary placement on the PBM Defendants' drug formularies, have paid the PBM Defendants ever-increasing rebates, fees, and kickbacks and have inflated the list prices of rapid- and long-acting analog insulins, human insulin drugs, and other diabetes medications to fund these rebates, fees, and kickbacks.

- 2. The PBM Defendants and Manufacturer Defendants conspired to prevent disclosure of this scheme by obscuring the true price of insulin, the amount and nature of rebates and fees paid by the Manufacturer Defendants to the PBM Defendants in exchange for preferred formulary placement, and the fraction of rebates passed through to clients and health plan payors. This misconduct, and the misconduct described below, is referred to herein as the Insulin Pricing Scheme.
- 3. Defendants' Insulin Pricing Scheme directly and foreseeably causes payors like Clark County to overpay for these life-saving medications. Thus, this action is brought to redress Plaintiff's injuries flowing from Defendants' Insulin Pricing Scheme—which has driven up the price of insulin to the substantial benefit of PBMs and insulin manufacturers—and to obtain prospective injunctive relief to

curtail Defendants' practices, provide greater transparency in insulin pricing, and lower the price health plans and consumers pay for insulin going forward.

- 4. Over the past twenty years, the prices paid by consumers and health plan payors, like Clark County, for diabetes medications have skyrocketed—the prices of some diabetes medications have risen more than tenfold.¹ In contrast, the average cost of consumer goods and services has merely doubled during the same period. The surging costs of diabetes medications are not due to competitive market forces or climbing expenditures on goods, production, or research and development. Defendants have engineered these escalating prices to exponentially increase their profits at the expense of payors, like Plaintiff, and their plan beneficiaries.
- 5. Diabetes is an epidemic in the United States. In total, nearly forty million people, or 11.6% of the country, live with diabetes.<sup>2</sup> Of this number, approximately six million people rely on daily insulin treatments to survive. In addition to natural or synthetic human insulin, several analogs of human insulin have been developed since the mid-1990s. These insulin analogs act more rapidly and for

<sup>&</sup>lt;sup>1</sup> Brenna Miller, *After Decades of Profiteering, Insulin Manufacturer Finally Cuts the Price*, Lown Inst. (Mar. 2, 2023), <a href="https://lowninstitute.org/after-decades-of-profiteering-insulin-manufacturer-finally-cuts-the-price/#:~:text=Just%20twenty%20years%20later%2C%20the,rationing%20or%20foregoing%20their%20medication.">https://lowninstitute.org/after-decades-of-profiteering-insulin-manufacturer-finally-cuts-the-price/#:~:text=Just%20twenty%20years%20later%2C%20the,rationing%20or%20foregoing%20their%20medication.</a>

<sup>&</sup>lt;sup>2</sup> Am. Diabetes Assoc., *Statistics About Diabetes*, Diabetes.org, <a href="https://diabetes.org/about-diabetes/statistics/about-diabetes">https://diabetes.org/about-diabetes/statistics/about-diabetes</a> (last visited May 29, 2024).

a longer period of time than earlier developed drugs, making them potentially more convenient and effective for patients.

6. Interruptions to or interference with insulin therapy (e.g., cutting back insulin use due to cost) lead to severe consequences, including sustained damage to the kidneys, heart, nerves, eyes, feet, and skin. Indeed, diabetes is the leading cause of kidney failure, adult-onset blindness, and lower-limb amputations in the United States.<sup>3</sup> Missed or inadequate insulin therapy can leave people with diabetes with too little insulin in their system, triggering hyperglycemia (hyperosmolar hyperglycemic state or "HHS") followed by diabetic ketoacidosis ("DKA"). Left untreated, DKA can lead to loss of consciousness and death within days.<sup>4</sup> DKA is responsible for more than 500,000 hospital days per year in the United States, and the annual hospital cost for patients with DKA is approximately \$2.4 billion.<sup>5</sup>

<sup>&</sup>lt;sup>3</sup> *Diabetes Basics*, Ctrs. for Disease Control and Prevention (May 14, 2024), <a href="https://www.cdc.gov/diabetes/about/?CDC\_AAref\_Val=https://www.cdc.gov/diabetes/basics/diabetes.html">https://www.cdc.gov/diabetes/basics/diabetes.html</a>.

<sup>&</sup>lt;sup>4</sup> *Diabetic Ketoacidosis*, Mayo Clinic: Diseases and Conditions, <a href="http://www.mayoclinic.org/diseases-conditions/diabetic-ketoacidosis/basics/definition/con-20026470">http://www.mayoclinic.org/diseases-conditions/diabetic-ketoacidosis/basics/definition/con-20026470</a> (last visited May 29, 2024).

<sup>&</sup>lt;sup>5</sup> Abbas E. Kitabchi, *et al.*, *Hyperglycemic Crises in Adult Patients with Diabetes*, 32 Diabetes Care 7, 1335–1343 (2009), <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2699725/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2699725/</a>.

According to the Centers for Disease Control and Prevention, the total annual cost of diabetes in the U.S. is \$327 billion.<sup>6</sup>

- 7. The amount consumers and health plan payors spend on these medications is in addition to the hundreds of dollars people living with diabetes must spend every year on diabetes management supplies (e.g., test strips and glucose meters used to read blood sugar levels and syringes, pen needles, infusion sets, and/or pods needed to administer insulin). In short, living with diabetes now costs more than \$1,000 per month per patient, resulting in significant costs to individuals and payors like Plaintiff, who cover some or all costs of such care.<sup>7</sup>
- 8. From 2021 through 2023 alone, diabetes cost an estimated \$6.7 billion in Washington State. In 2021, more than 530,000 Washingtonians—9% of the adult population—had a diagnosis of diabetes. In 2021, over 690,000 Washingtonians—11% of the adult population—had a diagnosis of prediabetes. The Washington

<sup>&</sup>lt;sup>6</sup> Health and Economic Benefits of Diabetes Interventions, Ctrs. for Disease Control and Prevention (May 15, 2024), <a href="https://www.cdc.gov/nccdphp/priorities/diabetes-interventions.html?CDC\_AAref\_Val=https://www.cdc.gov/chronicdisease/programs-impact/pop/diabetes.htm">https://www.cdc.gov/chronicdisease/programs-impact/pop/diabetes.htm</a>.

<sup>&</sup>lt;sup>7</sup> Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug, U.S. S. Fin. Comm., <a href="https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf">https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf</a> (last visited May 29, 2024).

<sup>8</sup> Diabetes Epidemic & Action Report, Wash. Dep't Health, at 4 (Dec. 2023), <a href="https://doh.wa.gov/sites/default/files/2024-01/140255-DiabetesEpidemicAction">https://doh.wa.gov/sites/default/files/2024-01/140255-DiabetesEpidemicAction</a> Report-20240124.pdf.

<sup>&</sup>lt;sup>9</sup> *Id*.

<sup>&</sup>lt;sup>10</sup> *Id*.

Department of Health crucially notes, however, that it is "very likely that many people in Washington may not know they are prediabetic," suggesting this figure is likely a significant undercount.<sup>11</sup>

- 9. In Clark County, whose residents comprise nearly 7% of the state's population, the incidence of diabetes is similar, with approximately 9% of adults having been diagnosed. Since 2014, Plaintiff has spent over \$3.3 million on the atissue drugs.<sup>12</sup>
- 10. Defendants Eli Lilly, Novo Nordisk, and Sanofi manufacture insulins, analog insulins, and other medications used to treat diabetes. In 2020, as in years past, the three Manufacturer Defendants controlled 92% (by volume) and 96% (by revenue) of the global market for diabetes drugs.<sup>13</sup>
- 11. Between 2004 and 2022, each Manufacturer has raised the list prices of their respective at-issue drugs in an astounding and inexplicable manner. For example, between 2004 and 2006, four of the main analog insulins—Levemir, Novolog, Lantus, and Humalog—cost consumers between \$50 and \$75 per prescription. In 2022, the cost per prescription for those drugs was between \$275

<sup>&</sup>lt;sup>11</sup> *Id*.

<sup>&</sup>lt;sup>12</sup> The at-issue drugs are listed in a chart at the beginning of the Factual Allegations.

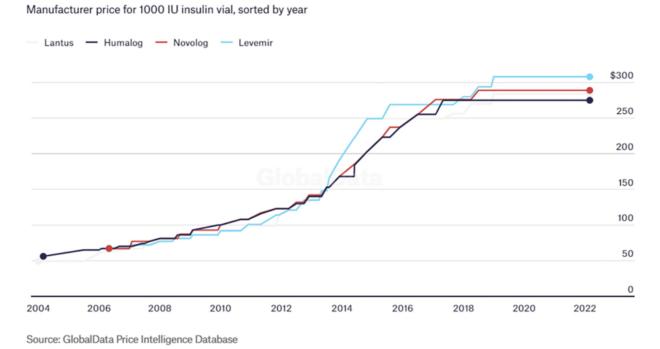
<sup>&</sup>lt;sup>13</sup> William Herman & Shihchen Kuo, 100 years of insulin: Why is insulin so expensive and what can be done to control its cost, Endocrinol Metab. Clin. North Am., (Sept. 2021), at e21.

<sup>&</sup>lt;sup>14</sup> See infra ¶ 12.

and \$308. Between 2004 and 2022, Eli Lilly, Novo Nordisk, and Sanofi have raised their list prices for analog insulins by more than 150%. 15

12. Eli Lilly, Novo Nordisk, and Sanofi's analog insulin price increases have been both rapid and in lockstep for years, as shown below:<sup>16</sup>

#### Comparison of Analog Insulin Price Increases—Lantus, Humalog, Novolog, and Levemir, 2004-2022



13. These rapid and lockstep price increases are seen across all at-issue drugs.

<sup>&</sup>lt;sup>15</sup> *Id*.

<sup>&</sup>lt;sup>16</sup> William Newton, *Insulin pricing: could an e-commerce approach cut costs?*, Pharm. Tech. (Mar. 31, 2022), <a href="https://www.pharmaceutical-technology.com/features/insulin-pricing-could-an-e-commerce-approach-cut-costs/">https://www.pharmaceutical-technology.com/features/insulin-pricing-could-an-e-commerce-approach-cut-costs/</a>; see also Robert Langreth, *Hot Drugs Show Sharp Price Hikes in Shadow Market*, Bloomberg (May 6, 2015), <a href="https://www.bloomberg.com/news/articles/2015-05-06/diabetes-drugs-compete-with-prices-that-rise-in-lockstep">https://www.bloomberg.com/news/articles/2015-05-06/diabetes-drugs-compete-with-prices-that-rise-in-lockstep</a>.

- 14. The skyrocketing cost of insulin cannot be explained away by the drug companies' typical rationalizations for high prices. Indeed, the manufacturers admit that their price hikes are unrelated to any increase in production or research and development costs. Instead, the inflated list prices result from the Insulin Pricing Scheme.
- 15. In furtherance of this scheme, the Manufacturer Defendants effectively set two different prices for the at-issue drugs: a publicly-available "list" price, which serves as the basis for what health plans and consumers pay for insulin, and an undisclosed, lower "net" price that reflects what Manufacturer Defendants actually receive after accounting for their rebates and other kickbacks to the PBM Defendants. The gap between the "list" price and the "net" price of these medications has increased significantly in the last twenty years.<sup>17</sup> This widening gap means that health plan payors, like Plaintiff, pay ever-increasing amounts for the at-issue drugs.
- 16. Defendants CVS Caremark, Express Scripts, and OptumRx are pharmacy benefit managers that, together with the Manufacturer Defendants, dictate the availability and price of the at-issue drugs for most of the U.S. market. The PBM Defendants serve as both middlemen and gatekeepers between drug manufacturers on one side, and health insurers, payors, and patients on the other. The PBM

<sup>&</sup>lt;sup>17</sup> See, e.g., Adam Fein, Five Top Drugmakers Reveal List vs. Net Price Gaps (Plus: The Trouble With Insulin Prices), Drug Channels (Aug. 11, 2020), <a href="https://www.drugchannels.net/2020/08/five-top-drugmakers-reveal-list-vs-net.html">https://www.drugchannels.net/2020/08/five-top-drugmakers-reveal-list-vs-net.html</a>

Defendants control nearly 80% of the PBM market; additionally, they own three of the largest pharmacies in the United States (three of the top five dispensing pharmacies) and are housed within the same corporate families as three of the largest insurance companies in the United States—Aetna (CVS Health), Cigna (Express Scripts), and UnitedHealthcare (OptumRx). Together, the PBM Defendants report more than \$300 billion a year in revenue.

- 17. Indeed, for transactions where the PBM Defendants also control the insurer and the pharmacy (e.g., Aetna–Caremark–CVS Pharmacy), these middlemen capture as much as half of the money spent on each insulin prescription, even though they contribute nothing to the development, manufacture, or innovation of the drugs.<sup>18</sup>
- 18. The PBM Defendants establish national formulary offerings, which are lists of medications covered by health plans which influence which drugs patients use and determine out-of-pocket costs. The PBM Defendants develop and control these formularies, and are therefore able to extract rebates, fees, and discounts from the Manufacturer Defendants in exchange for favorable or exclusive formulary placement.

<sup>&</sup>lt;sup>18</sup> Testimony of Karen Van Nuys before the U.S. S. Fin. Comm. (Mar. 30, 2023), at 4, <a href="https://www.finance.senate.gov/imo/media/doc/Van%20Nuys%20Senate%20Finance%20Committee%20Statement%2003.27.23.pdf">https://www.finance.senate.gov/imo/media/doc/Van%20Nuys%20Senate%20Finance%20Committee%20Statement%2003.27.23.pdf</a>.

19. Formularies also include a ranked list of drugs, with each drug placed into a "tier" dictating the cost and resulting accessibility to consumers. Health plans rely on these formularies to determine what proportion of their members' drug costs they will cover; for higher formulary tiers, plan members will pay the highest copay. Drugs in lower, "preferred" formulary tiers are supposed to be cheaper for plan members.<sup>19</sup>

Drug tier	Type of drugs included	Your cost
Tier 1	Most generic drugs	Lowest copay
Tier 2	Most common brand name drugs  Preferred brand name drugs  Some high-cost generic drugs	Medium copay
Tier 3	Non-preferred brand name drugs	Highest copay
Tier 4 (Specialty Tier)	Unique or very high-cost drugs	Percentage of total drug cost, called "coinsurance"

20. Where two medicines are largely interchangeable, a pharmacy benefit manager will sometimes exclude the more expensive of the two from its formulary—again purportedly based on the price of the drug for patients. When a drug is excluded from or disfavored in the formulary, health insurers using that formulary will either not cover any portion of the cost of the drug or require their members to

<sup>&</sup>lt;sup>19</sup> See What is a tiered formulary and what does it mean for me?, UnitedHealthcare, <a href="https://www.uhc.com/news-articles/medicare-articles/what-is-a-tiered-formulary-and-what-does-it-mean-for-me">https://www.uhc.com/news-articles/medicare-articles/what-is-a-tiered-formulary-and-what-does-it-mean-for-me</a> (last visited May 29, 2024).

pay a larger coinsurance amount. As a result, exclusionary formularies enable pharmacy benefit managers, including the PBM Defendants here, to push patients toward certain brands of drugs over others. This power gives pharmacy benefit managers enormous control over drug purchasing behavior as well as leverage over drug manufacturers.

21. While the PBM Defendants could use their considerable market power to drive down drug prices by forcing drug manufacturers to compete on price for formulary placement, instead, they and the Manufacturer Defendants figured out a way to game the system for their mutual benefit. To gain formulary access, the Manufacturer Defendants raised their published list prices and then "rebate" a significant portion of the list price to the PBM Defendants. The rebates<sup>20</sup> are provided under a variety of labels—discounts, credits, concession fees, etc. But however they are described, they are a quid pro quo for formulary inclusion or placement.<sup>21</sup>

<sup>&</sup>lt;sup>20</sup> In the context of this Complaint, "rebates" should be understood to include all payments, fees, or financial benefits of any kind conferred by the Manufacturer Defendants to the pharmacy benefit managers, either directly via contract or indirectly via Manufacturer or pharmacy benefit manager-controlled intermediaries. But the actual "Manufacturer Payments" are distinct from and much larger than "Payor Rebates," which in some cases are required by contract to be provided to health plans by their respective pharmacy benefit managers.

<sup>&</sup>lt;sup>21</sup> See, e.g., Linda Cahn, Don't Get Trapped By PBMs' Rebate Labeling Games, Managed Care (Jan. 2009), <a href="https://web.archive.org/web/20170624235524/https://www.managedcaremag.com/archives/2009/1/don-t-get-trapped-pbms-rebate-labeling-games">https://web.archive.org/web/20170624235524/https://www.managedcaremag.com/archives/2009/1/don-t-get-trapped-pbms-rebate-labeling-games</a>.

- 22. The result of this rebate scheme is a significant difference between the list price set by the Manufacturer Defendants, and the net price realized by the manufacturers once all rebates paid to the PBM Defendants are taken into account. The PBM Defendants may pass a portion of the rebates on to their insurer clients (some of which are owned by or affiliated with them) and pocket the rest. The greater the rebate, the more the PBM Defendants pocket. Although the true rebate amounts are unknown, the difference between the list price and the net price suggest that the rebates may be as great as, or even greater than, 50% of the list price.
- 23. While the PBM Defendants' contracts imply that such rebates benefit consumers and health plan payors such as Plaintiff, in reality, the rebates that the PBM Defendants pass along ("Payor Rebates") are a fraction of the rebates and other fees the PBM Defendants actually received from the manufacturers ("Manufacturer Payments"). The total amount and nature of the Manufacturer Payments, the amount the PBM Defendants pocket, and the amount the PBM Defendants pass through to clients/payors are all carefully guarded secrets. The true nature of the scheme is thus concealed from patients and health plan payors, such as Plaintiff.
- 24. This rebate scheme creates a "best of both worlds" scenario for the Defendants. The PBM Defendants obtain ever larger rebates in exchange for granting access to the exclusionary formularies, increasing their take, and the Manufacturer Defendants increase their list prices so they can pay the rebates to the

PBM Defendants without cutting into their profit margins. In effect, the quid pro quo arrangement between the PBM Defendants and Manufacturer Defendants creates a price war in reverse. The Manufacturer Defendants keep raising their list prices, so that they can pay larger and larger "rebates" to the PBM Defendants. One astute commentator refers to this as "bubblenomics." The "gross-to-net bubble"—that is, the gap between sales based on the list prices and sales based on the net prices of drugs—was \$204 billion in 2021 for patent-protected brand name drugs. 23

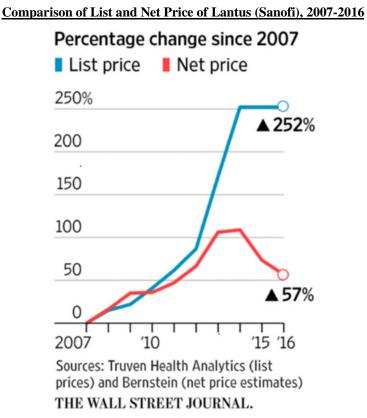
25. The result of the scheme is an ever-widening gap between the publicly available Manufacturer list price, which determines what consumers and health plans pay, and the net realized price actually received by Manufacturer Defendants. The following chart shows this gap for Lantus, Sanofi's top-selling analog insulin.<sup>24</sup>

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<sup>&</sup>lt;sup>22</sup> Adam J. Fein, *Novo Nordisk Sheds New Light on PBM Rebates, the Gross-to-Net Bubble, and Warped Channel Incentives*, Drug Channels (Dec. 6, 2016), <a href="http://www.drugchannels.net/2016/12/novo-nordisk-sheds-new-light-on-pbm.html">http://www.drugchannels.net/2016/12/novo-nordisk-sheds-new-light-on-pbm.html</a>.

<sup>&</sup>lt;sup>23</sup> Adam J. Fein, *Warped Incentives Update: The Gross-to-Net Bubble Exceeded* \$200 Billion in 2021, Drug Channels (Mar. 22, 2022), <a href="https://www.drugchannels.net/2022/03/warped-incentives-update-gross-to-net.html">https://www.drugchannels.net/2022/03/warped-incentives-update-gross-to-net.html</a>.

<sup>&</sup>lt;sup>24</sup> Denise Roland & Peter Loftus, *Insulin Prices Soar While Drugmakers' Share Stays Flat*, Wall St. J. (Oct. 7, 2016), <a href="https://www.wsj.com/articles/insulin-prices-soar-while-drugmakers-share-stays-flat-1475876764">https://www.wsj.com/articles/insulin-prices-soar-while-drugmakers-share-stays-flat-1475876764</a>.



26. And in more recent years, the gap has continued to widen, as confirmed by Eli Lilly and Sanofi's own reports:<sup>25</sup>

<sup>&</sup>lt;sup>25</sup> Eli Lilly and Company, *Twenty Nineteen Eli Lilly and Company Integrated Summary Report*, <a href="https://assets.ctfassets.net/srys4ukjcerm/4OhD66szgxpdHhhCqzE2Ev/983bd8407c49928f309936e1161bec47/Lilly-2019-Integrated-Summary-Report.pdf#page=23">https://983bd8407c49928f309936e1161bec47/Lilly-2019-Integrated-Summary-Report.pdf#page=23</a>; Sanofi, *Sanofi: 2023 Pricing Principles Report*, <a href="https://www.sanofi.com/assets/dotcom/pages/docs/investor-relations/environmental-social-governance/Sanofi-2023-Pricing-Principles-Report.pdf">https://www.sanofi.com/assets/dotcom/pages/docs/investor-relations/environmental-social-governance/Sanofi-2023-Pricing-Principles-Report.pdf</a>.

#### Comparison of List and Net Price of Humalog (Eli Lilly), 2015-2019

#### Humalog List and Net Price Per Vial<sup>4</sup>

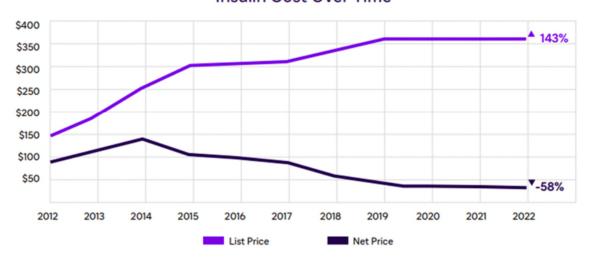




The last list price increase for Humalog vial was May 2017. The net price in the chart represents the revenue Lilly realized per Humalog and Insulin Lispro vial after rebates and discounts. Increases in list prices do not always create increases in net prices.

#### Comparison of List and Net Price of Sanofi Insulin, 2012-2022

#### Insulin Cost Over Time



27. The PBM Defendants tout their market power to drive down drug prices. They boast about the "rebates" or "discounts" they bargain with drug manufacturers. The story they tell is that these rebates and discounts are obtained for the benefit of patients since they purportedly result in lower costs for prescription

drugs. For example, Cigna, which owns Express Scripts Holding, claims, "[w]e consult with our clients on how best to structure and leverage the pharmacy benefit to meet plan objectives for affordable access to the prescription medications customers need to stay healthy and to ensure the safe and effective use of those medications."<sup>26</sup>

- 28. CVS Health Corp. contends it "assists its PBM clients in designing pharmacy benefit plans that help improve health outcomes while minimizing the costs to the client."<sup>27</sup>
- 29. OptumRx claims that its PBM businesses "improve overall health system performance by optimizing care quality and delivery, reducing costs and improving consumer and provider experience, leveraging distinctive capabilities in data and analytics, pharmacy care services, health care operations, population health and health care delivery."<sup>28</sup>
- 30. But the story the PBM Defendants tell is far from the whole truth. While it is true that they obtain rebates and discounts, they neglect to reveal the large portion of these payments that they pocket. They also neglect to reveal that their formulary decisions are based on the amount of the rebates paid by drug manufacturers, including the Manufacturer Defendants, even if other, lower-priced

<sup>&</sup>lt;sup>26</sup> The Cigna Group Annual Report (Form 10-K) (Feb. 23, 2023) at 5.

<sup>&</sup>lt;sup>27</sup> CVS Health Corp., Annual Report (Form 10-K) (Feb. 8, 2023) at 8.

<sup>&</sup>lt;sup>28</sup> UnitedHealth Group, Annual Report (Form 10-K) (Feb. 24, 2023) at 1.

alternatives exist. And they neglect to reveal that the consequence of this scheme is higher drug costs for payors like Clark County, whose payments (like the payments of their health plan beneficiaries) are calculated based on the list price (i.e., average wholesale price), not the lower "net" price actually received by the Manufacturer Defendants once all rebates and other payments to PBM Defendants are taken into account. Indeed, the PBM Defendants misrepresent the role they play in the supply chain, and their impact on the prices actually paid by health plan payors like Plaintiff for drugs.

- 31. The PBM Defendants are avaricious middlemen, with a stranglehold on the prescription drug supply chain. Their scheme to sell formulary access for rebates drives up the cost of prescription drugs for the people who need to use them to stay alive. This scheme serves one simple purpose for the PBM Defendants—to make more money.
- 32. The Manufacturer Defendants are equally at fault. Their conduct deprives patients of a fair price—a price that would result from the operation of normal market forces. Through the scheme, they maintain the ability to sell the atissue medications to the millions of Americans who depend on them, without having to lower the "real," net prices to gain market share. They bargain for market share by providing ever-larger rebates to the PBM Defendants and entering into exclusive relationships with those PBM Defendants, inflating the prices paid by consumers

and health plan payors in order to preserve their net realized price and to ensure that they maximize the number of individuals and payors like Clark County who continue purchasing the insulin they manufacture. The Manufacturer Defendants' refusal to disclose their net realized prices for insulins and the web of confidentiality agreements they have created and/or participated in with PBM Defendants have been critical to the furtherance of the Insulin Pricing Scheme.

33. Recognizing the growing discrepancy between published list prices and net prices, a New York Times op-ed called for transparency in setting prices:

In the meantime, we need a fair and transparent system for setting prices. In much of Europe, insulin costs about a sixth of what it does here. That's because the governments play the role of pharmacy benefit managers. They negotiate with the manufacturer directly and have been very effective at driving down prices. In the United States, we rely on the private sector and a free market for drug pricing. But in order for this to work, we need to regulate it better and demand greater transparency.<sup>29</sup>

34. The physical, emotional, and financial tolls of the excessive prices for the at-issue medications, are devastating. Many patients cannot afford their medications and suffer dire consequences as a result. Others resort to under-dosing their insulin, injecting expired insulin, and starving themselves to control their blood sugars with as little insulin as possible. These behaviors are dangerous for people

<sup>&</sup>lt;sup>29</sup> Kasia Lipska, *Break Up the Insulin Racket*, N.Y. Times (Feb. 20, 2016), <a href="https://www.nytimes.com/2016/02/21/opinion/sunday/break-up-the-insulin-racket">https://www.nytimes.com/2016/02/21/opinion/sunday/break-up-the-insulin-racket</a> .html.

living with diabetes. Because such behaviors ineffectively control those individuals' blood sugar levels, they can lead to serious complications such as kidney failure, heart disease, blindness, infection, and amputations. In some cases, patients are forced by exclusionary formulary tiering to use an insulin brand that is less effective in controlling their individual blood sugars, or to which they have some degree of allergic reaction—or to pay increased cost-sharing to access the non-preferred brand of insulin they need.

- 35. The cost of analog insulin—the most effective and favored type—has gone up so much that some prominent physicians have started encouraging patients to switch to human insulin despite its many disadvantages, thus undermining the U.S. standard of care in relation to international best medical practices for diabetes.<sup>30</sup>
- 36. These price increases also put significant strain on states, counties, and municipalities like Clark County, which pay increasing costs for insulin through self-funded health plans for its government employees. Clark County currently provides health benefits to nearly 3,000 individuals and makes payments to its PBM on a regular basis to cover a portion of the cost of insulin for beneficiaries of the plan. Indeed, since 2014, the gross amount that Clark County has paid just to cover its portion of the cost of the at-issue drugs for the beneficiaries of its self-funded

<sup>&</sup>lt;sup>30</sup> Irl B. Hirsch, MD, *Changing Cost of Insulin Therapy in the U.S.* (Mar. 6, 2016), <a href="https://web.archive.org/web/20201005020028/https://professional.diabetes.org/files/media/Changing Cost Insulin.pdf">https://web.archive.org/web/20201005020028/https://professional.diabetes.org/files/media/Changing Cost Insulin.pdf</a>.

insurance plan is over \$3.3 million—costs that will continue in the future under the ongoing Insulin Pricing Scheme.

- 37. Yet, even amid public scrutiny and government investigations, the full magnitude of the Insulin Pricing Scheme and its impact on pricing to patients and payors was never fully revealed. In particular, the Defendants conspired to conceal from payors, including Clark County, the marked difference between the size of the Manufacturer Payments obtained by the PBM Defendants when compared to the rebates passed along to the County and other customers, the extent of the resulting pricing overcharges secured by the Manufacturer Defendants, and the vast sums that the PBM Defendants retained as kickbacks.
- 38. This profound lack of transparency continues to this day. In March 2023, in the face of consumer litigation and mounting public and political pressure, Eli Lilly announced price concessions that were matched shortly thereafter by its competitors. While the price concessions are substantial, the announced price reduction of 70%, capping out of pocket costs at \$35 per month not only demonstrates the magnitude of overcharge previously enforced, it is a significant markup over the \$6 per vial production cost, and does not apply to all insulin products, nor to all insulin purchasers.<sup>31</sup> Indeed, some commentators have claimed

<sup>&</sup>lt;sup>31</sup> Dzintars Gotham, Melissa J. Barber, & Andrew Hill, *Production Costs and Potential Prices for Biosimilars of Human Insulin and Insulin Analogues*, BMJ Glob. Health (Sept. 25, 2018), <a href="https://gh.bmj.com/content/3/5/e000850.info">https://gh.bmj.com/content/3/5/e000850.info</a>.

that the coordinated price reductions might ultimately lead to even higher profits for manufacturers. In short, these recent concessions merely demonstrate the depth and magnitude of the Insulin Pricing Scheme; the full extent of which is still not fully, publicly known.

39. This action seeks to hold the PBM Defendants and Manufacturer Defendants liable for their exploitation of the pharmaceutical supply chain for their financial benefit. There is simply no reason that prices for the at-issue medications—which costs just a fraction of the price health plans and consumers pay to produce—has skyrocketed other than to increase the profits of the Defendants.

## II. PARTIES

# A. Plaintiff Clark County

- 40. Plaintiff Clark County, a body corporate and politic, is a chartered home rule county of the State of Washington established under article 11, section 4 of the State Constitution. Plaintiff has all the powers of local self-government and all other powers possible for a county to have under the Constitution and the laws of the State of Washington.
- 41. Clark County brings this case in its sovereign capacity for the benefit of the State of Washington. This action is brought to promote the public welfare and for the common good of the State of Washington.

- 42. Plaintiff, as a government entity, provides vital services including public safety, emergency management, and health services to over 500,000 residents.
- 43. Any increase in spending has a detrimental effect on Plaintiff's overall budget and, in turn, negatively impacts its ability to provide necessary services to the community.
  - 44. The Insulin Pricing Scheme has had such an effect.
- 45. Additionally, as a government employer, Plaintiff provides health benefits to nearly 3,000 individuals, including employees, their dependents, and retirees ("Beneficiaries"). One benefit Plaintiff offers its Beneficiaries is paying a substantial share of the purchase price of their pharmaceutical drugs, including the at-issue medications, as further defined below.
- 46. Plaintiff maintains self-insured health plans for its Beneficiaries. As of January 1, 2023, Clark County's plan covers nearly 3,000 individuals, including employees, their dependents, and retirees.
- 47. Insulin drugs, including those manufactured by the Manufacturer Defendants, are a significant prescription expense for the County. As prices continued to rise over the past several years, Plaintiff spent substantial public monies on overcharges to the detriment of its Beneficiaries and the residents of Clark County.

48. Plaintiff seeks relief for the harm suffered as a result of Defendants' misrepresentations and omissions regarding their illegal Insulin Pricing Scheme.

#### **B.** Manufacturer Defendants

49. As set forth above, Defendants Eli Lilly, Novo Nordisk, and Sanofi are all manufacturers of insulins, analog insulins, and other diabetes medications.

# 1. Eli Lilly

- 50. Defendant Eli Lilly and Company ("Eli Lilly") is an Indiana corporation with its principal place of business in Indianapolis, Indiana.
- 51. Eli Lilly manufactures, promotes, and distributes several at-issue diabetes medications in Washington, including: Humulin N (first approved in 1982), Humulin R (first U.S. approval in 1982), Humalog (first approved in 1996), Trulicity (first approved in 2014), and Basaglar (first approved in 2015).
- 52. Eli Lilly transacts business in Washington, including in Clark County, by targeting the local market with its products, including the at-issue diabetes medications. From 2019 to 2021, Eli Lilly's domestic revenues were \$11.9 billion from Trulicity, \$4.48 billion from Humalog, \$2.58 billion from Humulin, and \$2.31 billion from Basaglar.
- 53. Eli Lilly also directs advertising and informational materials to Washington and Clark County physicians and potential users of Eli Lilly's products

and employs sales representatives throughout Washington to promote and sell its diabetes medications.

- 54. At all relevant times, in furtherance of the Insulin Pricing Scheme, Eli Lilly caused the publication of prices for the at-issue diabetes medications throughout Washington with the express knowledge that payment by Plaintiff would be based on those false list prices.
- 55. During the relevant period, Plaintiff purchased Eli Lilly's at-issue drugs at prices based on false list prices generated by the Insulin Pricing Scheme through its employee health plans.

## 2. Sanofi-Aventis

- 56. Defendant Sanofi-Aventis U.S. LLC ("Sanofi") is a Delaware limited liability company with its principal place of business in Bridgewater, New Jersey.
- 57. Sanofi manufactures, promotes, and distributes pharmaceutical drugs in Washington, including several at-issue diabetes medications: Lantus (first approved in 2000), Apidra (first approved in April 2004), Toujeo (first approved in 2015), and Soliqua (first approved in 2016).
- 58. Sanofi transacts business in Washington, including in Clark County, by targeting the local market with its products, including the at-issue diabetes medications. In 2019, Sanofi's U.S. net sales were \$1.29 billion from Lantus, \$323.7 million from Toujeo, and \$51.5 million from Apidra.

- 59. Sanofi directs advertising and informational materials to Washington physicians and potential users of Sanofi's products for the specific purpose of selling the at-issue drugs in Washington, including Clark County, and profiting from the Insulin Pricing Scheme.
- 60. At all relevant times, in furtherance of the Insulin Pricing Scheme, Sanofi caused the publication of prices of its at-issue diabetes medications in Washington for the purpose of payment by payors, including Plaintiff Clark County.
- 61. During the relevant period, Plaintiff purchased Sanofi's at-issue drugs at prices based on false list prices generated by the Insulin Pricing Scheme through its employee health plans.

## 3. Novo Nordisk

- 62. Defendant Novo Nordisk Inc. ("Novo Nordisk") is a Delaware corporation with its principal place of business in Plainsboro, New Jersey.
- 63. Novo Nordisk manufactures, promotes, and distributes pharmaceutical drugs in Washington, including at-issue diabetes medications: Novolin R (first approved in 1991), Novolin N (first approved in 1991), Novolog (first approved in 2002), Levemir (first approved in 2005), Victoza (first approved in 2010), Tresiba (first approved in 2015), and Ozempic (first approved in 2017). Nordisk's combined net sales of these drugs in the U.S. from 2018 to 2020 totaled approximately \$18.1 billion.

- 64. Novo Nordisk transacts business in Washington and in Clark County, by targeting the local market with its products, including the at-issue diabetes medications. In 2015, Novo Nordisk's revenue from Novolog was \$3.03 billion, and its revenue from Levemir was \$2.68 billion.
- 65. Novo Nordisk directs advertising and informational materials to Washington and Clark County physicians and potential users of Novo Nordisk's products.
- 66. At all relevant times, in furtherance of the Insulin Pricing Scheme, Novo Nordisk caused the publication of prices of its at-issue diabetes medications in Washington for the purpose of payment by Plaintiff.
- 67. During the relevant period, Plaintiff purchased Novo Nordisk's at-issue drugs at prices based on false list prices generated by the Insulin Pricing Scheme through its employee health plans.

## C. PBM Defendants

# 1. Express Scripts

68. Collectively, Defendants Evernorth Health, Inc., Express Scripts, Inc., Express Scripts Administrators, LLC, Express Scripts Pharmacy, Inc., Medco Health Solutions, Inc., and The Cigna Group, including all predecessor and successor entities, are referred to as "Express Scripts."

- 69. Defendant Evernorth Health, Inc. ("Evernorth"), formerly known as Express Scripts Holding Company, is a Delaware corporation with its principal place of business in St. Louis, Missouri. Evernorth Health, Inc. is a wholly owned subsidiary of The Cigna Group. Evernorth, through its executives and employees, including its CEO and Vice Presidents, 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. Evernorth is the immediate or indirect parent of pharmacy and PBM subsidiaries operating in Washington, who engaged in the activities giving rise to this action.
- 70. 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. Express Scripts, Inc. holds one or more pharmacy licenses in Washington. Express Scripts, Inc. is the immediate or indirect parent of pharmacy and PBM subsidiaries that operate throughout Washington that engaged in the conduct, which gave rise to this action.
- 71. Defendant Express Scripts Administrators, LLC, doing business as Express Scripts and formerly known as Medco Health, LLC, is a Delaware limited liability company and is a wholly owned subsidiary of Evernorth. Its principal place of business is in Franklin Lakes, New Jersey. During the relevant period, Express Scripts Administrators, LLC provided the PBM services to Clark County that gave

rise to and implemented the Insulin Pricing Scheme that damaged payors, including Plaintiff.

- 72. 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. During the relevant period, Express Scripts Pharmacy, Inc. provided mail-order pharmacy services in Washington that gave rise to and implemented the Insulin Pricing Scheme, which damaged payors such as Clark County.
- 73. Defendant Medco Health Solutions, Inc. is a Delaware corporation with its principal place of business in Franklin Lakes, New Jersey. Medco Health Solutions, Inc. is a wholly owned subsidiary of The Cigna Group. Prior to 2012, Medco provided the at-issue PBM and mail order pharmacy services in Washington; following its merger with Express Scripts in 2012, Medco continued to provide those services under the Express Scripts name.
- 74. Defendant The Cigna Group is a Delaware corporation with its principal place of business in Bloomfield, Connecticut. The Cigna Group, through its executives and employees, including its CEO and Vice Presidents, 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. The Cigna Group is the immediate or indirect parent of

pharmacy and PBM subsidiaries operating in Washington, who engaged in the activities giving rise to this action.

- 75. Express Scripts offered pharmacy benefit services to Washington payors, including through its collaboration with Prime Therapeutics, to Plaintiff, and derived substantial revenue therefrom. In doing so, it made misrepresentations while concealing the Insulin Pricing Scheme and utilized the false prices generated by the Insulin Pricing Scheme.
- 76. During the relevant period, Express Scripts handled rebate negotiations with the Manufacturer Defendants for the at-issue drugs. In doing so, Express Scripts effectively set the prices that Plaintiff paid for these at-issue drugs based on the false list prices generated by the Insulin Pricing Scheme.
- 77. At all relevant times, Express Scripts dispensed the at-issue insulin medications to the County's Beneficiaries through its mail service and participating retail pharmacies and indirectly through partner pharmacies, charged prices based on the false list prices generated by the Insulin Pricing Scheme, and derived substantial revenue from these activities in Washington.
- 78. In short, Express Scripts played a critical role in the overall Insulin Pricing Scheme and caused Plaintiff harm.
- 79. Express Scripts also purchased drugs from manufacturers for dispensing through its pharmacy network.

- 80. In its capacity as a mail service pharmacy and through its participating retail pharmacies, Express Scripts knowingly profited from the false list prices generated through the Insulin Pricing Scheme by pocketing the spread between the acquisition cost for the at-issue drugs (an amount well below the list price published through the Insulin Pricing Scheme), and the amounts it received from payors (amounts based on the false list prices).
- 81. At all relevant times, Express Scripts had express agreements with Defendants Eli Lilly, Novo Nordisk, and Sanofi related to the payments made by the Manufacturer Defendants to Express Scripts, as well as agreements related to the Manufacturers' at-issue drugs sold through Express Scripts' pharmacies.

## 2. CVS Caremark

- 82. Collectively, and as set forth below, Defendants CVS Health, CVS Pharmacy, Caremark Rx, LLC, CaremarkPCS Health, L.L.C., and Caremark, LLC, including all predecessor and successor entities, are referred to as "CVS Caremark."
- 83. Defendant CVS Health Corporation ("CVS Health") is a Delaware corporation with its principal place of business in Woonsocket, Rhode Island.
- 84. CVS Health is a pharmacy benefit manager that contracts on behalf of health plans and insurers with the Manufacturer Defendants for purchase of the analog insulin medications that the manufacturers make. CVS Health Corporation provides comprehensive prescription benefit management services to numerous

health plans, including corporations, managed care organizations, insurance companies, unions and government entities. CVS Health transacts business and has locations throughout the United States and Washington, including in Clark County.

- 85. Defendant CVS Pharmacy, Inc. ("CVS Pharmacy") is a Rhode Island corporation whose principal place of business is at the same location as CVS Health. It is a citizen of the State of Rhode Island. CVS Pharmacy is a wholly owned subsidiary of CVS Health. During the relevant period, CVS Pharmacy provided retail pharmacy services in Washington that gave rise to and implemented the Insulin Pricing Scheme, which damaged payors, including Plaintiff.
- 86. Defendant Caremark Rx, LLC is a Delaware limited liability company whose principal place of business is in Rhode Island. Caremark Rx, LLC is a subsidiary of Defendant CVS Pharmacy, which is a wholly owned subsidiary of Defendant CVS Health.
- 87. Defendant CaremarkPCS Health, L.L.C. is a Delaware limited liability company whose principal place of business is at the same location as CVS Health. CaremarkPCS Health, L.L.C. is a subsidiary of CaremarkPCS, LLC, which is a subsidiary of Caremark Rx, LLC, which is a subsidiary of Defendant CVS Pharmacy, which is a wholly owned subsidiary of Defendant CVS Health. It is also directly involved in PBM and mail-order pharmacy services giving rise and in furtherance of the Insulin Pricing Scheme.

- 88. 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 subsidiary of Caremark Rx, LLC, which is a subsidiary of Defendant CVS Pharmacy, which is a wholly owned subsidiary of Defendant CVS Health. During the relevant period,
- 89. Defendants CVS Health, CVS Pharmacy, Caremark Rx, LLC, CaremarkPCS Health, L.L.C., and Caremark, LLC all operate as a single business entity, doing business as CVS Caremark. As a result of their numerous interlocking directorships and shared executives, each entity is directly involved in the conduct and control of CVS Caremark's operations, management, and business decisions related to the at-issue diabetic medications. For example:
  - A. During the relevant period, these entities had common officers and directors, including:
    - i. Thomas S. Moffatt, Vice President and Secretary of Caremark Rx, LLC, CaremarkPCS Health, L.L.C., and Caremark, LLC, also served as Vice President, Assistant Secretary, and Senior Legal Counsel at CVS Health and as Vice President, Secretary and Senior Legal Counsel of CVS Pharmacy;
    - ii. Melanie K. Luker, Assistant Secretary of Caremark Rx,LLC, CaremarkPCS Health, L.L.C., and Caremark, LLC, also served

as Manager of Corporate Services at CVS Health;

- iii. Carol A. Denale, Senior Vice President and Treasurer of Caremark Rx, LLC, also served as Senior Vice President, Treasurer, and Chief Risk Officer at CVS Health;
- iv. John M. Conroy was VP of Finance at CVS Health in 2011 and President and Treasurer of Caremark, LLC and CaremarkPCS Health, L.L.C. in 2019; and
- v. Sheelagh Beaulieu served as Senior Director of Income
  Tax at CVS Health while also acting as the Assistant Treasurer at
  CaremarkPCS Health, L.L.C. and Caremark, LLC.
- B. CVS Health owns all the stock of CVS Pharmacy, which owns all the stock of Caremark Rx, LLC, which owns all the stock of Caremark LLC. CVS Health directly or indirectly owns CaremarkPCS Health, L.L.C. in its entirety.
- C. CVS Health, as a corporate family, does not operate as separate entities. Its public filings, documents, and statements present its subsidiaries—including CVS Pharmacy, Caremark Rx, LLC, Caremark, LLC, and Caremark PCS Health, L.L.C. as divisions or departments of one unified "diversified health services company" that "works together across our disciplines" to "create unmatched human connections to transform the health

care experience." The day-to-day operations of this corporate family reflect these public statements. These entities are a single business enterprise and should be treated as such as to all legal obligations discussed in this Complaint.

- D. All executives of CaremarkPCS Health, L.L.C., Caremark, LLC, Caremark Rx, LLC, and CVS Pharmacy ultimately report to the executives at CVS Health, including its President and CEO.
- 90. CVS Caremark offered pharmacy benefit services to Washington payors, and derived substantial revenue therefrom. In doing so, it made misrepresentations while concealing the Insulin Pricing Scheme and utilized the false prices generated by the Insulin Pricing Scheme.
- 91. At all relevant times, CVS Caremark dispensed the at-issue insulin medications to the County's Beneficiaries through its retail pharmacies, and indirectly through partner pharmacies, charged prices based on the false list prices generated by the Insulin Pricing Scheme, and derived substantial revenue from these activities in Washington.
- 92. In short, CVS Caremark played a critical role in the overall Insulin Pricing Scheme and caused Plaintiff harm.
- 93. CVS Caremark also purchased drugs from manufacturers for dispensing through its pharmacy network.

- 94. In its capacity as a retail pharmacy, CVS Caremark knowingly profited from the false list prices generated through the Insulin Pricing Scheme by pocketing the spread between the acquisition cost for the at-issue drugs (an amount well below the list price published through the Insulin Pricing Scheme), and the amounts it received from payors (amounts based on the false list prices).
- 95. At all relevant times, CVS Caremark had express agreements with Defendants Eli Lilly, Novo Nordisk, and Sanofi related to the payments by the Manufacturer Defendants to CVS Caremark.

#### 3. OptumRx

- 96. Collectively, Defendants UnitedHealth Group, Inc., OptumRx, Inc., and Optum, Inc., including all predecessor and successor entities, are referred to as "OptumRx."
- 97. Defendant UnitedHealth Group, Inc. is a corporation organized under the laws of Delaware with its principal place of business in Minnetonka, Minnesota. UnitedHealth Group, Inc. is a diversified managed healthcare company that offers a spectrum of products and services including health insurance plans through its wholly owned subsidiaries and prescription drugs through its PBM, OptumRx. Its total revenues in 2021 exceeded \$287 billion, which was up more than \$30 billion from 2020. The company has been ranked fifth on the Fortune 500 list. UnitedHealth Group's conduct had a direct effect in Washington and damaged Plaintiff.

- 98. UnitedHealth Group states in its annual reports that UnitedHealth Group "utilizes Optum's capabilities to help coordinate patient care, improve affordability of medical care, analyze cost trends, manage pharmacy benefits, work with care providers more effectively and create a simpler consumer experience." Its most recent annual report states plainly that UnitedHealth Group is "involved in establishing the prices charged by retail pharmacies, determining which drugs will be included in formulary listings and selecting which retail pharmacies will be included in the network offered to plan sponsors' members ...." As of December 31, 2021, "total pharmaceutical manufacturer rebates receivable included in other receivables in the Consolidated Balance Sheets amounted to \$7.2 billion [2021] and \$6.3 billion [2020]."
- 99. Defendant Optum, Inc. is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. Optum, Inc. is a health services company managing subsidiaries that administer pharmacy benefits, including Defendant OptumRx, Inc. Optum, Inc. is directly involved, through its executives and employees, in the company policies that inform its PBM services and formulary construction, including with respect to the at-issue drugs and related to the Insulin Pricing Scheme, which had a direct effect in Washington and damaged Plaintiff.
- 100. For example, according to Optum Inc.'s press releases, Optum, Inc. is "UnitedHealth Group's information and technology-enabled health services

business platform serving the broad healthcare marketplace, including care providers, plan sponsors, payors, life sciences companies and consumers." In this role, Optum, Inc. is directly responsible for the "business units – OptumInsight, OptumHealth and OptumRx" and the CEOs of all these companies report directly to Optum, Inc. regarding their policies, including those that inform the at-issue formulary construction and mail-order activities.

- 101. Defendant OptumRx, Inc. is a California corporation with its principal place of business in Irvine, California. OptumRx, Inc. operates as a subsidiary of OptumRx Holdings, LLC, which in turn operates as a subsidiary of Defendant Optum, Inc. During the relevant period, OptumRx, Inc. provided PBM and mail order pharmacy services in Washington that gave rise to and implemented the Insulin Pricing Scheme, which damaged Plaintiff. OptumRx is named as a Defendant in its capacities as a PBM and mail order pharmacy.
- 102. OptumRx is a pharmacy benefit manager and, as such, coordinates with Eli Lilly, Novo Nordisk, and Sanofi regarding the price of the at-issue diabetes medications, as well as for the placement of these firms' diabetes medications on OptumRx's drug formularies.
- 103. OptumRx provides pharmacy care services to more than 65 million people in the nation through a network of more than 67,000 retail pharmacies and multiple delivery facilities. It is one of UnitedHealth Group Inc.'s "four reportable

segments" (along with UnitedHealthcare, Optum Health, and Optum Insight). In 2021, OptumRx "managed \$112 billion in pharmaceutical spending, including \$45 billion in specialty pharmaceutical spending."

- 104. OptumRx, through UnitedHealth, offered pharmacy benefit services to Washington payors, including Plaintiff, and derived substantial revenue therefrom. In doing so, it made misrepresentations while concealing the Insulin Pricing Scheme and utilized the false prices generated by the Insulin Pricing Scheme.
- 105. At all relevant times, OptumRx offered PBM services nationwide and maintained standard formularies that were used nationwide, including in Washington. Those formularies included the diabetes medications at issue here, and OptumRx participated in pricing these drugs based off the list prices it knew to be false.
- 106. During the relevant period, OptumRx dispensed the at-issue medications nationwide through its pharmacies. OptumRx derived substantial revenue from these activities in Washington.
- 107. In short, OptumRx played a critical role in the overall Insulin Pricing Scheme as a co-conspirator and caused Plaintiff harm.
- 108. OptumRx purchased drugs directly from manufacturers for dispensing through its pharmacy network.

- 109. In its capacity as a retail pharmacy, OptumRx further and knowingly profited from the false list prices produced by the Insulin Pricing Scheme by pocketing the spread between acquisition cost for the at-issue drugs (an amount well below the list price generated by the Insulin Pricing Scheme), and the amounts it received from payors (which amounts were based on the false list prices and, in many cases, were set by OptumRx in its capacity as a PBM).
- and within the State of Washington and employed prices based on the false list prices generated by the Insulin Pricing Scheme and dispensed the at-issue medications within the State of Washington through its pharmacies, and it derived substantial revenue from these activities in Washington.

#### III. JURISDICTION AND VENUE

- 111. Pursuant to this Court's Case Management Order No. 9 ("CMO 9"), this Complaint is filed as an original action in the United States District Court for the District of New Jersey.
- 112. But for CMO 9, Plaintiff would have filed this Complaint in the United States District Court for the Western District of Washington (hereinafter, the "Western District of Washington"). In accordance with CMO 9, the "Designated Forum" for this action is the Western District of Washington.

- 113. The Western District of Washington has subject-matter jurisdiction pursuant to 28 U.S.C. § 1331 and pursuant to 18 U.S.C. § 1964(c) because this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962. The Western District of Washington also has supplemental jurisdiction over the state law claims in this action pursuant to 28 U.S.C. § 1367.
- 114. The Western District of Washington has personal jurisdiction over Defendants. Each Defendant: (1) transacts business in Washington; (2) maintains substantial contacts in Washington, and (3) committed the violations of federal statutes, the Washington statute, and the common law at issue in this action, in whole or part within the State of Washington. This action arises out of and relates to each Defendant's contacts with this forum.
- 115. 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 Washington, including Plaintiff. All transactions at issue occurred in the State of Washington and involved Washington residents.
- 116. Each Defendant purposefully availed itself of the privilege of doing business within this state, including within this district and division, and each derived substantial financial gain from doing so. These continuous, systematic, and case-related business contacts—including the tortious acts described herein—are

such that each Defendant should reasonably have anticipated being brought into the Western District of Washington.

- 117. Each Defendant submitted itself to jurisdiction through marketing; encouraging the use of its services, and its purposeful cultivation of profitable relationships in the State of Washington and within this forum.
- 118. In short, each Defendant has systematically served a market in Washington relating to the Insulin Pricing Scheme and has caused injury in Washington such that there is a strong relationship among Defendants, this forum, and the litigation.
- 119. The Western District of Washington has personal jurisdiction over all Defendants pursuant to Fed. R. Civ. P. 4(k)(1)(A) because they would be subject to the jurisdiction of a court of general jurisdiction in Washington.
- 120. The Western District of Washington also has personal jurisdiction over all Defendants under 18 U.S.C. § 1965(b). The Western District of Washington may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contacts. The interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the Western District of Washington in a single action for a single trial.

- U.S.C. § 1391(b) and (c), because each Defendant transacts business in, is found in, and/or has agents in this District, and because a substantial part of the events or omissions giving rise to this action took place, or had their ultimate injurious impact, within the Western District of Washington. In particular, at all times relevant, Defendants provided pharmacy benefit services, mail-order pharmacy services, and retail pharmacies; employed sales representatives; promoted and sold diabetes medications; caused and directed the published prices of the at-issue drugs; and manufactured, distributed, and sold the at-issue drugs in and caused injury to Plaintiff in the Western District of Washington.
- 122. Venue is proper in the Western District of Washington pursuant to 18 U.S.C. § 1965, because all Defendants reside, are found, have an agent, or transact their affairs in this District, and the ends of justice require that any Defendant residing elsewhere be brought into the Western District of Washington.

#### IV. FACTUAL ALLEGATIONS

## A. Life Saving Insulin Is Not a New Drug.

## 1. Diabetes Requires Insulin

123. Diabetes is a condition in which the body does not properly process food for use as energy. 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 bloodstream so as to be effectively used by the body as energy. People with diabetes are unable to make enough insulin or cannot use it as effectively as necessary, causing glucose to build up in the bloodstream. These consistently high levels of blood glucose pose a number of serious health risks including "heart disease, vision loss, and kidney disease." Diabetes-related complications are the "seventh leading cause of death in the United States." Though treatable, diabetes can be fatal or severely debilitating if left untreated.

124. As of 2019, 37.3 million people in the United States, or 11.3% of the population, had diabetes—and that number continues to grow.<sup>34</sup> The most common types of diabetes in the U.S. are type 1, type 2, and gestational diabetes.<sup>35</sup> Individuals with type 1 diabetes are unable to produce insulin at all; as their immune system attacks and destroys the cells in the pancreas that make it.<sup>36</sup> With type 2 diabetes, although people with the condition are able to produce insulin, they are unable to use it effectively, and about 95% of cases of diabetes in adults are type 2.<sup>37</sup> Regular

<sup>&</sup>lt;sup>32</sup> Ctr.'s for Disease Control & Prevention, *supra* n.3.

<sup>&</sup>lt;sup>33</sup> Am. Diabetes Assoc., *supra* n.2.

<sup>&</sup>lt;sup>34</sup> National Diabetes Statistics Report, Ctr.'s for Disease Control & Prevention (May 15, 2024), <a href="https://www.cdc.gov/diabetes/php/data-research/?CDC\_Aaref\_Val=https://www.cdc.gov/diabetes/data/statistics-report/index.html">https://www.cdc.gov/diabetes/data/statistics-report/index.html</a>.

<sup>&</sup>lt;sup>35</sup> What is Diabetes?, Nat'l Inst. of Diabetes & Digestive & Kidney Diseases (Apr. 2023), <a href="https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes">https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes</a>.

<sup>&</sup>lt;sup>36</sup> *Id*.

<sup>&</sup>lt;sup>37</sup> Am. Diabetes Assoc., *supra* n.2.

use of prescription insulin is necessary to treat type 1 and type 2 diabetes to prevent life-threatening health complications.<sup>38</sup>

125. At-issue in this lawsuit are several insulin medications as well as other medications used to treat type 2 diabetes. The following is a table of diabetes medications at issue in this lawsuit:

Insulin Type	Action	Name	Company	FDA Approval	Current/Recent List Price
Human	Rapid-Acting	Humulin R	Eli Lilly	1982	\$178 (vial)
		Humulin R 500	Eli Lilly	1982	\$1784 (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)
	Pre-mixed	Humalog 50/50	Eli Lilly	1999	\$93 (vial) \$180 (pens)
		Humalog 75/25	Eli Lilly	1999	\$99 (vial) \$140 (pens)
		Novolog 70/30	Novo Nordisk	2001	\$203 (vial) \$246 (pens)

<sup>&</sup>lt;sup>38</sup> Valencia Higuera, *Everything You Need to Know About Insulin*, Healthline (Apr. 20, 2023), <a href="http://www.healthline.com/health/type-2-diabetes/insulin">http://www.healthline.com/health/type-2-diabetes/insulin</a>.

	Long-Acting	Lantus	Sanofi	2000	\$340 (vial) \$510 (pens)
		Levemir	Novo Nordisk	2005	\$370 (vial) \$555 (pens)
		Basaglar (Kwikpen)	Eli Lilly	2015	\$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 (Dulaglutide)	Eli Lilly	2014	\$1013 (pens)
	GLP-1	Mounjaro (Tirzepatide/GIP)	Eli Lilly	2022	\$1068 (pens)
		Victoza (Liraglutide)	Novo Nordisk	2010	\$813 (2 pens) \$1220 (3 pens)
		Xultophy (insulin degludec/liraglutide)	Novo Nordisk	2016	\$1295 (pens)
		Ozempic (Semaglutide)	Novo Nordisk	2017	\$1022 (pens)
		Rybelsus (semaglutide tablets)	Novo Nordisk	2019	\$1029 (30 day supply)
		Adylxin (lixisenatide)	Sanofi	2016	Discontinued 2023
		Soliqua (insulin glargine/lixisenatide)	Sanofi	2016	\$928 (pens)

# 2. Discovery and History of Insulin

126. Until 1922, diabetes was considered a death sentence, but that changed with the discovery of insulin in the pancreas of dogs in 1921 by an unknown orthopedic surgeon, Dr. Frederic Banting, and a medical student, Charles Best, at the University of Toronto.<sup>39</sup> Less than a year later, in 1922, Banting and Best used the hormone to successfully treat human patients.<sup>40</sup>

<sup>40</sup> *Id.* 

<sup>&</sup>lt;sup>39</sup> *History of Insulin*, Diabetes.co.uk (Jan. 25, 2023), <a href="http://www.diabetes.co.uk/insulin/history-of-insulin.html">http://www.diabetes.co.uk/insulin/history-of-insulin.html</a>.

- 127. In an act of gratitude and humanitarianism, Banting and Best sold the patent for insulin to the University of Toronto for just one dollar.<sup>41</sup> "It was the best way, they believed, to ensure that no company would have a monopoly and patients would have affordable access to a safe, effective drug."<sup>42</sup>
- 128. In order to facilitate widespread distribution of the medication, the University of Toronto partnered with drug manufacturers in the United States and abroad, including Eli Lilly & Co., which as early as 1923 was producing enough insulin to supply the entire North American continent. In exchange for this assistance with widespread insulin distribution, however, the University gave up its exclusive control over the patent for insulin to private manufacturers.<sup>43</sup>
- 129. Nevertheless, the drug was made widely available at a low cost. In fact, the New York Times estimated that, in 1924, many patients received the drug for less than seven cents a week in 2016 dollars.<sup>44</sup>
- 130. The earliest insulin available to the public was derived from cow and pig hormones and, until the 1980s, this "animal-derived" insulin was the only

<sup>&</sup>lt;sup>41</sup> Serena Gordon, *Insulin prices skyrocket*, *putting many diabetics in a bind*, Chi. Trib. (Nov. 30, 2016, 11:54 AM), <a href="https://www.chicagotribune.com/2016/11/30/insulin-prices-skyrocket-putting-many-diabetics-in-a-bind">https://www.chicagotribune.com/2016/11/30/insulin-prices-skyrocket-putting-many-diabetics-in-a-bind</a>.

<sup>&</sup>lt;sup>42</sup> Carolyn Y. Johnson, *Why treating diabetes keeps getting more expensive*, Wash. Post (Oct. 31, 2016), <a href="https://www.washingtonpost.com/news/wonk/wp/2016/10">https://www.washingtonpost.com/news/wonk/wp/2016/10</a> /31/why-insulin-prices-have-kept-rising-for-95-years.

<sup>&</sup>lt;sup>43</sup> Gordon, *supra* n.41.

<sup>&</sup>lt;sup>44</sup> Hirsch, *supra* n.30.

treatment for diabetes.<sup>45</sup> Although effective, animal-derived insulin created the risk of an allergic reaction in many human patients. That risk was lessened in 1982 when synthetic insulin, or "human insulin," was developed and marketed by Eli Lilly and other manufacturers, after insulin became the first protein in history to be sequenced and chemically synthesized.<sup>46</sup> This type of insulin was marketed as Humulin R (rapid) and N (NPH, intermediate-acting).<sup>47</sup>

- 131. But, even after the development of "human insulin," doctors found that "there's no one insulin that's right for everyone," and each diabetes patient may react differently to each formulation of the protein.<sup>48</sup> This recognition gave rise to the most recent iteration of insulin available on the market today: "analog insulin."
- 132. Analog insulin is a "genetically modified form of insulin whereby the amino acid sequence is altered to change how the insulin is absorbed, distributed, metabolized and excreted."<sup>49</sup>
- 133. Analog insulins are closely related to the human insulin structure and were developed for specific aspects of glycemic control in terms of fast action

<sup>&</sup>lt;sup>45</sup> *Animal Insulin*, Diabetes.co.uk (Apr. 25, 2023), <a href="http://www.diabetes.co.uk/insulin/animal-insulin.html">http://www.diabetes.co.uk/insulin/animal-insulin.html</a>.

<sup>&</sup>lt;sup>46</sup> History of Insulin, supra n.39.

<sup>&</sup>lt;sup>47</sup> Celeste C. Quianzon & Issam Cheikh, MD, *History of insulin*, J. Cmty. Hosp. Intern. Med. Perspect. (July 16, 2012), <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3714061/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3714061/</a>.

<sup>&</sup>lt;sup>48</sup> Gordon, *supra* n.41.

<sup>&</sup>lt;sup>49</sup> History of Insulin, supra n.39.

(prandial insulins) and long action (basal insulins). The first biosynthetic insulin analog was developed by Eli Lilly and Company for clinical use at mealtime (prandial insulin): Humalog (insulin lispro). It is more rapidly absorbed after subcutaneous injection than regular insulin, with an effect just fifteen minutes after injection. Other rapid-acting analogs with similar profiles are Novolog (insulin aspart) and Apidra (insulin glulisine). These are often used in combination basalbolus therapy with longer-acting insulins Lantus and Levemir. These rapid-acting and long-acting analog insulins were introduced in the U.S. between 1996 and 2006. They replaced older insulins, such as NPH, that had been developed during the 1940s, and regular insulin (e.g., Lente, Humulin) that was developed in the 1970s and marketed in the early 1980s.

134. When first introduced—and for many years after—analog insulins remained affordable. Today, however, Defendants' Insulin Pricing Scheme has resulted in extreme price increases that have put the 100-year-old medicine out of reach for many people in the United States with diabetes.<sup>50</sup>

135. The newer, analog insulins provide important benefits over older "human" insulin for some people with diabetes. As the mother of a diabetic child

<sup>&</sup>lt;sup>50</sup> Hirsch, *supra* n.30.

explained, older types of insulin require diabetics to follow rigid meal schedules that correspond to insulin doses so that they can avoid blood sugar fluctuations.<sup>51</sup>

- 136. More modern insulins, such as Humalog, which is rapid acting, and Lantus, a long-acting insulin, can help diabetics maintain blood sugar levels and improve their quality of life.<sup>52</sup> The analog insulins are particularly important for children, who face a higher risk of nocturnal hypoglycemia; there is a known prevalence of dead-in-bed syndrome among children and young adults with type 1 diabetes.<sup>53</sup>
- 137. The prices of the at-issue insulin drugs have gone through the roof since they have been on the market.

### 3. The Unavailability of Generic Insulin.

138. While generic forms of many drugs are available to purchase for as little as a few dollars, in the United States there is no true generic form of insulin. Even though insulin was first extracted nearly 100 years ago, only three major pharmaceutical companies hold patents in the United States that allow them to

<sup>&</sup>lt;sup>51</sup> Nicki Nichols, *Why Walmart Insulins Aren't the Answer to High Insulin Prices*, Insulin Nation (Sept. 16, 2016), <a href="http://insulinnation.com/treatment/why-walmart-insulins-arent-the-answer-to-high-insulin-prices/">http://insulinnation.com/treatment/why-walmart-insulins-arent-the-answer-to-high-insulin-prices/</a>.

<sup>&</sup>lt;sup>52</sup> See id.

<sup>&</sup>lt;sup>53</sup> A.M. Secrest et al., *Characterising sudden death and dead-in-bed syndrome in Type 1 diabetes*, 28 Diabetes Med. 7, 293-300 (Mar. 2011), <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3045678/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3045678/</a>.

manufacture insulin.<sup>54</sup> Part of the reason that no generic insulin is available in the United States may be that large-molecule biologic drugs, such as insulin, are more difficult to copy than small-molecule drugs.<sup>55</sup> But insulin manufacturers also have incrementally changed their insulin products, and "the trailing edge of old insulin products did not generate a market for generic competition but rather became a set of obsolete products that were promptly removed from the U.S. market."<sup>56</sup> Even when practitioners prescribe cheaper versions of insulin that still are available in the United States, the prescriptions instead are filled with newer recombinant products.<sup>57</sup>

139. In 2019, Eli Lilly introduced a lower-priced insulin called Lispro—a "generic" version of their Humalog insulin.<sup>58</sup> But Eli Lilly has not lived up to its promise to make insulin more affordable for Americans. In 2023, a study conducted by the offices of Senators Elizabeth Warren, Richard Blumenthal, and Raphael Warnock found that "[w]hile Eli Lilly's list price for [Lispro] was \$25, the average

<sup>&</sup>lt;sup>54</sup> See Lipska, supra n.29.

<sup>&</sup>lt;sup>55</sup> Jeremy A. Greene & Kevin R. Riggs, *Why Is There No Generic Insulin? Historical Origins of a Modern Problem*, 372 N. Eng. J. Med. 1171, 1172–73 (2015), <a href="https://www.nejm.org/doi/full/10.1056/NEJMms1411398">https://www.nejm.org/doi/full/10.1056/NEJMms1411398</a>.

<sup>&</sup>lt;sup>56</sup> *Id.* at 1174.

<sup>&</sup>lt;sup>57</sup> *Id*.

<sup>&</sup>lt;sup>58</sup> Lilly to Introduce Lower-Priced Insulin, Lilly: Invs. (Mar. 4, 2019), <a href="https://investor.lilly.com/news-releases/news-release-details/lilly-introduce-lower-priced-insulin">https://investor.lilly.com/news-releases/news-release-details/lilly-introduce-lower-priced-insulin</a>.

cost of Lispro at the pharmacy—without health insurance coverage—was \$97.51," with the most expensive pharmacy in the study pricing Lispro at \$330.<sup>59</sup>

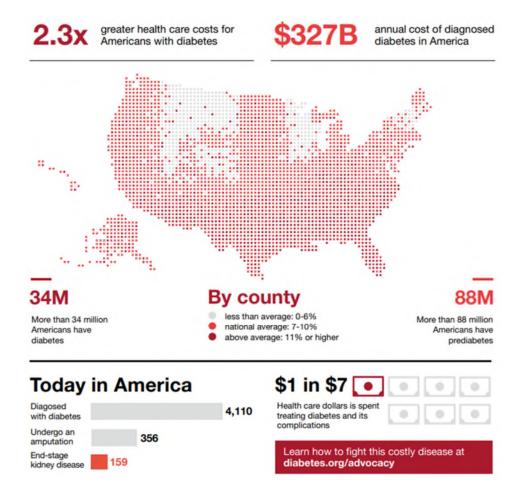
#### **B.** The Insulin Market Is Enormous.

140. More than 34 million Americans live with diabetes, and another 88 million Americans have prediabetes, a health condition that significantly increases a person's risk of type 2 diabetes. The condition is a significant source of health care costs. One in four health care dollars nationwide—and one in three Medicare dollars—is spent caring for people with diabetes.<sup>60</sup>

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<sup>&</sup>lt;sup>59</sup> Kelsey Waddill, *Generic Insulin Drug Pricing*, *Access Still Pose Problems for Uninsured*, HealthPayer Intelligence (July 17, 2023), <a href="https://healthpayerintelligence.com/news/generic-insulin-drug-pricing-access-still-pose-problems-for-uninsured">https://healthpayerintelligence.com/news/generic-insulin-drug-pricing-access-still-pose-problems-for-uninsured</a>.

<sup>60</sup> New American Diabetes Association Report Finds Annual Costs of Diabetes to be \$412.9 Billion, Am. Diabetes Assoc. (Nov. 1, 2023), <a href="https://diabetes.org/newsroom/press-releases/new-american-diabetes-association-report-finds-annual-costs-diabetes-be">https://diabetes.org/newsroom/press-releases/new-american-diabetes-association-report-finds-annual-costs-diabetes-be</a>; Adam Edelstein, Affordable Insulin Now Act Includes a Monthly Out-Of-Pocket Patient Maximum of \$35 for Insulin Prescriptions, UMass Diabetes Ctr. of Excellence, <a href="https://www.umassmed.edu/dcoe/news/umass-diabetes-news/2022/02/affordable-insulin-now-act">https://www.umassmed.edu/dcoe/news/umass-diabetes-news/2022/02/affordable-insulin-now-act">https://www.umassmed.edu/dcoe/news/umass-diabetes-news/2022/02/affordable-insulin-now-act</a> (last visited May 29, 2024).



- 141. Thus, millions of purchasers of insulin whose lives depend on the drug are captive to the market manipulation and other harmful aspects of Defendants' Insulin Pricing Scheme that has unlawfully hiked the price of this needed drug.
- 142. This conduct occurred throughout the United States and its territories and concerned the at-issue drugs listed above.
- 143. As evidence of the astronomical prices of the at-issue drugs, revenue from these top selling analog insulins tops \$15.9 billion (\$6.98 billion for Sanofi's

Lantus and \$376 million for its Apidra; \$3.03 billion for Novo Nordisk's NovoLog and \$2.68 billion for its Levemir; \$62 and \$2.84 billion for Eli Lilly's Humalog). \$63 It is reported that by 2029 the global insulin market is expected to top \$90 billion. \$64 This price tag has severely limited access and hurt patients physically, financially, and psychologically.

### C. The Pharmaceutical Supply and Payment Chains

144. Just as only three large companies manufacture insulin for the entire United States market—Eli Lilly, Novo Nordisk, and Sanofi—there are three large pharmacy benefit managers that control the vast majority of the PBM market. PBM Defendants CVS Caremark, Express Scripts, and OptumRx control nearly 80% of the PBM market and excise enormous control over the cost of insulin in tandem with the Manufacturer Defendants.

145. Pharmaceutical products originate in manufacturing sites; are transferred to wholesale distributors (in the case of insulin); are stocked at retail, mail-order, and other types of pharmacies; are subject to price negotiations and processed through quality and utilization management screens by pharmacy benefit

<sup>&</sup>lt;sup>61</sup> Sanofi, Annual Report (Form 20-F) (Mar. 3, 2017) at 24.

<sup>&</sup>lt;sup>62</sup> The world's top selling diabetes drugs, Pharm. Tech. (Mar. 30, 2016), <a href="http://www.pharmaceutical-technology.com/features/featurethe-worlds-top-selling-diabetes-drugs-4852441/">http://www.pharmaceutical-technology.com/features/featurethe-worlds-top-selling-diabetes-drugs-4852441/</a>.

<sup>&</sup>lt;sup>63</sup> *Id*.

<sup>&</sup>lt;sup>64</sup> *Global Insulin Market \$90 Billion by 2029*, ihealthcare (Sept. 4, 2023), <a href="https://www.ihealthcareanalyst.com/global-human-insulin-market/">https://www.ihealthcareanalyst.com/global-human-insulin-market/</a>.

managers; are dispensed by pharmacies; and ultimately are delivered to and taken by patients.<sup>65</sup>

146. The technical function of a pharmacy benefit manager is to administer a health coverage provider's prescription drug program. A pharmacy benefit manager develops the coverage provider's drug formulary (the list of drugs included in coverage at various pricing "tiers"), processes claims, creates a network of retail pharmacies that provide discounts in exchange for access to a provider's plan participants, and negotiates with pharmaceutical manufacturers. Often, pharmacy benefit managers are also responsible for performing drug utilization reviews and operating their own mail-order and specialty pharmacies. Pharmacy benefit managers also contract with a network of retail and community pharmacies. Pharmacies agree to dispense prescription drugs to covered patients. The contract provides for a payment rate for each prescription, plus a dispensing fee. Pharmacies are also responsible for collecting patient cost-sharing payments. Many pharmacy benefit managers also own mail-order and specialty pharmacies, which directly supply prescription drugs to patients.

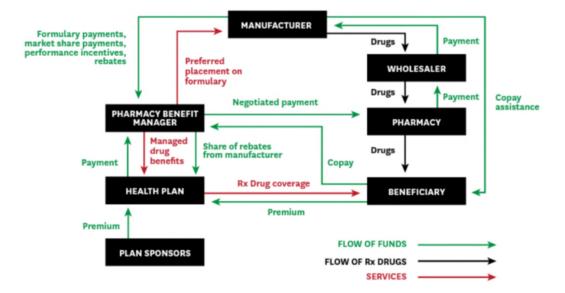
147. In addition, and of particular significance here, pharmacy benefit managers have contractual relationships with pharmaceutical manufacturers.

<sup>&</sup>lt;sup>65</sup> Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain, Health Strategies Consultancy LLC (Mar. 2005), <a href="https://www.kff.org/other/report/follow-the-pill-understanding-the-u-s/">https://www.kff.org/other/report/follow-the-pill-understanding-the-u-s/</a>.

Pharmacy benefit managers negotiate rebates, fees, and other concessions with the manufacturers. These relationships allow pharmacy benefit managers to exert tremendous influence and control over what drugs are made available to health plans and insureds.

148. The following figure illustrates the flow of funds, products, and services between pharmaceutical manufacturers, pharmacy benefit managers, health plans, health plan sponsors, drug wholesalers, pharmacies, and beneficiaries. Importantly, this figure does not include all relevant relationships and entities, nor does this figure capture the vertical integration that occurs between some of these entities.

Conceptual Model of the Flow of Products, Services, and Funds for Non-Specialty Drugs Covered under Private Insurance and Purchased in a Retail Setting<sup>66</sup>



- 149. At a high level, the complex supply chain for the flow of brand name drugs, including the at-issue insulin drugs, generally works as follows: (1) the manufacturer sells a drug to a wholesaler at a discounted rate; (2) the wholesaler marks up the drug and sells it to the pharmacy; (3) the pharmacy fills the prescription for a beneficiary; and (4) the pharmacy benefit manager reimburses the pharmacy for the drug resulting in a meager amount of profit (if not at a loss) for the pharmacy.
- 150. The core of this case centers, however, not on the flow of brand-name drugs through the system, but on the flow of funds and services between health plan payors, such as Plaintiff, the pharmacy benefit managers, and the pharmaceutical

<sup>&</sup>lt;sup>66</sup> Neeraj Sood et al., *Flow of Money Through the Pharmaceutical Distribution System*, USC Schaeffer Ctr. for Health Policy & Econ. (June 6, 2017), <a href="https://healthpolicy.usc.edu/research/flow-of-money-through-the-pharmaceutical-distribution-system/">https://healthpolicy.usc.edu/research/flow-of-money-through-the-pharmaceutical-distribution-system/</a>.

manufacturers. Here, the complex chain generally works as follows: (1) the pharmacy benefit managers negotiate with the drug manufacturers to receive discounts from list prices, rebates, and other fees in exchange for preferred placement on their plan formularies; (2) the pharmacy benefit managers manage the drug benefits for the health plan payors, such as Plaintiff; (3) the health plan payors pay their pharmacy benefit managers for the prescription drugs purchased by their beneficiaries; and (4) the health plan payors, such as Plaintiff, receive an unknown portion of the rebate amount negotiated between the pharmacy benefit managers and manufacturers from their pharmacy benefit managers.

## 1. The Rise of PBMs in the Pharmaceutical Supply Chain

151. When they first came into existence in the late 1960s, pharmacy benefit managers provided administrative services to health plans by processing claims and maintaining formularies. Over time, they began to play a larger role, including negotiating prices with drug manufacturers. Since pharmacy benefit managers were independent, they generally were thought to pass savings back to health plans and consumers by using their leverage to negotiate lower reimbursement rates with pharmacies and discounts with drug manufacturers.<sup>67</sup>

<sup>&</sup>lt;sup>67</sup> Brian Feldman, *Big pharmacies are dismantling the industry that keeps US drug costs even sort-of under control*, Quartz (Mar. 17, 2016), <a href="https://qz.com/636823/big-pharmacies-are-dismantling-the-industry-that-keeps-us-drug-costs-even-sort-of-under-control/">https://qz.com/636823/big-pharmacies-are-dismantling-the-industry-that-keeps-us-drug-costs-even-sort-of-under-control/</a>.

152. In the 1990s, drug manufacturers began acquiring pharmacy benefit managers, which caused an "egregious conflict[] of interest," prompting the Federal Trade Commission to undo those deals. The deals allowed drug manufacturers to coordinate pricing policies, see their competitors' sensitive pricing information, and favor their own drugs over those of their competitors.<sup>68</sup>

153. In the early and late 2000s, pharmacy benefit managers started buying pharmacies, which has caused a similar conflict of interest that resulted from the merger of drug manufacturers and pharmacy benefit managers in the 1990s. When a pharmacy benefit manager combines with a pharmacy, they "lose the incentive to police against pharmaceutical company schemes to steer patients to more expensive drugs. Indeed, they may collude in them." The power of the largest pharmacy benefit managers has continued to grow and has allowed them to distort the pharmaceutical supply chain to their own financial advantage.

# 2. The Current Size and Role of PBMs in the Pharmaceutical Supply Chain

154. According to the Pharmaceutical Care Management Association, the trade group that represents the PBM industry, pharmacy benefit managers manage

<sup>&</sup>lt;sup>68</sup> *Id*.

<sup>&</sup>lt;sup>69</sup> *Id*.

pharmacy benefits for over 275 million Americans.<sup>70</sup> Three large companies dominate the PBM market: Express Scripts, CVS Health, and OptumRx.

- 155. These PBM Defendants provide services to plans that administer prescription drug benefits to more than 275 million Americans and process more than 3 billion claims per year, and the PBM Defendants earn an enormous amount of revenue from the services described above.
- 156. Express Scripts is the largest PBM in the United States.<sup>71</sup> In 2022, annual revenue for Express Scripts' parent, Cigna Corp., was approximately \$180.5 billion.<sup>72</sup> As of December 31, 2022, more than 67,000 retail pharmacies participated in one or more of Express Scripts' networks.<sup>73</sup>
- 157. Insulin is a substantial part of Express Scripts' business. Indeed, Express Scripts reported that diabetes was the second highest therapeutic class of drugs in terms of spending in both 2021 and 2022.<sup>74</sup>

<sup>&</sup>lt;sup>70</sup> *About PCMA*, Pharm. Care Mgmt. Ass'n, <a href="https://www.pcmanet.org/about">https://www.pcmanet.org/about</a> (last visited May 29, 2024).

<sup>&</sup>lt;sup>71</sup> Anne Steele, *Express Scripts Revenue Falls*, Wall St. J. (Feb. 14, 2017), <a href="https://www.wsj.com/articles/express-scripts-revenue-falls-1487108990">https://www.wsj.com/articles/express-scripts-revenue-falls-1487108990</a>.

<sup>&</sup>lt;sup>72</sup> The Cigna Group Annual Report, *supra* n.26.

<sup>&</sup>lt;sup>73</sup> *Id*.

<sup>&</sup>lt;sup>74</sup> Express Scripts Canada, 2023 Drug Trend Report, <a href="https://www.express-scripts.ca/sites/default/files/2023-04/ESC%20DTR%20EN%20April%205%202023%20final.pdf">https://www.express-scripts.ca/sites/default/files/2023-04/ESC%20DTR%20EN%20April%205%202023%20final.pdf</a> (last visited May 29, 2024).

\$322.5 billion. The pharmacy services segment, which includes the corporation's PBM activities, but not its retail/long-term care segment, brought in \$169.2 billion in net revenues in 2022. And Defendant CVS Health's health services business, which includes its PBM CVS Caremark, saw revenue of \$90.8 billion for the first half of 2023 alone, up 8.9% with the same period in 2022.

159. CVS Health, through its subsidiary PBM, provides pharmacy benefit administration for a network of more than 66,000 retail pharmacies, including approximately 40,000 chain pharmacies and 26,000 independent pharmacies. RCVS Health Corporation's PBM filled or managed approximately 2.3 billion prescriptions during the year ending on December 31, 2022.

160. The third largest PBM, OptumRx, owned by UnitedHealth, provides pharmacy care services through a network of more than 67,000 retail pharmacies

<sup>&</sup>lt;sup>75</sup> CVS Health Corp., Annual Report (Form 10-K) (Feb. 8, 2023) at 8.

<sup>&</sup>lt;sup>76</sup> *Id*.

<sup>&</sup>lt;sup>77</sup> Denise Myshko, *CVS's Health Services Business Grows 9% in First Half of 2023*, Formulary Watch (Aug. 3, 2023),

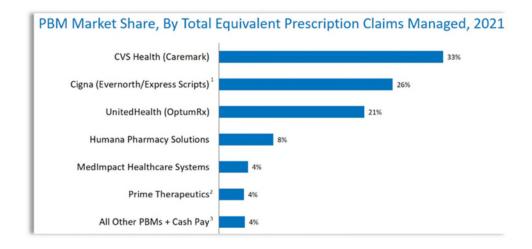
 $<sup>\</sup>underline{https://www.formularywatch.com/view/cvs-s-health-services-business-grows-9-first-half-of-2023.}$ 

<sup>&</sup>lt;sup>78</sup> *Id*.

<sup>&</sup>lt;sup>79</sup> *Id.* 

and multiple delivery facilities. In 2022, UnitedHealth Group's total revenue was \$324.2 billion.<sup>80</sup> In 2022, total revenue for OptumRx alone was \$99.8 billion.<sup>81</sup>

- 161. In 2022, OptumRx managed more than \$124 billion in pharmaceutical spending, <sup>82</sup> and fulfilled 1,438 million adjusted scripts. <sup>83</sup>
- 162. As described above, the PBM Defendants also control the market nationally. In particular, as recently as 2021, PBM Defendants make up nearly 80% of the market in terms of total prescription claims managed.<sup>84</sup>



163. The PBM Defendants' total earnings come directly from the pockets of payors, including municipal corporation payors such as Clark County, which cover the ever-increasing costs of insulin for their Beneficiaries.

<sup>80</sup> UnitedHealth Group, Annual Report (Form 10-K) (Feb. 24, 2023) at 1.

<sup>&</sup>lt;sup>81</sup> *Id*.

<sup>&</sup>lt;sup>82</sup> *Id*.

<sup>&</sup>lt;sup>83</sup> *Id*.

<sup>&</sup>lt;sup>84</sup> Adam J. Fein, *The Top Pharmacy Benefit Managers of 2021: The Big Get Even Bigger*, Drug Channels (Apr. 5, 2022), <a href="https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html">https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html</a>.

- 164. Due to the PBM Defendants' market share, smaller pharmacy benefit managers and other health insurers have significantly less bargaining power with drug manufacturers.
- 165. Recognizing this disadvantage, smaller pharmacy benefit managers have partnered with the major PBM Defendants, delegating responsibility for rebate negotiations with drug manufacturers to the major PBM Defendants.
- 166. On December 19, 2019, Express Scripts entered into a three-year collaboration agreement with Prime Therapeutics LLC ("Prime Therapeutics"), Plaintiff's PBM, under which Express Scripts would provide Prime Therapeutics services related to pharmaceutical manufacturer contracts. This agreement was renewed as of July 5, 2023. Under this agreement, Express Scripts handles negotiations for pharmacy benefit drugs, including the at-issue drugs, with the Manufacturer Defendants and retail pharmacy network contracting for most of Prime's business.
- 167. Due to the collaboration with Prime Therapeutics, Express Scripts now provides pharmacy benefit services to an additional 28 million individuals. As a result, Express Scripts has gained substantial additional bargaining leverage in the marketplace.
- 168. Earlier in 2019, prior to entering into a collaboration agreement with Prime Therapeutics, Express Scripts formed Ascent, a group purchasing

organization. Express Scripts later invited Prime Therapeutics into Ascent's ownership. Under Express Scripts and Prime Therapeutic's collaboration, rebate negotiations with manufacturers for a number of pharmacy benefit drugs were to be handled by Ascent.

169. The partnership between Express Scripts and Prime Therapeutics has come under scrutiny. On this partnership, the 2021 Grassley-Wyden Senate Report on the rising cost of insulin wrote that "it 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 Swissbased group purchasing organization (GPO), Ascent."85

170. Although Prime Therapeutics and Express Scripts touted their new partnership as a means to deliver "more affordable health care," in reality, their partnership has enabled both Express Scripts and Prime Therapeutics to profit off of increased rebates, while further escalating the already artificially high cost of insulin for consumers.

<sup>85</sup> U.S. S. Fin. Comm., supra n.7.

# 3. The Close Relationship Between the PBM Defendants and Manufacturer Defendants

- 171. The Insulin Pricing Scheme relies on close negotiations and communications between the PBM Defendants and Manufacturer Defendants. The pharmaceutical industry, being especially insular in nature, has provided both the Manufacturer Defendants and the PBM Defendants opportunities for contact and communication with their direct competitors, in addition to negotiations and communications between the PBM and Manufacturer Defendants.
- 172. All Manufacturer Defendants are members of the Pharmaceutical Research and Manufacturers of America ("PhRMA"). Each Manufacturer Defendant routinely interacts and communicates with the other Manufacturer Defendants through PhRMA meetings and platforms. David Ricks, CEO of Eli Lilly, Paul Hudson, CEO of Sanofi, and Douglas Langa, President of Novo Nordisk, all serve on the PhRMA Board of Directors.
- 173. All PBM Defendants are members of the Pharmaceutical Care Management Association ("PCMA").
- 174. David Joyner, Executive Vice President of CVS Health and President of CVS Caremark, Patrick Conway, CEO of OptumRx, Adam Kautzner, President of Express Scripts, and Mostafa Kamal, President and CEO of Prime Therapeutics, all serve on the PCMA Board of Directors.

175. The PBM Defendants regularly interact with the Manufacturer Defendants at trade associations and conferences. For example, the PCMA Annual Meeting's website states that the conference is "tailored specifically for senior executives from PBMs and their affiliated business partners – most notable drug manufacturers." These conferences "offer excellent opportunities for interactions between PBM members, drug manufacturers, and industry partners." These conferences specifically advertise the opportunities for members to have conversations in "private reception rooms." \*\*88\*\*

176. Not only are the Manufacturer Defendants attendees at the PCMA conferences, but they are also sponsors. Novo Nordisk is listed as a 2023 Partner Sponsor for the PCMA Annual Meeting, and Eli Lilly and Sanofi are listed as Presidential Sponsors.<sup>89</sup>

177. Through these conferences and other communications, the PBM Defendants and the Manufacturer Defendants are free to secretly discuss rebates, administrative fee arrangements, and the like, to artificially inflate the price of insulin, while pocketing substantial sums of money.

<sup>&</sup>lt;sup>86</sup> PCMA Annual Meeting, <a href="https://www.pcmanet.org/pcma-event/annual-meeting-2021/">https://www.pcmanet.org/pcma-event/annual-meeting-2021/</a> (last visited May 29, 2024).

<sup>&</sup>lt;sup>87</sup> *Id*.

<sup>&</sup>lt;sup>88</sup> *Id*.

<sup>&</sup>lt;sup>89</sup> *Sponsors*, PCMA Annual Meeting 2023, <a href="https://www.pcmanet.org/pcma-event/annual-meeting-2023/sponsors/">https://www.pcmanet.org/pcma-event/annual-meeting-2023/sponsors/</a> (last visited May 29, 2024).

178. In fact, at-issue lockstep price increases for insulin occurred shortly following PCMA meetings. For example, on May 30, 2014, a few weeks following a Spring 2014 PCMA conference, Novo Nordisk raised the list price of Levemir mere hours after Sanofi increased the list price of Lantus.

179. On September 26 and 27, 2017, the PCMA held its annual meeting. On October 1, 2017, Sanofi increased the list price of Lantus by 3% and the list price of Toujeo by 5.4%. Also shortly after the PCMA meeting, Novo Nordisk recommended a 4% increase in the list price of their insulin drugs, effective January 1, 2018.

180. Given the enormous size of the PBM Defendants and their role in the pharmaceutical supply chain dealing with manufacturers, health plans, pharmacies, and insureds, it is crucial that the PBM Defendants avoid conflicts of interest. This fact has been expressly recognized by the PCMA, the trade association for pharmacy benefit managers, and by pharmacy benefit managers individually.

181. The PCMA has Principles of Professional and Ethical Conduct to which all PCMA members, including the three PBM Defendants, agree.<sup>90</sup> Among these is an agreement to "[a]void any and all conflicts of interest and advise all parties, including my organization, of any situations where a conflict of interest exists."<sup>91</sup>

<sup>91</sup> *Id*.

<sup>&</sup>lt;sup>90</sup> Code of Ethics, PCMA <a href="https://www.pcma.org/about/principles-of-professional-and-ethical-conduct/">https://www.pcma.org/about/principles-of-professional-and-ethical-conduct/</a> (last visited May 29, 2024).

182. Defendant Express Scripts also has a published Code of Conduct, which stresses avoiding conflicts of interest.<sup>92</sup>

#### **D.** The Insulin Pricing Scheme

183. The Insulin Pricing Scheme describes the coordinated unfair and deceptive conduct of the three largest PBMs—CVS Health, Express Scripts, and OptumRx—and the three largest insulin manufactures—Eli Lilly, Novo Nordisk, and Sanofi—to artificially inflate the cost of insulin, analog insulins, and related diabetes medications. As a result of the Insulin Pricing Scheme, the PBM Defendants, in exchange for placing the Manufacturer Defendants' drugs in premium placements on their formulary lists, receive higher rebates along with other payments from the Manufacturer Defendants. Because the PBM Defendants and the Manufacturer Defendants are both rewarded handsomely for the inflated list prices resulting from the Insulin Pricing Scheme, they have, as a result, conspired to prevent disclosure of the drugs' net prices to payors and consumers, including Plaintiff.

184. The Insulin Pricing Scheme is evidenced by the astronomic increase in the price of insulin, the lockstep increases in insulin prices across all three Manufacturer Defendants, the growing gap between the list price of insulin and the

<sup>&</sup>lt;sup>92</sup> *Code of Conduct*, Express Scripts, <a href="https://www.express-scripts.com/aboutus/codeconduct/ExpressScriptsCodeOfConduct.pdf">https://www.express-scripts.com/aboutus/codeconduct/ExpressScriptsCodeOfConduct.pdf</a> (last visited May 29, 2024).

net price realized by the Manufacturer Defendants, and the massive profits the PBM Defendants receive as a result of the negotiated drug rebates and fees paid to them by the Manufacturer Defendants in exchange for favorable formulary placement.

185. As a direct and proximate cause of Defendants' Insulin Pricing Scheme, payors like Clark County are overpaying for life-saving medications.

## 1. Insulin's Price Has Risen Dramatically.

186. The prices of the at-issue drugs have increased dramatically. For example, since 2003, the list price of certain insulins has increased by more than 500%—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." 93

187. According to a report by Business Insider, similar price increases can be identified across insulin products and across manufacturers: A version of insulin that carried a list price of \$93 a vial in 2009 was priced at close to \$275 in September 2019. Another type of insulin that cost only \$93 in 2009 cost nearly \$290 a vial in September 2019. The prices of insulin have increased especially sharply in the past two decades. According to a report published by the American Journal of Managed Care, in 1996, the price an individual would need to pay for a vial of insulin made

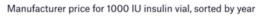
<sup>&</sup>lt;sup>93</sup> Hirsch, *supra* n.30.

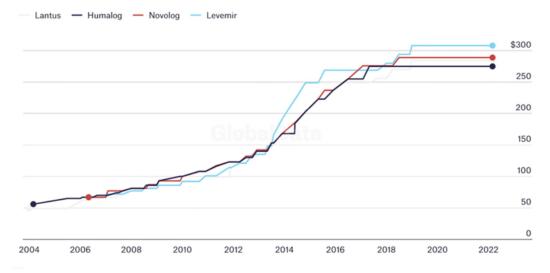
<sup>&</sup>lt;sup>94</sup> Rachel Gillett & Shayanne Gal, *One chart reveals how the cost of insulin has skyrocketed in the US, even though nothing about it has changed*, Bus. Insider (Sept. 18, 2019), <a href="https://www.businessinsider.com/insulin-price-increased-last-decade-chart-2019-9">https://www.businessinsider.com/insulin-price-increased-last-decade-chart-2019-9</a>.

by one manufacturer was \$21.95 In 2001, this same vial cost an individual \$35, and in 2019, that vial cost approximately \$275—a 1200% increase from its original price.96

188. Since 2004, analog insulin from the Manufacturer Defendants have more than quadrupled in price, as shown below:<sup>97</sup>

# <u>Comparison of Insulin Price Increases—Lantus, Humalog, Novolog, and Levemir, 2004-2022</u> Analog insulin prices have steadily risen in US





189. These price increases have occurred even in the face of supposed competition between manufacturers making similar drugs. Since the mid-1990s, there have been more than two dozen price increases on a vial of Humalog insulin.<sup>98</sup>

<sup>&</sup>lt;sup>95</sup> Danielle K. Roberts, *The Deadly Costs of Insulin*, Am. J. Managed Care (June 10, 2019), <a href="https://www.ajmc.com/view/the-deadly-costs-of-insulin">https://www.ajmc.com/view/the-deadly-costs-of-insulin</a>. <sup>96</sup> *Id*.

<sup>&</sup>lt;sup>97</sup> Newton, *supra* n.16.

<sup>&</sup>lt;sup>98</sup> Johnson, *supra* n.42.

- 190. The Manufacturer Defendants have represented that the price of the atissue insulin drugs is determined, in part, by the need to fund research, development, and innovation. And the PBM Defendants have continually claimed that they intentionally work to reduce insulin prices. For example:
  - A. In 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. In the same year, Andrew Sussman, CVS Caremark's Chief Medical Officer, stated that CVS was "working to develop programs to hold down [diabetes] costs." 100
- 191. In 2016, the SVP and Chief Innovation Officer at Express Scripts stated that "[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," and that it "broaden[s]

<sup>&</sup>lt;sup>99</sup> Chain Drug Review, *CVS Expands Extracare for Diabetes Products* (May 11, 2010), <a href="https://www.chaindrugreview.com/cvs-expands-extracare-for-diabetes-products/">https://www.chaindrugreview.com/cvs-expands-extracare-for-diabetes-products/</a> (last visited May 29, 2024).

<sup>&</sup>lt;sup>100</sup> CBS News, *Diabetes Epidemic Growing* (June 22, 2010), <a href="https://www.cbsnews.com/news/diabetes-epidemic-growing/">https://www.cbsnews.com/news/diabetes-epidemic-growing/</a>.

insulin options for patients and bend[s] down the cost curve of what is currently the costliest class of traditional prescription drugs."<sup>101</sup>

- 192. Despite this, the U.S. House of Representatives Committee on Oversight and Reform concluded in its Drug Pricing Investigation that these claims were unsupported. 102
- 193. For example, between 2005 and 2018, Eli Lilly spent only \$680 million on research and development costs for Humalog, while its net sales for Humalog were \$31.35 billion. <sup>103</sup> In other words, net sales were 46 times the reported research and development costs.

<sup>&</sup>lt;sup>101</sup> Jon Kamp & Peter Loftus, *CVS' PBM Business Names Drugs It Plans to Block Next Year*, Wall St. J. (Nov. 8, 2012), <a href="https://www.wsj.com/articles/SB100014">https://www.wsj.com/articles/SB100014</a> <a href="https://www.bizjournals.com/stlouis/news/2016/08/31/express-scripts-launches-program-to-control.html">https://www.bizjournals.com/stlouis/news/2016/08/31/express-scripts-launches-program-to-control.html</a>.

<sup>&</sup>lt;sup>102</sup> U.S. H.R., Comm. on Oversight and Reform, *Drug Pricing Investigation*, OVERSIGHTDEMOCRATS.HOUSE.GOV (Dec. 2021), <a href="https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPE">https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPE</a>
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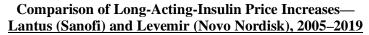
194. Driven by these price hikes, patient and health plan payor spending on insulin has skyrocketed, with totals in the tens of billions of dollars. In Washington, "many find insulin inaccessible or unaffordable due to its high list price," and as a result skip doses or otherwise ration their insulin.<sup>104</sup>

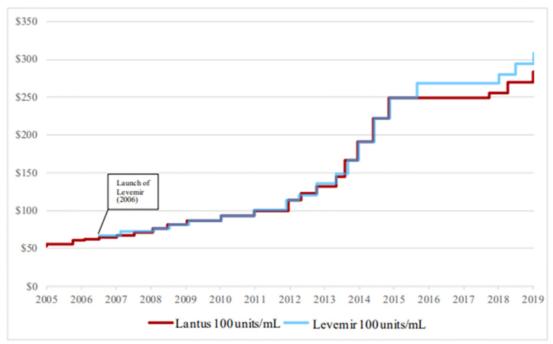
#### 2. Insulin List Prices Have Increased in Lockstep.

195. These price increases are even more troubling when one considers their timing and context, which seem to bear little relation to developmental advances or market demand. For example, as indicated below, between 2006 and 2019, prices for two competing long-acting analog insulin products—Sanofi's Lantus and Novo Nordisk's Levemir—went up in lockstep.<sup>105</sup>

<sup>&</sup>lt;sup>104</sup> Wash. Health Care Auth., *Total Cost of Insulin Work Group: Final Report* 4 (July 1, 2023), <a href="https://app.leg.wa.gov/ReportsToTheLegislature/Home/GetPDF?">https://app.leg.wa.gov/ReportsToTheLegislature/Home/GetPDF?</a> fileName=Total%20Cost%20of%20Insulin%20Work%20Group%20Final%20Report\_14954d3d-cc6d-41d2-bb5a-ecb01027fa31.pdf.

<sup>&</sup>lt;sup>105</sup> U.S. H.R., Comm. on Oversight and Reform, *supra* n.102; *see also* Langreth, *supra* n.16.





196. Similarly, the price of Humalog, a rapid-acting analog insulin produced by Eli Lilly, and the price of its direct competitor, Novolog, produced by Novo Nordisk, increased in lockstep from 2001 through 2018. 106

<sup>&</sup>lt;sup>106</sup> U.S. H.R., Comm. on Oversight and Reform, *supra* n.102.

#### \$300 \$250 Price per Package 0018 0019 Launch of NovoLog (2001) \$50 \$0 1996 1998 2002 2004 2006 2008 2010 2012 2014 2016 2018 Effective Date

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

197. This practice of increasing drug prices in lockstep with competitors is known as "shadow pricing" and, as noted by Dr. Irl B. Hirsch, has functioned to precipitously increase the price of insulin in the United States. 108

NovoLog100units/mL

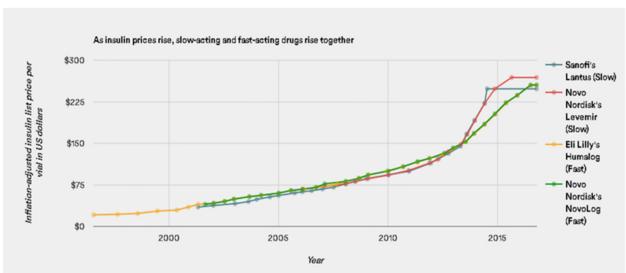
Humalog 100 units/mL -

198. The overlap in price hikes across both categories of analog insulins (rapid and long-acting) is remarkable as well:<sup>109</sup>

<sup>&</sup>lt;sup>107</sup> Lydia Ramsey, *There's something odd about the way insulin prices change*, Bus. Insider (Sept. 17, 2016), <a href="https://www.businessinsider.com/rising-insulin-prices-track-competitors-closely-2016-9">https://www.businessinsider.com/rising-insulin-prices-track-competitors-closely-2016-9</a>.

<sup>&</sup>lt;sup>108</sup> Hirsch, supra n.30.

<sup>&</sup>lt;sup>109</sup> Rebecca Robbins, *The Insulin Market is Heading for a Shakeup. But Patients May Not Benefit*, STAT (Oct. 14, 2016), <a href="https://www.statnews.com/2016/10/14/insulin-prices-generics/">https://www.statnews.com/2016/10/14/insulin-prices-generics/</a>.



Comparison of Insulin List Prices of Rapid-Acting and Long-Lasting Insulin

JEFFERY DELVISCIO/STAT Source: Truven Health Analytics

199. In thirteen instances since 2009, Sanofi and Novo Nordisk raised the list prices of their long-acting analog insulins, Lantus and Levemir, in tandem, "taking the same price increase down to the decimal point within a few days of each other." As one healthcare analyst put it: "That is pretty much a clear signal that your competitor doesn't intend to price-compete with you." Eli Lilly and Novo Nordisk have engaged in the same lockstep behavior with respect to their rapidacting analog insulins, Humalog and Novolog.

200. Because of Defendants' Insulin Pricing Scheme and the lockstep increases in the price of insulin, "[n]early a century after its discovery, there is still no inexpensive supply of insulin for people living with diabetes in North

<sup>&</sup>lt;sup>110</sup> Langreth, *supra* n.16.

<sup>&</sup>lt;sup>111</sup> *Id*.

America...."<sup>112</sup> Instead, diabetes patients who need insulin to survive are forced to pay exorbitant costs to survive.

# 3. The Growing Gap Between List Prices and Net Prices

201. The Insulin Pricing Scheme is further evidenced by the growing gap between the list price of insulin drugs and net price realized by the Manufacturer Defendants once all rebates and fees paid to the PBM Defendants are taken into account.

202. While the Defendants often obscure their true net realized prices for insulin, the escalating list price is generally public information. Defendants know that the public list prices do not bear a reasonable relationship to the profits and actual net prices realized by Defendants, and that payors, including Plaintiff, made payments for insulin based on the false list prices generated by the scheme.

203. As noted above, the list prices for analog insulins sold by Eli Lilly, Novo Nordisk, and Sanofi have increased rapidly in lockstep with one another. The question, then, is why the Manufacturer Defendants are not competing on price. They sell similar, and in many ways interchangeable drugs, and have been for years. Indeed, the drugs are the same as they were ten years ago, and the clinical benefit of the drugs remains unchanged. Yet, the list price keeps going up.

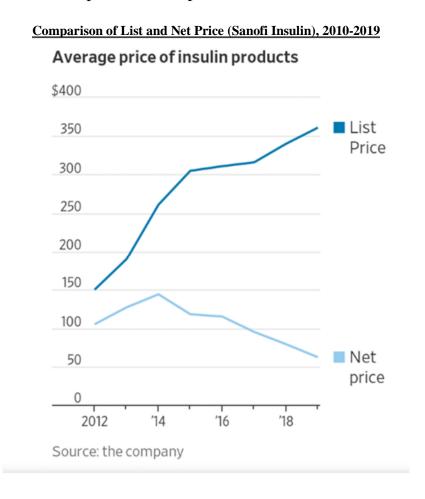
<sup>&</sup>lt;sup>112</sup> Greene & Riggs, *supra* n.55, at 1175.

204. The answer is the Insulin Pricing Scheme. The Manufacturer Defendants are not competing on price because, instead, they are competing on rebates and other fees paid to the PBM Defendants. This unfair and deceptive conspiracy explains the spectacular rise in list prices for the at-issue drugs, while the net prices realized by the Manufacturer Defendants remains relatively constant—though of course the volume of sales and the amount of drugs they are able to sell and provide on formularies remains high. Indeed, as set forth herein, Clark County continued to pay for the at-issue drugs throughout the relevant time period and several of the drugs were among the most the County paid for by gross cost.

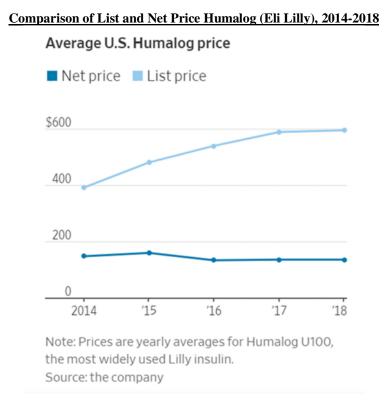
205. In exchange for the rebates and fees paid to the PBM Defendants, the PBM Defendants provide the Manufacturer Defendants with favorable formulary placement for their drugs. As explained by David Kliff, editor of the website Diabetic Investor, "Insulin is a commodity, so formulary position is everything. It's like location in real estate." The Manufacturer Defendants are thus incentivized to participate in the Insulin Pricing Scheme because this favorable formulary placement results in increased sales and revenue of their at-issue insulin drugs.

<sup>&</sup>lt;sup>113</sup> Arthur Allen, *Insulin's High Costs Goes Beyond Drugmakers to Industry's Price Mediators*, CNN (Mar. 9, 2023), <a href="https://www.cnn.com/2023/03/09/bealth/insulin-cost-khn-partner/index.html">https://www.cnn.com/2023/03/09/bealth/insulin-cost-khn-partner/index.html</a>.

206. The following figures, provided by Sanofi and Eli Lilly, illustrate the growing gap between list price and net price.<sup>114</sup>



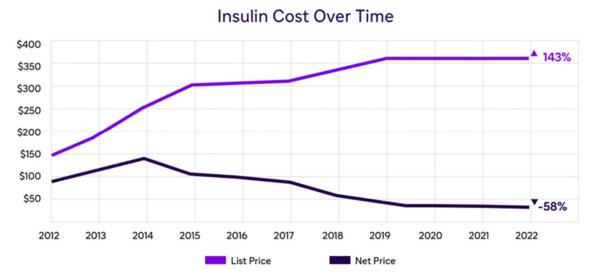
<sup>&</sup>lt;sup>114</sup> Denise Roland, *Sanofi, Fighting Back in Insulin Price Debate, Says Its Net Prices Fell 11%*, Wall St. J. (Mar. 4, 2020), <a href="https://www.wsj.com/articles/sanofi-fighting-back-in-insulin-price-debate-says-its-net-prices-fell-11-11583340721">https://www.wsj.com/articles/sanofi-fighting-back-in-insulin-price-debate-says-its-net-prices-fell-11-11583340721</a> (Figure 1); Peter Loftus, *As Political Scrutiny Mounts, Eli Lilly Divulges New Insulin Pricing Data*, Wall St. J. (Mar. 24, 2019), <a href="https://www.wsj.com/articles/as-political-scrutiny-mounts-eli-lilly-divulges-new-insulin-pricing-data-11553436000">https://www.wsj.com/articles/as-political-scrutiny-mounts-eli-lilly-divulges-new-insulin-pricing-data-11553436000</a> (Figure 2).



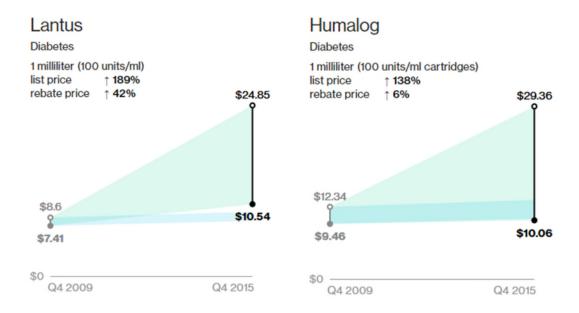
207. The below figure demonstrates the difference between the list price and net price of Sanofi insulins from 2012 to 2022.<sup>115</sup>

<sup>&</sup>lt;sup>115</sup> Prescription Medicine Pricing: Our principles and perspectives, Sanofi, <a href="https://web.archive.org/web/20230327030218/https://www.sanofi.us/dam/jcr:356cc1f5-92dd-47a1-9770-ba60dfdfab1e/Sanofi-2023-Pricing-Principles-Report.pdf">https://www.sanofi.us/dam/jcr:356cc1f5-92dd-47a1-9770-ba60dfdfab1e/Sanofi-2023-Pricing-Principles-Report.pdf</a>.

## Comparison of List and Net Price (Sanofi Insulin), 2012-2022



208. As indicated in the below diagrams prepared by SSR Health,<sup>116</sup> a health-industry research firm, the same widening gap between net price and list price has occurred for the other major analog insulins:



<sup>&</sup>lt;sup>116</sup> Robert Langreth, et al., *Decoding Big Pharma's Secret Drug Pricing Practices*, Bloomberg (June 29, 2016), <a href="https://www.bloomberg.com/graphics/2016-drug-prices/">https://www.bloomberg.com/graphics/2016-drug-prices/</a>.

209. The Manufacturer Defendants have publicly represented that these price increases are related to the drugs' value to the healthcare system and the need to fund research and development. For example, "briefing materials prepared for [Eli Lilly's] Chief Executive Officer (CEO) Dave Ricks as a panelist at the 2017 Forbes Healthcare Summit included 'Reactive Key Messages' on pricing that emphasized the significant research and development costs for insulin." Executives for other insulin manufacturers similarly represented that research and development costs were key factors driving the price increases for insulin. 118

210. Despite these representations, the Manufacturer Defendants' price increases far exceeded any related research and development costs. Eli Lilly, as mentioned above, reported that it spent approximately \$680 million on research and development related to Humalog globally between 2005 and 2018; over that same period, worldwide net sales of Humalog were \$31.35 billion—forty-six times more than reported research and development costs. Similarly, Sanofi spent 2.4% of its U.S. net sales generated by Lantus on research and development.

<sup>&</sup>lt;sup>117</sup> U.S. H.R., Comm. on Oversight and Reform, *supra* n.102.

 $<sup>^{118}</sup>$  *Id*.

<sup>&</sup>lt;sup>119</sup> *Id*.

 $<sup>^{120}</sup>$  *Id*.

# 4. Rebates Gone Awry

211. The PBM Defendants turn a profit in numerous ways. Their health plan clients pay them service fees for processing prescriptions and operating mail-order pharmacies. Health plans also pay transaction fees on the different operations required to manage the complex cash flows between insurers, pharmacists, and manufacturers. But one of the primary sources of PBM Defendants' profits in recent decades has been the drug "rebates" and other fees they negotiate with drug companies.

212. If the PBM Defendants operated ethically and honestly, they would negotiate lower drug prices in exchange for formulary access. <sup>121</sup> Indeed, pharmacy benefit managers have the greatest leverage to negotiate lower prices when two or more drug companies make ostensibly interchangeable products—i.e., drugs within the same therapeutic class. In such a scenario, the drug manufacturers should compete on price, as in normal competitive markets.

<sup>&</sup>lt;sup>121</sup> Although the pharmacy benefit managers treat different insulin as if they were completely interchangeable, in fact, they have different inactive ingredients that can cause allergic reactions for diabetes patients. Type 1 diabetes is an autoimmune disease, and many patients are sensitive to insulin changes. Moreover, the treatment of different insulins as therapeutically interchangeable is also based on the assumption that all insulins are absorbed based on the same normal curve, which is not always true. Patients can have different duration of insulin action on one insulin versus another.

- 213. The PBM Defendants acknowledge this leverage: CVS Health boldly boasts on its website that one of the "basic services" it provides is "negotiating low costs and rebates with pharmaceutical manufacturers." Express Scripts says in its "About Us FAQ" that it "make[s] prescription medications safer and more affordable for [its] members." And OptumRx says that members can expect "lowest net cost drug procurement and pharmaceutical manufacturer negotiations." 124
- 214. In addition to these general misrepresentations, the PBM Defendants have consistently specifically disavowed that their conduct drives prices higher:
  - A. In 2017, Express Scripts CEO Tim Wentworth stated that "[d]rugmakers set prices, and we exist to bring those prices down." 125

<sup>&</sup>lt;sup>122</sup> *Pharmacy benefit manager*, CVS Health, <a href="https://www.cvshealth.com/services/prescription-drug-coverage/pharmacy-benefits-management.html">https://www.cvshealth.com/services/prescription-drug-coverage/pharmacy-benefits-management.html</a> (last visited May 29, 2024).

<sup>&</sup>lt;sup>123</sup> About us, Express Scripts, <a href="https://www.express-scripts.com/frequently-asked-questions/about">https://www.express-scripts.com/frequently-asked-questions/about</a> (last visited May 29, 2024).

<sup>&</sup>lt;sup>124</sup> Pharmacy benefit management (PBM), Optum, <a href="https://www.optum.com/business/employers/pharmacy-care-services.html">https://www.optum.com/business/employers/pharmacy-care-services.html</a> (last visited May 29, 2024).

<sup>&</sup>lt;sup>125</sup> Samantha Liss, *Express Scripts CEO Addresses Drug Pricing 'Misinformation'*, St. Louis Post-Dispatch (Feb. 17, 2017), <a href="https://www.stltoday.com/business/local/express-scripts-ceo-addresses-drug-pricing-misinformation/article\_8c65cf2a-96ef-5575-8b5c-95601ac51840.html">https://www.stltoday.com/business/local/express-scripts-ceo-addresses-drug-pricing-misinformation/article\_8c65cf2a-96ef-5575-8b5c-95601ac51840.html</a>.

- B. In the same year, CVS Caremark's Larry Merlo stated that "[a]ny suggestion that PBMs are causing prices to rise is simply erroneous." <sup>126</sup>
- C. OptumRx's Sumit Dutta, when asked by Congress if PBM-negotiated rebates and discounts were causing the price of insulin to increase, said that "we can't see a correlation when rebates raise list prices." <sup>127</sup>
- D. And in 2019, Amy Bricker—who worked for Express Scripts at the time before moving to CVS—testified, "I have no idea why the prices [for insulin] are so high, none of it is the fault of rebates." <sup>128</sup>
- 215. However, contrary to the PBM Defendants' representations, their arrangement with the Manufacturer Defendants is not operated ethically and honestly. The Manufacturer Defendants and PBM Defendants are gaming the system. They have realized that they both benefit if, instead of forcing the Manufacturer Defendants to sell their drugs for cheaper prices, the PBM Defendants induce the Manufacturer Defendants to compete by paying ever-increasing rebates and fees to the PBM Defendants. Because they are no longer competing on price, this arrangement induces the Manufacturer Defendants to raise their publicly

<sup>&</sup>lt;sup>126</sup> Lynn R. Webster, *Who is to blame for skyrocketing drug prices?*, The Hill (July 27, 2017), <a href="https://thehill.com/blogs/pundits-blog/healthcare/344115-who-is-to-blame-for-skyrocketing-drug-prices/">https://thehill.com/blogs/pundits-blog/healthcare/344115-who-is-to-blame-for-skyrocketing-drug-prices/</a>.

<sup>&</sup>lt;sup>127</sup> Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin, Congress.gov (Apr. 10, 2019), <a href="https://www.congress.gov/event/116th-congress/house-event/109299?s=1&r=3">https://www.congress.gov/event/116th-congress/house-event/109299?s=1&r=3</a>.

<sup>128</sup> Id.

reported list prices, which enables them to largely maintain their net realized price. The increased list prices create what is, in effect, a massive slush fund that can be used by the Manufacturer Defendants to pay the larger and larger rebates and fees demanded by the PBM Defendants for preferred formulary placement.<sup>129</sup>

216. The Insulin Pricing Scheme allows the Manufacturer Defendants to maintain their profit margins on drugs sold in the United States—which are higher than anywhere else in the world—and ensure their access to the millions of Americans whose drugs are made available via the PBM Defendants' formularies. And the Insulin Pricing Scheme allows the PBM Defendants to leverage their control over formularies to obtain kickbacks. With list prices going up, the rebates get bigger, and so does the PBM Defendants' cut. The Insulin Pricing Scheme artificially drives up list prices so the Manufacturer Defendants can earn more profit. And the Manufacturer Defendants can pay the PBM Defendants what they demand without significantly impacting their profits.

217. Thus, far from using their prodigious bargaining power to lower drug prices, as they repeatedly claim, the PBM Defendants abuse their position to benefit both themselves and the Manufacturer Defendants. It is a profitable enterprise, though deeply unethical and damaging to consumers and health plan payors, who do not pay the "net" price but instead pay amounts derived from the ever-increasing list

<sup>129</sup> Roland & Loftus, supra n.24.

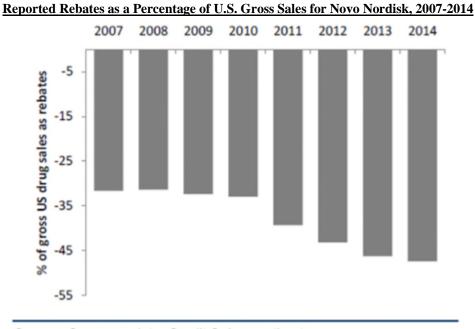
price. Thus, while the PBM and Manufacturer Defendants benefit, it is consumers and health plans who shoulder the burden of the higher list prices through increased payments. This dynamic lies at the heart of the surging cost of insulin, and the resulting public health disaster.

- 218. Drug manufacturers well understand the power of pharmacy benefit managers.<sup>130</sup> Because of their size, and the many thousands of health plan clients they serve, pharmacy benefit managers can steer business from one drug manufacturer to another based on which one pays the larger kickback.
- 219. Pharmacy benefit managers make outsize profits by exploiting the United States' complex pharmaceutical distribution system. While the existence of pharmacy benefit managers in the supply chain is known, the nature and magnitude of the rebates and other fees they extract from drug companies for formulary placement, and the portion of these payments they pocket, are carefully guarded secrets.<sup>131</sup>
- 220. Although the true amount of rebates received by the PBM Defendants is unknown, available data demonstrates an increase over time in the aggregate rebates made by Defendant Manufacturers Eli Lilly, Novo Nordisk and Sanofi to

<sup>&</sup>lt;sup>130</sup> See Roland & Loftus, supra n.24.

<sup>&</sup>lt;sup>131</sup> See, e.g., Lydia Ramsey, One of the largest middlemen in the drug industry just released a video showing why it should be able to remain secretive, Bus. Insider (Feb. 9, 2017), <a href="http://www.businessinsider.com/what-pharmacy-benefit-managers-are-doing-about-trump-and-drug-pricing-2017-2">http://www.businessinsider.com/what-pharmacy-benefit-managers-are-doing-about-trump-and-drug-pricing-2017-2</a>.

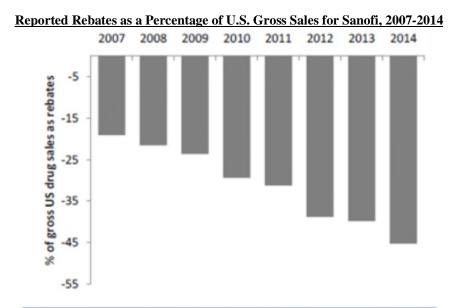
pharmacy benefit managers and insurers. This is illustrated in the figures below. The figure below illustrates the growth in Novo Nordisk's aggregate rebates from 2007 to 2014. 132



Source: Company data, Credit Suisse estimates

221. Sanofi has also greatly increased its rebates. The figure below shows the amount Sanofi has increased its rebates from 2007 to 2014.

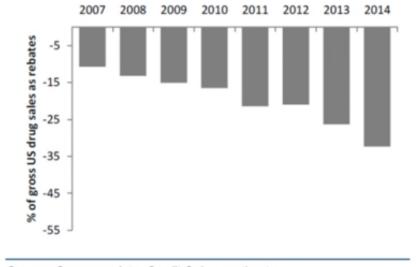
<sup>&</sup>lt;sup>132</sup> Jeffrey Balin, et al., *Global Pharma: Rising US Rebates Limit Margin Expansion*, Credit Suisse, 23 (May 1, 2015).



Source: Company data, Credit Suisse estimates

222. Finally, Eli Lilly has greatly increased its rebates. The figure below shows the amount Eli Lilly has increased its rebates from 2007 to 2014. Contrary to Novo Nordisk, for which insulin represents a substantial amount of gross revenues, Eli Lilly is an extremely diversified manufacturer. As a result, the impact of the very steep insulin rebating that has gained Lilly the lion's share of the U.S. insulin market in recent years is attenuated in the graph below by less aggressive rebating on other drug classes.

#### Reported Rebates as a Percentage of U.S. Gross Sales for Eli Lilly, 2007-2014



Source: Company data, Credit Suisse estimates

#### 5. Clawbacks

- 223. In addition to profiting off increasing rebates, the PBM Defendants use clawbacks to profit from the Insulin Pricing Scheme.
- 224. Non-PBM affiliated pharmacies state that pharmacy benefit managers have forced them to sign contracts that include clawbacks or post-purchase discount provisions, under which the pharmacies have to pay the pharmacy benefit managers money, sometimes long after sales take place. Mel Brodsky, the Executive Director of the Philadelphia Association of Retail Druggists noted that the contracts

<sup>&</sup>lt;sup>133</sup> Arthur Allen, *What to know about the drug price fight in those TV ads*, NPR.org (July 7, 2023), <a href="https://www.npr.org/sections/health-shots/2023/07/07/1186317">https://www.npr.org/sections/health-shots/2023/07/07/1186317</a> 498/pharmacy-benefit-manager-pbm-ads-congress.

between pharmacies and pharmacy benefit managers are "usually take-it-or-leave-it contracts." 134

225. Clawbacks are typically a percentage of a drug's list price. Because the Insulin Pricing Scheme has artificially inflated the list price of insulin drugs, it creates greater clawbacks for the PBM Defendants. This further adds to the already strong incentives for the PBM Defendants to aggressively pursue conduct that artificially inflates list prices.

# 6. Spread Pricing

- 226. Another way that the PBM Defendants profit from the Insulin Pricing Scheme is through spread pricing.
- 227. The PBM Defendants determine which pharmacies they want to contract with and include in their networks. In these contractual agreements, the PBM Defendants determine how much they will reimburse pharmacies for drugs (typically a percentage of the list price).
- 228. The PBM Defendants charge health plan payor clients more for a drug (a higher percentage of the list price) than the PBM Defendants pay the pharmacies. The PBM Defendants keep the difference. Because both the client and pharmacy

<sup>&</sup>lt;sup>134</sup> Tatiana Ayazo, *Here's Why You're Probably Overpaying for Medicine*, RD.com (May 22, 2018), <a href="https://www.rd.com/article/overpaying-for-medicine/">https://www.rd.com/article/overpaying-for-medicine/</a>. <sup>135</sup> Bob Herman, *How drug middlemen take back money from pharmacies*, Axios.com (July 25, 2019), <a href="https://www.axios.com/2019/07/25/express-scripts-pharmacies-quality-clawbacks-contract">https://www.axios.com/2019/07/25/express-scripts-pharmacies-quality-clawbacks-contract</a>.

contracts are structured as a percentage of the list price, the amount of "spread" the PBM Defendants retain increases as the list price increases, thus further adding to the PBM Defendants' incentives to artificially increase list prices.

- 229. In 2022, the Pharmacy Benefit Manager Transparency Act S. 4293, was introduced to prohibit spread pricing: when a pharmacy benefit manager "[charges] a health plan or payer a different amount for a prescription drug's ingredient cost or dispensing fee than the amount the pharmacy benefit manager reimburses a pharmacy for the prescription drug's ingredient cost or dispensing fee where the pharmacy benefit manager retains the amount of any such difference."<sup>136</sup> The bill has not yet been enacted into law.
- 230. The PBM Defendants also benefit from a related concept when health plan members fill prescriptions through the PBM Defendant's affiliated retail and mail-order pharmacies. The PBM Defendants' in-house pharmacies acquire drugs at a lower cost than what the PBM Defendants charge their health plan payor clients. The PBM Defendants (together with their affiliated pharmacies) thus profit off the spread between their acquisition costs and the amounts paid by health plan payors.
- 231. The size of this spread is further increased by various discounts the PBM Defendants and their affiliated pharmacies negotiate with the Manufacturer

<sup>&</sup>lt;sup>136</sup> Pharmacy Benefit Manager Transparency Act of 2022, S. 4293, 117th Cong., <a href="https://www.govtrack.us/congress/bills/117/s4293">https://www.govtrack.us/congress/bills/117/s4293</a> (last visited May 29, 2024).

Defendants. Moreover, the PBM Defendants' negotiations with the Manufacturer Defendants may give them inside information as to when the Manufacturer Defendants will increase list prices, allowing the PBM Defendants (and their affiliated pharmacies) to maximize their spread income by stocking up on drugs before price increases and then later selling them to health plan members and payors at the increased price.

# 7. Defendants' Admissions

- 232. Defendants have acknowledged these price increases and their impact on payors and patients. On April 10, 2019, the United States House of Representatives Committee on Energy and Commerce held a hearing on industry practices titled, "Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin."
- 233. Representatives from all Defendants testified at the hearing and admitted that the price for insulin had increased exponentially over the past fifteen years.
- 234. Each Defendant also conceded that the price that diabetics pay out-of-pocket for insulin is too high. For example:
  - A. Dr. Sumit Dutta, SVP and Chief Medical Officer of OptumRx since 2015, stated that "[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, General Counsel for CVS Health admitted that "[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, 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."<sup>137</sup>
- 235. 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.
- 236. Instead, Novo Nordisk's President Doug Langa's written testimony for the April 2019 hearing recognized "misaligned incentives" that have led to higher drug costs, including for insulin: "Chief among these misaligned incentives is the fact that the rebates pharmaceutical companies pay to PBMs are calculated as a percentage of WAC [list] price. That means a pharmaceutical company fighting to remain on formulary is constrained from lowering WAC price, or even keeping the price constant, if a competitor takes an increase. This is because PBMs will then earn less in rebates and potentially choose to place a competitor's higher-priced product on their formulary to the exclusion of others." Likewise, Mr. Langa's responses to

<sup>&</sup>lt;sup>137</sup> Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin, Hearing before the Subcomm. on Oversight and Investigations, 116 Cong. (Apr. 10, 2019), <a href="https://www.govinfo.gov/content/pkg/CHRG-116hhrg39747/htm">https://www.govinfo.gov/content/pkg/CHRG-116hhrg39747/htm</a>.

questions for the record conceded that "[t]he disadvantage of a system in which administrative fees are paid as a percentage of the list price is that there is increased pressure to keep list prices high. . . . "

237. The hearing transcript records Mr. Langa's further comments in this regard:

[T]here is this perverse incentive and misaligned incentives 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're spending almost \$18 billion a year in rebates, discount, and fees, and we have people with insurance with diabetes that don't get the benefit of that.

238. Eli Lilly 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 ...\$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 that [formulary position] so that people can use our insulin.

In the very next question, Mr. Langa of Novo Nordisk was asked, "[H]ave you ever lowered a list price?" His answer, "We have not."

239. Sanofi's Executive Vice President for External Affairs, Kathleen Tregoning, testified: "The rebates is [sic] 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." Her written response to questions for the record acknowledged that "it is clear that payments based on a percentage of list price result in a higher margin [for PBMs] for the higher list price product than for the lower list price product."

- 240. The PBM Defendants also conceded at the April 2019 Congressional hearing that they grant preferred, or even exclusive, formulary position because of higher Manufacturer Payments paid by the Manufacturer Defendants.
- 241. In her responses to questions for the record, Amy Bricker—former President of Express Scripts, a former PCMA board member, and now an executive at CVS Health—confirmed that "manufacturers lowering their list prices" would give patients "greater access to medications;" yet 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 discounts [i.e., payments] for exclusive [formulary] position . . ." When asked why the PBM would not include both costly and lower-priced insulin medications on its formulary, Ms. Bricker stated plainly, "We'll receive less discount in the event we do that."
- 242. As Dr. Dutta, SVP of OptumRx, perversely reasoned, the cheaper list-priced alternative Admelog is not given preference on the formulary because "it would cost the payer more money to do that . . . [b]ecause the list price is not what the payer is paying. They are paying the net price." But, of course, health plan payors do not pay the "net" price, even when "rebates" are passed-through, because the

PBMs receive and retain countless other forms of payments that drive up the gap between the "list" price and the "net" price retained by drug manufacturers.

- 243. While all Defendants acknowledged before Congress their participation in conduct integral to the Insulin Pricing Scheme, none revealed its inner workings or the connection between their coordination and the economic harm that payors, like Plaintiff, and its Beneficiaries were unwittingly suffering. Instead, in an effort to obscure the true reason for precipitous price increases, each Defendant group pointed the finger at the other as the more responsible party.
- 244. The PBM Defendants testified to Congress that the Manufacturer Defendants are solely responsible for their list price increases and that the Manufacturer Payments that the PBM Defendants receive are not correlated to rising insulin prices.
- 245. On the contrary, the amount the Manufacturers kick back to the PBM Defendants is directly correlated to an increase in list prices—on average, a \$1 increase in Manufacturer Payments is associated with a \$1.17 increase in list price. Reducing or eliminating Manufacturer Payments would lower prices and reduce health plan expenditures.

<sup>&</sup>lt;sup>138</sup> Neeraj Sood et al., *The Association Between Drug Rebates and List Prices*, Univ. of S. Cal. (Feb. 11, 2020), <a href="https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/">https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/</a>.

246. Further, in large part because of the increased list prices and related Manufacturer Payments, the PBM Defendants' profit per prescription has grown substantially over the same period that insulin prices have steadily increased. For example, since 2003 Defendant Express Scripts has seen its profit per prescription increase more than 500% per adjusted prescription. 139

247. Novo Nordisk's President Doug Langa submitted written testimony to Congress acknowledging "there is no doubt that the WAC [list price] is a significant component" of "what patients ultimately pay at the pharmacy counter." Yet, the Manufacturers urged upon Congress the fiction that the pharmacy benefit managers were solely to blame for insulin prices because of their demands for rebates in exchange for formulary placement. The Manufacturers claimed their hands were tied and sought to conceal their misconduct by suggesting that they have not profited from rising insulin prices.

248. Given the Manufacturers' claims that rebates were the sole reason for rising prices, each was asked directly during the Congressional hearing to guarantee it would decrease list prices if rebates were restricted or eliminated. The spokespersons for Eli Lilly, Novo Nordisk, and Sanofi all said only that they would "consider it."

<sup>&</sup>lt;sup>139</sup> David Balto, *How PBMs Make the Drug Price Problem Worse*, The Hill (Aug. 31, 2016), <a href="https://thehill.com/blogs/pundits-blog/healthcare/294025-how-pbms-make-the-drug-price-problem-worse/">https://thehill.com/blogs/pundits-blog/healthcare/294025-how-pbms-make-the-drug-price-problem-worse/</a>.

- 249. In January 2021, the Senate Finance Committee (Grassley-Wyden) issued a report titled "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug" that detailed Congress's findings after reviewing more than 100,000 pages of internal company documents from Sanofi, Novo Nordisk, Eli Lilly, CVS Caremark, Express Scripts, OptumRx, and Cigna. The report concluded, among other things:
  - A. The Manufacturer Defendants retain 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. the Manufacturer Defendants have aggressively raised the list price of their insulin products absent significant advances in the efficacy of the drugs; and
  - C. the 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.

- 250. The 2021 Senate Finance Committee Report summed up the benefit to the Manufacturer Defendants finding that "drug manufacturers increased insulin WAC [wholesale cost], in part to give them room to offer larger rebates to PBM and health insurers, all in the hopes that their product would receive preferred formulary placement. This pricing strategy translated into higher sales volumes and revenue for manufacturers."<sup>140</sup>
- 251. Under the Insulin Pricing Scheme, the Manufacturer Defendants pay the PBM Defendants opaque but significant Manufacturer Payments in exchange for formulary placement, which garners the Manufacturers greater revenues and steady profit margins. The PBM Defendants grant national formulary position to at-issue drugs in exchange for large Manufacturer Payments generated by inflated drug prices.
- 252. Inflated list prices also earn the Manufacturers hundreds of millions of dollars in tax breaks because they can base their deductions for insulin donations on the inflated list prices.
- 253. Because of the increased list prices, and related Manufacturer Payments, the PBM Defendants' profit per prescription has grown exponentially during the relevant period as well. A recent study published in the Journal of the American Medical Association concluded that the amount of money that goes to the

<sup>&</sup>lt;sup>140</sup> U.S. S. Fin. Comm., *supra* n.7.

PBM Defendants for each insulin prescription increased more than 150% from 2014 to 2018.<sup>141</sup> In fact, for transactions in which the PBM Defendants control the PBM and the pharmacy (e.g., Caremark-CVS pharmacy), these Defendants were capturing an astonishing 40% of the money spent on each insulin prescription (up from 25% just four years earlier), even though they do not contribute to the development, manufacture, innovation, or production of the product.

254. As detailed above, the PBM Defendants profit from the artificially inflated prices created by the Insulin Pricing Scheme in several ways, including: (1) retaining a significant, yet undisclosed, percentage of Manufacturer Payments under a variety of labels (2) using rebate aggregators to further shield Manufacturer Payments from pass-through obligations; (3) using the inflated list price to generate profits from pharmacies, including through clawbacks and post-purchased discounts; and (4) relying on the inflated list price to drive up the PBMs' spread income, including through increased margins captured by their own affiliated pharmacies.

255. Over time, payors such as Clark County did secure contract provisions guaranteeing payment to them of a certain amount of prescription drug rebate payments per paid brand name prescription drug claim. Critically, however, these

<sup>&</sup>lt;sup>141</sup> Karen Van Nuys, et al., *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*, J. Am. Med., Nov. 2021, at 11.

"rebates" to Clark County were shrouded in secrecy and are only a fraction of the total secret Manufacturer Payments, particularly as "rebates" are narrowly defined and qualified by vague exceptions in the PBM Defendants' contracts with payors.

# E. The Insulin Pricing Scheme Reflects the PBM Defendants' Self-Dealing

256. The PBM Defendants depend on the lack of transparency to conduct their business. They have vigorously resisted any requirement that they disclose the details of their agreements with drug manufacturers and the kickbacks they receive from them—as well as their agreements with the insurers and pharmacies.<sup>142</sup>

257. At the same time, the PBM Defendants have consistently insisted that they are transparent about the rebate payments and the amounts they remit to payors. For example, in 2011, OptumRx's President stated that "[w]e want our clients to fully understand our pricing structure . . . [e]very day 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." Express Scripts' CEO similarly stated in 2017 that Express Scripts was "absolutely transparent" about rebate payments and that

 $<sup>^{142}</sup>$  *Id*.

<sup>&</sup>lt;sup>143</sup> UnitedHealth Group, *Prescription Solutions by OptumRx Receives 4th Consecutive TIPPS Certification for Pharmacy Benefits Transparency Standards* (Sept. 13, 2011), <a href="https://web.archive.org/web/20210805182422/https://www.unitedhealthgroup.com/newsroom/2011/0913tipps.html">https://web.archive.org/web/20210805182422/https://www.unitedhealthgroup.com/newsroom/2011/0913tipps.html</a>.

payors "know exactly how the dollars flow" with respect to those payments. And CVS executives have stated that it "provide[s] full visibility to our clients of all our contracts and the discounts that we negotiate on their behalf... And transparency—today we report and fully disclose not only to our clients, but to [Centers for Medicare and Medicaid Services]." 145

258. Health plan payors were not involved in the negotiation of the contracts between the PBM Defendants and Manufacturers, and the PBM Defendants disclosed only the fact that such relationships may exist. But the terms of the contracts, the consideration exchanged between the PBM Defendants and Manufacturers, and the means of reaching these determinations all were—and remain—shrouded in secrecy.

259. The PBM and Manufacturer Defendants thus created a "hide-the-ball" system where health plan payors like Plaintiff are not privy to rebate negotiations or contracts between the Manufacturers and the PBM Defendants. Through this "hide-the-ball" system, the PBM and Manufacturer Defendants are able to manipulate their rebate negotiations and contracts in their best interest, rather than in the best interest of health plan payors like Plaintiff.

<sup>&</sup>lt;sup>144</sup> CBS News, Express Scripts CEO Tim Wentworth Defends Role of PBMs in Drug Prices (Feb 7, 2017), <a href="https://www.cbsnews.com/news/express-scripts-tim-wentworth-pbm-rising-drug-prices-mylan-epipen-heather-bresh/">https://www.cbsnews.com/news/express-scripts-tim-wentworth-pbm-rising-drug-prices-mylan-epipen-heather-bresh/</a>.

<sup>&</sup>lt;sup>145</sup> Congress.gov, *supra* n.127.

- 260. Despite the PBM Defendants' insistence that they are transparent with their health plan payors, there is zero transparency as to what money the PBM Defendants receive from the Manufacturer Defendants and what money the PBM Defendants remit to health plan payors like Plaintiff. The system is designed so that the PBM and Manufacturer Defendants retain control and profit.
- 261. This is evidenced by the PBM's efforts to relabel manufacturer rebates to minimize their pass-through obligations, the PBM's increasing use of and reliance on rebate aggregators, and the inability of health plan payors, such as Plaintiff, to conduct a meaningful audit of the PBM's rebate arrangements with the Manufacturer Defendants and rebate aggregators.

## 1. Relabeling of "Rebates"

262. The consideration exchanged between the PBM Defendants and the Manufacturer Defendants is continually labeled and relabeled in order to allow the PBM Defendants to retain an increasing percentage of the total payments received from the Manufacturer Defendants while purporting to pass through increasing rebate amounts to health plan payors, such as Plaintiff. As more payors have moved to contracts with the PBM Defendants that require the PBM Defendants to remit some or all of the manufacturer "rebates" through to the payor, the PBM Defendants have moved to relabel these manufacturer "rebates" more broadly as various "fees,"

"discounts," and the like in order to better shield them from scrutiny and minimize their pass-through obligations.

- 263. Specifically, in order to maintain their ever-growing profits, while claiming that "rebates" are passed through to payors, the PBM Defendants have relabeled the payments they received from the Manufacturer Defendants as, inter alia, "administrative fees," "volume discounts," "concurrent or retrospective discounts," "service fees," "fees for services rendered," "fees for property provided," "inflation fees," or other industry monikers designed to obfuscate the substantial sums being secretly exchanged between the PBM Defendants and the Manufacturers.
- 264. The Senate Commerce, Science and Transportation Committee recently released testimony from David Balto—a former antitrust attorney with the DOJ and Policy Director for the FTC's Bureau of Competition—from a hearing on fairness and transparency in drug pricing:

The PBM rebate system turns competition on its head with PBMs seeking higher, not lower prices to maximize rebates and profits. In the past decade, PBM profits have increased to \$28 billion annually...PBMs establish tremendous roadblocks to prevent payors from knowing the amount of rebates they secure. Even sophisticated buyers are unable to secure specific drug by drug rebate information. PBMs prevent payors from being able to audit rebate information. As the Council of Economic Advisors observed, the PBM market lacks transparency as "[t]he size of manufacturer rebates and the percentage of the rebate passed on to health plans and patients are secret." Without adequate transparency, plan sponsors cannot determine if the PBMs are

fully passing on any savings, or whether their formulary choices really benefit the plan and subscribers. 146

265. The relabeled, undisclosed Manufacturer Payments are substantial. "Administrative fees" are just one example. A heavily redacted complaint filed by Defendant Express Scripts in 2017 revealed that Express Scripts retains up to fifteen times more in "administrative fees" than it remits to payors in rebates. 147

266. These so-called administrative fees typically are based on a percentage of the list price—as opposed to a flat fee—such that even if the actual "administrative" cost associated with processing two drugs is the same, the "administrative fee" would be correspondingly higher for the higher-priced drug, which again creates (by design) a perverse incentive to give preference to more expensive drugs.

267. These administrative fees and other payments are typically beyond a payor's contractual audit rights because those rights are limited to "rebate" payments and these "administrative fees" have been carved out from the definition of "rebates."

<sup>&</sup>lt;sup>146</sup> Testimony of David A. Balto before the U.S. S. Comm. On Commerce, Science, and Transportation: Subcommittee Consumer Protection, Product Safety, and Data Security entitled "Ensuring Fairness and Transparency in the Market for Prescription Drugs" (May 5, 2022),

https://www.commerce.senate.gov/services/files/5807DDD6-EA20-42A4-97B1-73541F832839.

<sup>&</sup>lt;sup>147</sup> Complaint, *Express Scripts, Inc. et al. v. Kaleo, Inc.*, No. 4:17-cv-01520-RLW (E.D. Mo. May 16, 2017), ECF No. 1.

268. It has been suggested that pharmacy benefit managers "designate as much as twenty-five or thirty percent of the negotiated rebates as fees to avoid sharing the rebates." <sup>148</sup>

269. Although the proportion of rebates retained by the PBM Defendants remains a secret, evidence suggests that the amounts of rebates passed on to the client varies dramatically among the PBM Defendants and their clients. And there is reason to believe that the proportion of rebates retained by the PBM Defendants is substantial. A review of Texas-mandated pharmacy benefit manager disclosures showed that pharmacy benefit managers retain a much greater percentage of manufacturer rebates than they let on. Under the Texas law, pharmacy benefit managers are required to report the "aggregated rebates, fees, price protection payments, and any other payments collected from pharmaceutical drug manufacturers." This review showed that in 2021, pharmacy benefit managers retained 13% of manufacturers' total payments (\$752 million). Between 2016 and

<sup>&</sup>lt;sup>148</sup> Joanna Shepherd, *Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, Yale Law & Policy Rev., <a href="https://openyls.law.yale.edu/bitstream/handle/20.500.13051/17295/">https://openyls.law.yale.edu/bitstream/handle/20.500.13051/17295/</a>
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<sup>&</sup>lt;sup>149</sup> *Id*.

<sup>&</sup>lt;sup>150</sup> Adam Fein, *Texas Shows Us Where PBMs' Rebates Go*, Drug Channels (Aug. 9, 2022), <a href="https://www.drugchannels.net/2022/08/texas-shows-us-where-pbms-rebates-go.html">https://www.drugchannels.net/2022/08/texas-shows-us-where-pbms-rebates-go.html</a>.

<sup>&</sup>lt;sup>151</sup> *Id*.

2021, pharmacy benefit managers retained between 9% and 21% of total manufacturer payments. 152

270. In an attempt to quantify the revenue pharmacy benefit managers receive from retained rebates, a September 2023 report by Nephron Research found that pharmacy benefit managers' compensation from rebates and other kickbacks doubled between 2018 and 2022, from \$3.8 billion to \$7.6 billion. 153

271. Further, because many rebate-sharing arrangements are based on a percentage of rebates received by the PBM Defendants, as drug manufacturers continue to artificially increase the price of insulin, the dollar amount retained by the PBM Defendants will continue to increase, even if the percentage passed through stays the same.<sup>154</sup> Thus, through the Insulin Pricing Scheme, the PBM Defendants continue to garner greater and greater profits at the expense of health plan payors, like Plaintiff.

272. The opaque nature of these arrangements between the Manufacturer and PBM Defendants also makes it impossible for a given payor to discover, much

 $<sup>^{152}</sup>$  *Id*.

<sup>&</sup>lt;sup>153</sup> Sara Sirota, *Why We Should Ban PBM Rebates*, Am. Econ. Liberties Project (Feb. 13, 2024), <a href="https://www.economicliberties.us/our-work/why-we-should-ban-pbm-rebates/#\_ftnref32">https://www.economicliberties.us/our-work/why-we-should-ban-pbm-rebates/#\_ftnref32</a>.

<sup>&</sup>lt;sup>154</sup> A View from Congress: Role of Pharmacy Benefit Managers in Pharmaceutical Markets, H.R. Comm. On Oversight and Reform (Dec. 10, 2021), <a href="https://oversight.house.gov/wp-content/uploads/2021/12/PBM-Report-12102021.pdf">https://oversight.house.gov/wp-content/uploads/2021/12/PBM-Report-12102021.pdf</a>.

less assess or confront, conflicts of interest that may affect it or its members or beneficiaries. The Senate Insulin Report observed with respect to these arrangements: "Relatively little is publicly known about these financial relationships and the impact they have on insulin costs borne by consumers." <sup>155</sup>

#### 2. Rebate Aggregators

- 273. The PBM Defendants also use "rebate aggregators" to further the Insulin Pricing Scheme.
- 274. Rebate aggregators, sometimes called group purchasing organizations ("GPOs"), negotiate and collect manufacturer rebates on behalf of pharmacy benefit managers, including the PBM Defendants.
- 275. PCMA, the industry group of PBMs, stated that rebate aggregators "help PBMs to use scale and leverage to more aggressively negotiate with (drugmakers) to lower the cost of drugs for clients and consumers. The core mission of PBMs is to provide improved access to needed medications by lowering costs." <sup>156</sup>
- 276. In reality, the picture appears to be much different. The rebate aggregators are often either owned by the PBM Defendants or closely affiliated. The PBM Defendants' contracts with these (often affiliated) rebate aggregators provide

<sup>&</sup>lt;sup>155</sup> U.S. S. Fin. Comm., *supra* n.7.

<sup>&</sup>lt;sup>156</sup> Marty Schladen, *Already concerned with drug costs, large employers, family pharmacists worry about more middlemen*, Ohio Cap. J. (Sept. 2, 2021 1AM), <a href="https://ohiocapitaljournal.com/2021/09/02/already-concerned-with-drug-costs-large-employers-pharmacists-worry-about-another-layer-of-middlemen/">https://ohiocapitaljournal.com/2021/09/02/already-concerned-with-drug-costs-large-employers-pharmacists-worry-about-another-layer-of-middlemen/</a>.

that the aggregator will negotiate and receive rebates from drug manufacturers for certain drugs based on the drug utilization of the participants of plans served by the PBM Defendants. The rebate aggregator will then pay the PBM Defendants some amount per prescription, which becomes part of the "rebate" the PBM Defendants must pass through (in whole or in part) to its clients, including Plaintiff. This system allows the (often affiliated) rebate aggregators to retain any difference between the rebates paid by the Manufacturer Defendants and the payments the rebate aggregators pay to the PBM Defendants.

277. The rebates retained by the PBM Defendants' affiliated rebate aggregators and the revenues the PBM Defendants ultimately obtain from their rebate aggregators is hidden. The contractual provisions between PBM Defendants and rebate aggregators—as well as those between PBM Defendants, rebate aggregators, and pharmaceutical manufacturers—remain hidden from health plan payors. The contracts between health plan payors and the PBM Defendants are often silent on the role of rebate aggregators. For instance, a review of Orange County, California's contract with OptumRx showed that the contract language did not address rebate dollars retained by OptumRx's subcontracted or affiliated rebate aggregators. Thus, PBM Defendants can conceal payments through these rebate

<sup>&</sup>lt;sup>157</sup> Jonathan Levitt, *Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers*, Written Testimony Before the U. S. S. Comm. on Fin. (Feb. 2022), (<a href="https://www.finance.senate.gov/imo/media/doc">https://www.finance.senate.gov/imo/media/doc</a>

aggregator agreements, allowing them to falsely claim that they pass through all or a substantial portion of their rebates, while, pocketing large profits.

278. Discussing the lack of transparency regarding rebate aggregators, Stephanie Seadler, Vice President of Trade Relations at EmsanaRx noted that "And so while they [i.e., employers] are getting some rebates, they are not getting everything. They're also not getting the data to help validate what they're getting. I think that's changed a lot with the GPOs because it's easy for the PBM to say, 'The GPO is a third party. We don't own those contracts, and because we don't own them, we can't give the data and the transparency because they're not ours.' It's time to rethink what that looks like."<sup>158</sup>

279. Although the revenues retained by the PBM Defendants and their respective rebate aggregators remain hidden, there is evidence to suggest the retained rebate amounts are substantial. A Medicare plan audited its pharmacy benefit manager and found that the "rebate aggregator collected all the dollars, and it only gave about 40% of those dollars to the PBM." Thus, while the pharmacy benefit

<sup>/</sup>Jonathan%20Levitt%20Testimony%20US%20Senate%20Committee%20on%20F inance%20-%20Frier%20Levitt%20-%20March%202023\_Redacted1.pdf.

<sup>&</sup>lt;sup>158</sup> Angela Maas, *How Do Pharma/PBM Contracts Play Role in Rebate Leakage? Part 2*, Managed Mkts. Insight & Tech. (Apr. 21, 2022), <a href="https://www.mmitnetwork.com/aishealth/spotlight-on-market-access/how-do-pharma-pbm-contracts-play-role-in-rebate-leakage-part-2/">https://www.mmitnetwork.com/aishealth/spotlight-on-market-access/how-do-pharma-pbm-contracts-play-role-in-rebate-leakage-part-2/</a>.

<sup>&</sup>lt;sup>159</sup> Rose McNulty, *In Drug Pricing, PBMs Called the "Arsonist and the Firefighter in One"*, Am. J. of Managed Care (Dec. 16, 2020), <a href="https://www.ajmc.com/view/indrug-pricing-pbms-called-the-arsonist-and-the-firefighter-in-one-">https://www.ajmc.com/view/indrug-pricing-pbms-called-the-arsonist-and-the-firefighter-in-one-</a>.

manager contract stated that the pharmacy benefit manager would pass through 90% of the rebates to the plan, it neglected to mention that "the PBM rebate aggregator had sucked 62% of the money out of the system." <sup>160</sup>

- 280. The September 2023 report by Nephron Research demonstrated the increased reliance by pharmacy benefit managers on rebate aggregators, finding that payments to pharmacy benefit managers generated by their rebate aggregators was nearly \$0 in 2018, yet more than \$1.7 billion in 2022.<sup>161</sup>
- 281. Concerned about the rebate aggregators, the Federal Trade Commission issued compulsory orders to two rebate aggregators in May 2023 Zinc Health Services (which operates as the rebate aggregator for CVS Caremark) and Ascent Health Services (which operates as the rebate aggregator for Express Scripts and Prime Therapeutics, among others). <sup>162</sup>
- 282. Dave Ricks, CEO of Eli Lilly, stated that the majority of the \$8 billion Eli Lilly paid in 2022 in rebate checks went to rebate aggregators, rather than directly to pharmacy benefit managers. 163

 $<sup>^{160}</sup>$  *Id*.

<sup>&</sup>lt;sup>161</sup> Sirota, *supra* n.153.

<sup>&</sup>lt;sup>162</sup> Victoria Graham, *FTC Deepens Inquiry into Prescription Drug Middlemen*, FTC.gov (May 17, 2023), <a href="https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-deepens-inquiry-prescription-drug-middlemen">https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-deepens-inquiry-prescription-drug-middlemen</a>.

<sup>&</sup>lt;sup>163</sup> Arthur Allen, *A More Aggressive FTC Is Starting to Target Drug Mergers and Industry Middlemen*, KFFHealthNews.org (May 22, 2023), <a href="https://kffhealthnews.org/news/article/a-more-aggressive-ftc-is-starting-to-target-drug-mergers-and-industry-middlemen/">https://kffhealthnews.org/news/article/a-more-aggressive-ftc-is-starting-to-target-drug-mergers-and-industry-middlemen/</a>.

283. A number of the large rebate aggregators are headquartered abroad. For instance, Ascent, the aggregator for Express Scripts, is based in Switzerland and Emisar Pharma Services, the aggregator established by OptumRx, is based in Ireland. This only serves to help the pharmacy benefit managers keep the true rebate payments hidden from payors and plan sponsors.

284. As reported in the 2021 Grassley-Wyden Senate Report, there are presently no efforts to change or restrict the group purchasing organization safe harbor rules. 165

# 3. Illusory Audit Provisions

285. The PBM Defendants are able to shield the true magnitude of profit they make from rebates and other fees through the relabeling of these rebates and the use of rebate aggregators. They also shield the true magnitude of profit by providing health plan payors, such as Plaintiff, no meaningful opportunity to audit their pharmacy benefit services and their contracts with the Manufacturer Defendants and rebate aggregators.

286. The PBM Defendants assert that their contracts with the Manufacturer Defendants and the rebate aggregators are confidential and proprietary. Accordingly, any audit done by a health plan payor, such as Plaintiff, would not reveal the details

<sup>&</sup>lt;sup>164</sup> *Id*.

<sup>&</sup>lt;sup>165</sup> U.S. S. Fin. Comm., supra n.7.

of the rebate arrangements. And because the rebate aggregators contract directly with the Manufacturer Defendants, the PBM Defendants can tell health plan payors that they have no insight into those contracts. By creating rebate aggregators, the PBMs have created a new middleman that allows them to sequester off payments made from Drug Manufacturers, without having to include any contractual language regarding these rebate aggregators in their contracts with health plan payors.

287. Health plan payors, such as Plaintiff, are left with no real avenue to ascertain what amount of rebates and fees the PBM Defendants receive from the Drug Manufacturers. Likewise, health plan payors, such as Plaintiff, are left with no real avenue to ascertain whether these rebates and fees are being passed-through.

## F. Insulin Adjuncts: Type 2 Medications

288. Over the past 15 years, the Manufacturer Defendants released several non-insulin medications that help control insulin levels. In 2010, Novo Nordisk released Victoza, and thereafter Eli Lilly released Trulicity and Sanofi released Soliqua. Novo Nordisk further expanded their GLP-1 patent portfolio with the approval of Xultophy and Ozempic. In 2022, Eli Lilly received approval for yet another GLP-1, Mounjaro. Each of these medications can be used in conjunction with insulins to control diabetes.

<sup>&</sup>lt;sup>166</sup> Victoza, Trulicity, Ozempic, and Mounjaro are glucagon-like peptide-1 receptor agonists ("GLP-1") and mimic the GLP-1 hormone produced in the body. Soliqua and Xultophy are combination long-acting insulin and GLP-1 drugs.

- 289. Manufacturers negotiate rebates and other fees with PBMs as a single diabetes drug class that includes insulin and GLP-1 receptor agonist (GLP-1) medications. This practice is known as "bundling".
- 290. Manufacturer Defendants bundle medications to gain formulary access for multiple drugs in exchange for increased manufacturer payments to PBMs.
- 291. In 2013, Novo Nordisk tied its "exclusive" rebates for insulin to formulary access for GLP-1 medication, Victoza. The exclusive rebates of 57.5% for Novolin, Novolog, and Novolog Mix 70/30 were more than three times higher than the 18% rebate for plans that included two insulin products on their formulary. In order to qualify for the exclusive rebate, the plans would also need to list Victoza on their formulary, exclude all competing insulin products, and ensure existing patients switch from competitor diabetes medications. <sup>167</sup>
- 292. Upon information and belief all Manufacturer Defendants negotiate the prices of insulin and GLP-1 medications through bundling.
- 293. The first GLP-1 was approved by the FDA in 2005 and was indicated for the treatment of Type 2 diabetes. Currently, the GLP-1 market is consolidated among a limited number of patent-holding entities, with Manufacturer Defendants Eli Lilly, Novo Nordisk and Sanofi controlling much of this market.

<sup>&</sup>lt;sup>167</sup> U.S. S. Fin. Comm., *supra* n.7 at 78 and 79.

- 294. Through extensive patents and regulatory exclusivities, the Manufacturer Defendants have effectively barricaded competition from the GLP-1 market, giving them the ability to exercise comprehensive control over the price of GLP-1 medications.
- 295. To date, no generic alternative exists for any GLP-1 medication and the Manufacturer Defendants will continue to enjoy patent protection of their respective GLP-1 agonist molecules through at least 2030, if not later.<sup>168</sup>
- 296. Novo Nordisk developed and sells three GLP-1 drugs indicated for Type 2 diabetes: Victoza (liraglutide), Xultophy (insulin degludec/liraglutide) and Ozempic (semaglutide). Novo Nordisk holds 62 patents related to semaglutide and liragutide—46 of those patents are device patents unrelated to the therapeutic molecule of the GLP-1. 169
- 297. Eli Lilly developed and sells two GLP-1 drugs indicated for Type 2 diabetes: Trulicity (dulaglutide) and Mounjaro (tirzepatide/GIP). Eli Lilly holds 18 patents related to dulaglutide and tirzepatide. Of the 4 patents related to tirzepatide, 2 of those patents are device patents unrelated to the therapeutic molecule of the

<sup>&</sup>lt;sup>168</sup> Alhiary, Rasha et al. Patents and Regulatory Exclusivities on GLP-1 Receptor Agonists, J. Am. Med. Ass'n 650-657, 330 (2023).

<sup>&</sup>lt;sup>169</sup> Alhiary, Rasha, et al. Delivery Device Patents on GLP-1 Receptor Agonists, J. Am. Med. Ass'n 331, 794–796 (2023).

GLP-1. Eli Lilly has applied for 78 patents related to dulaglutide, 17 of which have

been granted to date.<sup>170</sup>

298. Sanofi developed Adylxin (lixisenatide) and Soliqua (insulin

glargine/lixisenatide) but currently only sells Soliqua in the United States. Sanofi

holds 42 patents related to lixisenatide—29 of those patents are device patents

unrelated to the therapeutic molecule of the GLP-1. 171

299. This patent stacking and evergreening ensures that generic and other

branded GLP-1 cannot enter the market and gives Novo Nordisk, Eli Lilly, and

Sanofi disproportionate pricing power over GLP-1 medications.

300. In addition to the limited competition in the GLP-1 landscape,

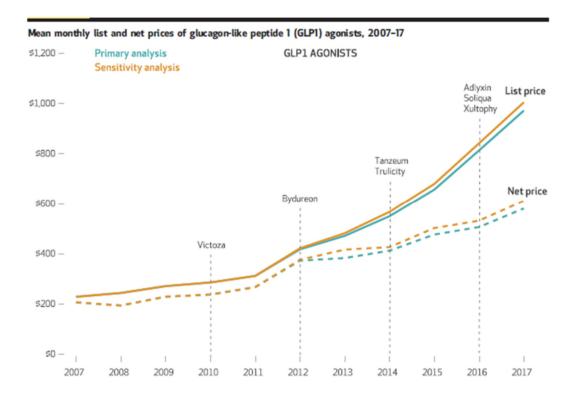
Manufacturer and PBM Defendants use this disproportionate pricing power to

steadily raise the price of GLP-1s, consistent with the broader Insulin Pricing

Scheme.

<sup>170</sup> *Id*.

<sup>171</sup> *Id*.



301. As shown above, counterintuitively, list and net prices increased as more GLP-1 medications were approved and introduced. Between 2007 and 2017 the average list price of GLP-1s rose 15% per year despite the introduction of competing brands. The net price increased an average of 10% per year during the same time period.<sup>172</sup>

302. The PBM Defendants are also central to these untethered price increases. As shown in the chart above, the growing disconnect between list prices

<sup>&</sup>lt;sup>172</sup> Sarpatwari, Ameet, et al. Diabetes Drugs: List Price Increases Were Not Always Reflected In Net Price; Impact Of Brand Competition Unclear, Health Affairs, 40, 772–778 (2021).

and net prices of these drugs further demonstrates the PBM Defendants ill-gotten gains through identical methods to those employed in the Insulin Pricing Scheme.

- 303. The absence of generics in the GLP-1 market allows manufacturers to keep prices artificially high. PBMs then realize the benefit of these artificially high prices through manufacturer payments in exchange for formulary placement. PBMs and manufacturers are thus incentivized to increase prices or maintain high, untethered prices for GLP-1s.
- 304. Further, GLP-1s are significantly more expensive in the United States compared to other countries, indicating that the increasing price of GLP-1s are untethered to any legal, competitive, or fair market price. For example, in 2023, the list price for a one-month supply of Ozempic was about \$936 in the United States, \$147 in Canada, \$103 in Germany, \$93 in the United Kingdom, \$87 in Australia, and \$83 in France.
- 305. In 2018, Victoza's list price in the United States was more than double its average list price in eleven comparable countries and Trulicity's list price in the United States was more than six times its average list price in eleven comparable countries. One study found that drug companies could profitably sell certain GLP-1s, including Ozempic, for \$0.89–\$4.73 per month.

306. In March 2024, PBM Defendant Evernorth entered into a financial guarantee agreement for GLP-1 spend with Manufacturer Defendants Novo Nordisk and Eli Lilly to limit the annual cost increase of GLP-1s to 15%.<sup>173</sup>

307. Like the caps put in place for insulin, Evernorth, Eli Lilly and Novo Nordisk's, agreement suggests that the prices of GLP-1s before March 2024, were not raised to cover costs of research and development, manufacture, distribution, or any other necessary expense. Such cost caps and savings guarantees indicate that the increasing price of GLP-1s were untethered to any legal, competitive, or fair market price. Further, this agreement is prospective and does not mitigate damages already incurred by payors like Plaintiff, who have spent substantial sums on GLP-1 drugs in connection with the self-insured plan at-issue in this case.

# **G.** Plaintiff Pays for the At-Issue Drugs

308. Defendants' schemes to make increasingly larger profit off of the atissue drugs have devastating effects on consumers and come at a significant cost to health plan payors, like Plaintiff, who pay for their beneficiaries' pharmaceutical purchases. Payors like Plaintiff rely on the PBM Defendants to control the costs of prescription medications and lower their administrative burdens. The resulting financial impact on Plaintiff is substantial given its unique obligations.

<sup>&</sup>lt;sup>173</sup> Evernorth Announces Industry-First Financial Guarantee GLP-1 Spend, Evernorth Health Servs. (Mar. 7, 2024) <a href="https://www.evernorth.com/articles/evernorth-announces-industry-first-financial-guarantee-glp-1-spend">https://www.evernorth.com/articles/evernorth-announces-industry-first-financial-guarantee-glp-1-spend</a>.

- 309. As a government entity, Plaintiff serves its residents by providing public safety, emergency management, and health services, among its numerous other vital roles. As local governments take on increased obligations traditionally borne by federal and state government, Plaintiff has more obligations with a limited budget. Consequently, any significant increase in spending can stress Plaintiff's overall budget and, in turn, negatively impact its ability to provide essential services to the community.
- 310. As an employer, Plaintiff provides its Beneficiaries with ample benefits, including paying for a large portion of its Beneficiaries' pharmaceutical purchases. In this role, since 2014, Plaintiff spent over \$3.3 million dollars on the atissue medications alone.
- 311. In Plaintiff's role as a payor, it maintains a self-funded plan. This means Plaintiff, rather than an insurance provider, pays for pharmaceutical benefits and prescription drugs, including the diabetes medications at issue here. Because of Plaintiff's self-funded status, it does not rely on a third-party insurer to pay for its Beneficiaries' medical care, pharmaceutical benefits, or prescription drugs.
- 312. Clark County pays for a significant portion of the price of the drugs at issue and has not knowingly participated in Defendants' Insulin Pricing Scheme. In particular, after beneficiaries pay their portions of the costs of insulin drugs manufactured by the Manufacturer Defendants, Clark County pays the remaining

portions of the cost in connection with its self-insured plan for its Beneficiaries.

Clark County pays these amounts on a regular basis.

- 313. By purchasing the drugs at issue, Plaintiff has suffered losses because of the inflated prices resulting from Defendants' Insulin Pricing Scheme. Plaintiff pays artificially inflated costs resulting from the Insulin Pricing Scheme because its payments are derived from the artificially inflated insulin list prices. Plaintiff cannot avoid paying these sky-high, artificially inflated prices because of Defendants' exclusive control over the market for these life-saving drugs.
- 314. As a result of Defendants' Insulin Pricing Scheme, diabetes medications have consistently been a significant financial expense for Plaintiff. Plaintiff purchased diabetes medications, including those manufactured by the Manufacturer Defendants, such as Novolog, Levemir, Humalog, and Lantus Solostar. Plaintiff has also purchased human insulin and GLP-1 diabetic drugs.
- 315. Plaintiff relies on Prime Therapeutics in administering its health plans' pharmaceutical services. The services Prime Therapeutics has provided Plaintiff include constructing and managing Plaintiff's pharmacy network (which included dispensing the at-issue drugs through the PBMs' retail and mail-order pharmacies) and adjudicating and processing pharmacy claims.
- 316. Through their agreement with Prime Therapeutics, Plaintiff relies on Express Scripts to limit and control its pharmaceutical drug costs. Specifically,

Plaintiff relies on Express Scripts to conduct negotiations with Defendant Manufacturers for the at-issue drugs.

- 317. Defendant Express Scripts participated in the Insulin Pricing Scheme, which increased the prices Plaintiff paid for these diabetic medications.
- 318. Neither the PBM nor the Manufacturer Defendants suffer losses from the Insulin Pricing Scheme. On the contrary, the PBM and Manufacturer Defendants financially benefit from the Insulin Pricing Scheme at Plaintiff's expense.

# H. The Insulin Pricing Scheme Has Injured Clark County.

- 319. Plaintiff Clark County provides health and pharmacy benefits to its Beneficiaries, including employees and their dependents. During the relevant period, Plaintiff has provided these benefits to approximately 3,000 employees, their dependents, and retirees on an annual basis.
- 320. One primary benefit Plaintiff provides its Beneficiaries through its employee health plans is paying a significant portion of the Beneficiaries' prescription drug costs.
- 321. Through purchasing its Beneficiaries' prescription drugs, including the at-issue diabetes medications, Plaintiff has interacted with and engaged in business with the PBM Defendants concerning their pharmacy benefit services and the at-issue diabetes medications for years.

- 322. At all times until 2023, Plaintiff was unaware of the full nature and extent of the Insulin Pricing Scheme, Defendants' involvement and control over the Insulin Pricing Scheme, and the artificial inflation of the insulin prices it was paying as a result of Defendants' Insulin Pricing Scheme.
- 323. Plaintiff relied on Defendants' statements and material omissions made in furtherance of the Insulin Pricing Scheme.
- 324. Plaintiff relied on Defendants' misrepresentations in paying for the diabetes medications at issue at prices that would have been lower but for the Insulin Pricing Scheme devised and carried out by Defendants.
- 325. Health plan payors, including Plaintiff, were the direct and intended victims of the Insulin Pricing Scheme.
- 326. Plaintiff made payments for insulin based on the artificially inflated list prices that resulted from Defendants' Insulin Pricing Scheme.
- 327. Since 2014, Plaintiff has spent over \$3.3 million dollars on the at-issue diabetes medications alone.
- 328. Defendants' relationship with Clark County are inherently unbalanced and their contracts adhesive. Although Defendants supply a vital service of a quasipublic nature, they nevertheless acted to exploit their superior bargaining positions to mislead Plaintiff and contravene Plaintiff's expectations, all at great expense to Plaintiff.

- 329. Defendants' misrepresentations, omissions, and misconduct in furtherance of the Insulin Pricing Scheme proximately caused economic damage to Plaintiff as a payor and purchaser of Defendant Manufacturers' at-issue drugs.
- 330. A substantial amount of Plaintiff's expenditures on diabetes medications is attributable solely to the artificial inflation of insulin list prices caused by Defendants' Insulin Pricing Scheme.
- 331. At all times before 2023, Plaintiff did not know and could not have known the full extent to which the prices it paid for diabetes medications were and continue to be artificially inflated due to Defendants' Insulin Pricing Scheme. Plaintiff lacked this knowledge because of Defendants' ongoing actions and omissions to conceal their scheme to raise the price of diabetic medications.
- 332. Consequently, Plaintiff unknowingly paid excess prices to the Manufacturer Defendants for diabetes medications for years despite receiving a pass-through of some portion of rebates. The prices Plaintiff paid for these diabetes medications would have cost less but for Defendants' acts in carrying out the Insulin Pricing Scheme.
- 333. In short, Defendants' Insulin Pricing Scheme has directly and proximately caused Plaintiff to substantially overpay—and continue to overpay—for diabetes medications.

334. Because Defendants continue to generate exorbitant, unfair, and deceptive prices for the at-issue drugs through the Insulin Pricing Scheme, the harm to Plaintiff is ongoing.

#### V. TOLLING OF THE STATUTES OF LIMITATIONS

- 335. Plaintiff has diligently pursued and investigated its claims. Through no fault of its own, Plaintiff did not learn and—given Defendants' coordinated, successful efforts to mislead consumers and health plan payors like Plaintiff—could not have learned the full extent of the Insulin Pricing Scheme and the factual bases for its claims or the injuries suffered therefrom.
  - 336. Consequently, the following tolling doctrines apply.

#### A. Accrual Rule

- 337. Defendants' acts, omissions, and misrepresentations alleged throughout this Complaint have continued to occur through the present day.
- 338. For example, in their 2022 SEC Form 10-K Annual Reports, the PBM Defendants represented that they work to reduce costs to the client.
- 339. Defendants continue to utilize rebates, relabeled fees, rebate aggregators, clawbacks, and spread pricing to profit from the Insulin Pricing Scheme.
- 340. Defendants set artificially inflated list prices for the at-issue insulin drugs. Each new list price is a new and independent act that harms Plaintiff. Plaintiff

has overpaid for the at-issue drugs based on the artificially inflated and misrepresented list prices.

- 341. Plaintiff is overcharged for the at-issue drugs on a regular basis as a result of the Insulin Pricing Scheme. Each individual charge to Plaintiff based on the artificially inflated and misrepresented list prices constitutes a new and independent act in furtherance of the Insulin Pricing Scheme.
- 342. With each overpayment, Plaintiff suffers a new and accumulating injury. Every additional overpayment arising from Defendants' acts, omissions, and misrepresentations places additional stress on Plaintiff's budget, and in turn, on Plaintiff's ability to provide necessary services to its beneficiaries and the residents of Clark County.
- 343. Had Defendants at any time ceased their wrongful conduct, further injury would have been avoided.
  - 344. Accordingly, all applicable statutes of limitations are tolled.

# **B.** Discovery Rule

345. Plaintiff was not aware of the full extent of the Insulin Pricing Scheme until shortly before filing this Complaint. Plaintiff was unaware of the extent to which it was economically injured and unaware that any economic injury was wrongfully caused. Nor did Plaintiff possess sufficient information concerning the

injury complained of here, or its cause, to put Plaintiff or any reasonable person on notice that actionable conduct might have occurred.

- 346. The PBM and Manufacturer Defendants refused to disclose the actual prices of diabetes medications realized by Defendants or the details of the Defendants' negotiations and payments between each other or their pricing structures and agreements—Defendants labeled these trade secrets, shrouded them in confidentiality agreements, and circumscribed payor audit rights to protect them.
- 347. Each Defendant group affirmatively and fraudulently blamed the other for the price increases described herein, both during their Congressional testimonies and through the media. All Defendants disavowed wrongdoing and falsely claimed that their dealings with payors like Plaintiff were honest and transparent.
- 348. Plaintiff did not discover and could not have discovered until shortly before filing this Complaint facts sufficient to cause it or any reasonable person to suspect that Defendants were engaged in the Insulin Pricing Scheme or that Plaintiff had suffered economic injury as a result of any or all Defendants' wrongdoing. Given Defendants' individual and coordinated efforts to obscure and conceal their misconduct, earlier diligent inquiry would not have disclosed the true facts had Plaintiff been aware of any cause to undertake such an inquiry.
- 349. Even today, lack of transparency in the pricing of diabetes medications and the arrangements, relationships, and agreements between and among the

Manufacturer Defendants and the PBM Defendants, i.e., the Insulin Pricing Scheme, continue to obscure the full nature and extent of Defendants' unlawful conduct from Plaintiff and the general public.

350. For these reasons, the statutes of limitation did not begin to run until 2023 at the earliest.

#### C. Nullum Tempus

- 351. Clark County brings this case in its sovereign capacity for the benefit of the residents of Clark County and the State of Washington.
- 352. The "regulatory oversight of health care benefit managers" is critical to "protect and promote the health, safety, and welfare of Washington residents." RCW 48.200.010(3).
- 353. In Washington, a pharmacy benefit manager "[m]ay not cause or knowingly permit the use of any advertisement, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading." RCW 48.200.280(2)(h).
- 354. Plaintiff provides numerous services for the public good of its residents and all residents of Clark County and Washington State, including maintaining facilities for public recreation, safeguarding the County's natural resources for the benefit of the public, and administering other services.

- 355. Defendants' Insulin Pricing Scheme has resulted in artificially inflated and misleading list prices for the at-issue drugs.
- 356. As a result of Defendants' Insulin Pricing Scheme, Plaintiff has overpaid for the at-issue drugs.
- 357. Each overpayment for the at-issue insulin drugs places additional stress on Plaintiff's overall budget, and in turn, harms Plaintiff's ability to provide these importance services for the public good of its residents and all residents of Washington State.
- 358. As a result of Defendants' deceptive and misleading acts and omissions, Plaintiff is harmed in its ability to safeguard the County's natural resources, maintain facilities for public recreation, and administer other important services.
- 359. Accordingly, Clark County is exempt from the applicable statutes of limitation.

#### **D.** Fraudulent Concealment

- 360. Through the acts, omissions, and representations alleged throughout this Complaint, Defendants individually and through their conspiracy fraudulently concealed the fact of Plaintiff's economic injury and its cause.
- 361. Defendants' acts, omissions, and representations were calculated to lull and induce payors, including Plaintiff, into forbearing legal action or any inquiry that might lead to legal action. Defendants' acts, omissions, and representations were

intended to and in fact did prevent Plaintiff from discovering operative facts supporting its claims.

- 362. Plaintiff acted diligently in pursuing this action once it became aware of facts sufficient to place it on notice of the extent to which it had been harmed and that such harm might have been attributable to misconduct by each or all Defendants, including through Defendants' coordinated efforts to implement and to conceal the Insulin Pricing Scheme.
  - 363. Accordingly, all applicable statutes of limitation have been tolled.

# E. Equitable Estoppel & Equitable Tolling

- 364. Defendants were under a continuous duty to disclose to Plaintiff the true character, quality, and nature of the prices upon which payments for diabetes medications were based, and the true nature of the services being provided—all of which would be and are now material to Plaintiff.
- 365. Instead of disclosing these facts, Defendants knowingly misrepresented and concealed them with a reasonable expectation that health plan payors, including Plaintiff, would act upon the misrepresentations and omissions.
- 366. Being unaware of the true facts and being unaware of the extent of the economic harm it was suffering, Plaintiff did indeed rely in good faith to its detriment on Defendants' misrepresentations and omissions.

- 367. In short, through Defendants' acts, omissions, and representations as alleged throughout this Complaint, Defendants knowingly misrepresented and concealed material facts with the expectation that Plaintiff would act upon them and would be misled thereby, which Plaintiff did in good faith and to its detriment.
- 368. Plaintiff acted diligently in pursuing this action once it became aware of facts sufficient to place it on notice of the extent to which it had been harmed and that such harm might have been attributable to misconduct by each or all Defendants, including through Defendants' coordinated efforts to implement and to conceal the Insulin Pricing Scheme. However, Defendants' misconduct served as an extraordinary circumstance that stood in Plaintiff's way and prevented Plaintiff from filing earlier.
- 369. Accordingly, Defendants are equitably estopped from relying on any statutes of limitation in defense of this action and all statutes of limitation have been equitably tolled.

#### VI. CLAIMS FOR RELIEF

# COUNT ONE — VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT ("RICO") 18 U.S.C. §1962(C) (Against All Defendants)

370. Plaintiff incorporates by reference all preceding paragraphs up to Section V of this Complaint as though fully set forth herein.

- 371. Plaintiff brings this count against all Defendants for violations of 18 U.S.C. § 1962(c).
- 372. Defendants are (1) culpable "persons" who (2) willfully and knowingly (3) committed and conspired to commit two or more acts of mail and wire fraud (4) through a "pattern" of racketeering activity that (5) involves an "association in fact" enterprise, (6) the results of which had an effect on interstate commerce.

#### A. Defendants Are Culpable "Persons" Under RICO.

- 373. Defendants, separately, are "persons" as that term is defined in 18 U.S.C. § 1961(3) because each is capable of holding a legal or beneficial interest in property.
- 374. Each one of Defendants are separate entities and "persons" that are distinct from the RICO enterprises alleged below.

# B. The Manufacturer-PBM RICO Enterprises

- 375. For the purposes of this claim, the RICO enterprises are nine separate associations-in-fact each consisting of one PBM Defendant and one Manufacturer Defendant, including those entities' directors, employees, and agents:
  - 1. the Eli Lilly–CVS Caremark Enterprise;
  - 2. the Eli Lilly–Express Scripts Enterprise;
  - 3. the Eli Lilly-OptumRx Enterprise (together with the Eli Lilly-CVS Caremark Enterprise and the Eli Lilly-Express Scripts Enterprise, the "Eli Lilly-PBM Defendant Enterprises");

- 4. the Sanofi-Aventis–CVS Caremark Enterprise;
- 5. the Sanofi-Aventis–Express Scripts Enterprise;
- 6. the Sanofi-Aventis-OptumRx Enterprise (together with the Sanofi-Aventis-CVS Caremark Enterprise and the Sanofi-Aventis-Express Scripts Enterprise, the "Sanofi-Aventis-PBM Defendant Enterprises");
- 7. the Novo Nordisk–CVS Caremark Enterprise;
- 8. the Novo Nordisk–Express Scripts Enterprise; and
- 9. the Novo Nordisk–OptumRx Enterprise (together with the Novo Nordisk–CVS Caremark Enterprise and the Novo Nordisk–Express Scripts Enterprise, the "Novo Nordisk–PBM Defendant Enterprises");
- 376. These nine association-in-fact enterprises are collectively referred to herein as the "Manufacturer–PBM Enterprises."
- 377. Each Manufacturer–PBM Enterprise is a separate, ongoing, and continuing business organization consisting of corporations and individuals associated for the common purpose of manufacturing, selling, and facilitating the purchase of the Manufacturer Defendants' products, including the at-issue drugs. For example:
  - A. Each of the three Eli Lilly–PBM Defendant enterprises associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Eli Lilly medications including Prozac, Cymbalta, and Zyprexa, as well as the at-issue Eli Lilly medications (Humulin N, Humulin R, Humulin R 500, Humulin 70/30, Humalog, Humalog Mix

50/50, Humalog Mix 75/25, and Basaglar), which are Eli Lilly's primary source of revenue.

- B. Each of the three Novo Nordisk–PBM Defendant enterprises associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Novo Nordisk medications for the treatment of obesity, hemophilia, and hormone imbalance, as well as the at-issue Novo Nordisk medications (Novolin R, Novolin N, Novolin 70/30, Novolog, Levemir, and Novolog Mix 70/30), which account for more than three-quarters of Novo Nordisk's revenue.
- C. Each of the three Sanofi–PBM Defendant enterprises associates for the common purpose of manufacturing, selling, distributing, and facilitating the purchase of Sanofi medications including Ambien, Plavix, and Dupixent, as well as the at-issue Sanofi medications (Lantus, Toujeo Solostar, and Apidra).
- 378. Each Manufacturer–PBM Enterprise engaged in the shared purpose of exchanging false list prices and secret Manufacturer Payments for preferred formulary positions for the at-issue drugs in order to control the market for diabetes medications and profit off diabetics and payors, including Plaintiff.
- 379. The members of each Manufacturer–PBM Enterprise are bound by contractual relationships, financial ties, and the ongoing coordination of activities.

- 380. There also is a common communication network by which the members of each Manufacturer-PBM Enterprise share information and meet on a regular basis. These communications include, but are not limited to, communications relating to the use of false list prices for the at-issue diabetes medications and the regular flow of Manufacturer Payments from each Manufacturer Defendant to the PBM Defendants in exchange for formulary placement.
- 381. Each Manufacturer–PBM Enterprise functions as a continuing but separate unit separate and apart from the pattern of racketeering activity in which it engages. Each Manufacturer–PBM Enterprise, for example, engages in the manufacture, distribution, and sale of medications and other products other than the at-issue insulin and insulin-analog medications. Additionally, each Manufacturer engages in conduct other than mail and wire fraud in furtherance of the Insulin Pricing Scheme.
- 382. At all relevant times, each of the Manufacturer–PBM Enterprises was operated and conducted for unlawful purposes by each Manufacturer Defendant and each PBM Defendant, namely, carrying out the Insulin Pricing Scheme.
- 383. Each Manufacturer–PBM Enterprise derived secret profits from these activities that were greater than those any one of the Manufacturer Defendants or PBM Defendants could obtain absent their misrepresentations regarding their non-transparent pricing schemes.

- 384. To accomplish this common purpose, each Manufacturer Defendant periodically and systematically inflated the prices of the at-issue drugs and then secretly paid a significant, yet undisclosed, portion of this inflated price back to each PBM Defendant in the form of Manufacturer Payments.
- 385. Each Manufacturer–PBM Enterprise did so willfully and with knowledge that Plaintiff paid for the at-issue drugs at prices directly based on the false list prices.
- 386. Each Manufacturer–PBM Enterprise's inflation of the list prices and secret Manufacturer Payments was a quid pro quo exchange for preferred formulary placement.
- 387. Each Manufacturer–PBM Enterprise concealed from Plaintiff that these false prices and secret Manufacturer Payments resulted in each Manufacturer gaining formulary access without requiring significant price reductions and resulted in higher profits for each PBM Defendant, whose earnings increase the more inflated the price is and the more payment it receives from each Manufacturer Defendant.
- 388. Each Manufacturer–PBM Enterprise also shares a common purpose of perpetuating the use of the false list prices for the at-issue drugs as the basis for the price that payors, including Plaintiff, and diabetics pay for diabetes medications.
- 389. The Manufacturer Defendants would not be able to offer large pricing spreads to the PBM Defendants in exchange for favorable formulary positions

without the use of the false list prices as the basis for the price paid by diabetics and payors, including Plaintiff, for the at-issue drugs.

390. The PBM Defendants share this common purpose because nearly all the revenue and profit generated from the at-issue drugs is tied to the falsely inflated prices generated by the Insulin Pricing Scheme. Without diabetics and payors, including Plaintiff, paying for diabetes medications based on the inflated list prices, the PBM Defendants' profits from the Insulin Pricing Scheme would decrease.

391. As a result, each PBM Defendant has, with the knowing and willful participation and assistance of each Manufacturer Defendant, engaged in hidden profit-making schemes falling into four general categories: (1) garnering undisclosed Manufacturer Payments from each Manufacturer Defendant that each PBM Defendant retains to a large extent, including by relabeling these payments and utilizing rebate aggregators to avoid their pass-through obligations; (2) generating substantial profits from pharmacies because of the falsely inflated prices, including through retaining clawbacks and post-purchase discounts; (3) generating spread income by charging their clients a higher amount than they pay pharmacies, with the spread income increasing with each list price increase; and (4) generating profits on the diabetes medications sold through each PBM Defendant's own mail-order and retail pharmacies, including by keeping secret discounts each Manufacturer Defendant provides to these affiliated pharmacies.

- 392. At all relevant times, each PBM Defendant and each Manufacturer Defendant has been aware of its respective Manufacturer–PBM Enterprise's conduct, has been a knowing and willing participant in and coordinator of that conduct and has reaped profits from that conduct.
- 393. Neither any PBM Defendant nor any Manufacturer Defendant alone could have accomplished the purposes of the Manufacturer–PBM Enterprises without the other entity.

# C. The Enterprises Misrepresent and Fail to Disclose Material Facts in Furtherance of the Insulin Pricing Scheme.

- 394. Each Manufacturer–PBM Enterprise knowingly made material misrepresentations to the public and health plan payors, including the Plaintiff, in furtherance of the Insulin Pricing Scheme, including publishing artificially inflated prices for insulin on published indices and representing that:
  - A. the false list prices for the at-issue diabetes medications were reasonably related to the actual prices realized by Defendants and were a reasonable and fair basis on which to base the price consumers and health plan payors, including Plaintiff, paid for these drugs;
  - B. each Manufacturer priced its at-issue drugs according to each drug's value to the healthcare system and the need to fund innovation;

- C. the Manufacturer Payments paid back to each PBM Defendant for each at-issue drug were for the benefit of health plan payors, including Plaintiff;
- D. all "rebates" and discounts negotiated by the PBM Defendants with the Manufacturer Defendants were remitted to health plan payors, including Plaintiff;
- E. the "rebates" negotiated by the members of each enterprise saved health plan payors, including Plaintiff, money;
- F. each Manufacturer Defendant and each PBM Defendant were transparent with health plan payors, including Plaintiff, regarding the Manufacturer Payments, and that the PBMs did not retain any funds associated with prescription drug rebates or the margin between guaranteed reimbursement rates and the actual amount paid to the pharmacies; and
- G. each PBM Defendant constructed formularies in a manner that lowered the price of the at-issue drugs and promoted the health and safety of diabetics.
- 395. Each false list price published by the Manufacturer Defendants constituted a material misrepresentation to consumers, health plan payors, including Plaintiff, and the public, in that each purported to be a fair market price for an atissue drug, and each omitted to disclose the fraudulent spread between the list price

and the net price of the medication or the basis therefor. Specific examples of such misrepresentations are set forth in Table 1 and Figures 3-11. Examples of other specific affirmative representations by each Defendant in furtherance of each enterprise's Insulin Pricing scheme are set forth in paragraphs 194, 198-99, 206, 234-43, and 248-49.

- 396. At all times relevant to this Complaint, each Manufacturer–PBM Enterprise knew the above-described representations to be false.
- 397. At all times relevant to this Complaint, each Manufacturer–PBM Enterprise intentionally made these representations for the purpose of inducing consumers and health plan payors, including Plaintiff, into paying artificially inflated prices for diabetes medications.
- 398. Consumers and health plan payors, including Plaintiff, relied on the material misrepresentations and omissions made by each Manufacturer–PBM Enterprise in paying prices for the at-issue diabetes medications based upon the false prices generated by Insulin Pricing Scheme.
- 399. Additionally, each PBM–Manufacturer Enterprise relied on the list prices negotiated and published by the other PBM–Manufacturer Enterprises in setting their own list prices and determining the value of the kickbacks paid to the PBMs. Health plan payors, including Plaintiff, were injured by the inflated prices that arose as a result.

- 400. Each PBM Defendant convinced health plan payors, including Plaintiff, to pay prices for the at-issue drugs based on the false list prices by using the misrepresentations listed above to convince the health plan payors, including Plaintiff, that they had secured lower prices when, in fact, they did the opposite, all while concealing the Insulin Pricing Scheme.
- 401. Without these misrepresentations and each Defendant's failure to disclose the Insulin Pricing Scheme, each Manufacturer–PBM Enterprise could not have achieved its common purpose, as consumers and health plan payors, including Plaintiff, would not have been willing to pay these false list prices.

### D. Defendants' Use of the U.S. Mails and Interstate Wire Facilities.

402. Each of the Manufacturer–PBM Enterprises engaged in and affected interstate commerce because each engaged in some or all of the following activities across state boundaries: the sale, purchase, and/or administration of diabetes medications; the setting and publishing of the prices of these drugs; and the transmission of pricing information of diabetes medications; and/or the transmission and/or receipt of sales and marketing literature; and/or the transmission of diabetes medications through mail-order and retail pharmacies; and/or the transmission and/or receipt of invoices, statements, and payments related to the use or administration of diabetes medications; and/or the negotiations and transmissions of contracts related to the pricing of and payment for diabetes medications.

- 403. Each Manufacturer–PBM Enterprise participated in the administration of diabetes medications to millions of individuals located throughout the United States, including in Clark County and elsewhere in this District.
- 404. The Manufacturer Defendants' and PBM Defendants' illegal conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information and products and funds through the U.S. mails and interstate wire facilities.
- 405. The nature and pervasiveness of the Insulin Pricing Scheme, which included each Manufacturer Defendant's and each PBM Defendant's corporate headquarters operations, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities with each other and with pharmacies, physicians, payors, and diabetics in Clark County and throughout Washington.
- 406. Each Manufacturer–PBM Enterprise's use of the U.S. mails and interstate wire facilities to perpetrate the Insulin Pricing Scheme involved thousands of communications including:
  - A. marketing materials about the published prices for diabetes medications, which each Manufacturer Defendant sent to each PBM

Defendant located across the country, including in Clark County and throughout Washington;

- B. written and oral representations of the false list prices of diabetes medications that each Manufacturer Defendant and each PBM Defendant made at least annually and, in many cases, several times during a single year to the public;
- C. thousands of written and oral communications discussing, negotiating, and confirming the placement of each Manufacturer Defendant's diabetes medications on each PBM Defendant's formulary;
- D. written and oral representations made by each Manufacturer

  Defendant regarding information or incentives paid back to each PBM

  Defendant for each diabetes medication sold and/or to conceal these incentives or the Insulin Pricing Scheme;
- E. written communications made by each Manufacturer Defendant, including checks, relating to Manufacturer Payments paid to each PBM Defendant to persuade it to advocate the at-issue diabetes medications;
- F. written and oral communications with U.S. government agencies that misrepresented what the published prices were or that were intended to deter investigations into the true nature of the published prices or to forestall changes to reimbursement based on something other than published prices;

- G. written and oral communications with payors, including Plaintiff, regarding the price of diabetes medications;
- H. written and oral communications to health plan payors, including Plaintiff, that included marketing and solicitation material sent by each PBM Defendant regarding the existence, amount, or purpose of payments made by each Manufacturer Defendant to each PBM Defendant for the diabetes medications described herein and the purpose of each PBM Defendant's formulary;
- I. transmission of published prices to third parties and payors, including Plaintiff; and
- J. receipts of money on tens of thousands of occasions through theU.S. mails and interstate wire facilities—the wrongful proceeds of the InsulinPricing Scheme.
- 407. Although Plaintiff pleads the dates of certain communications in allegations incorporated into this Count, it cannot allege the precise dates of others without access to books and records within each Defendant's exclusive custody and control. Indeed, an essential part of the successful operation of the Insulin Pricing Scheme depended upon secrecy, and each of the Manufacturer Defendants and each PBM Defendant took deliberate steps to conceal its wrongdoing.

### E. Conduct of the Manufacturer-PBM Enterprises' Affairs.

- 408. Each Manufacturer Defendant and each PBM Defendant participates in the operation and management of Manufacturer–PBM Enterprises with which they are associated and, in violation of Section 1962(c) of RICO, and conduct or participate in the conduct of the affairs of those association-in-fact RICO enterprises, directly or indirectly. Such participation is carried out in the following ways:
  - A. Each Manufacturer Defendant and each PBM Defendant directly negotiates and controls the secret Manufacturer Payments provided to each PBM Defendant for diabetes medications.
  - B. Each PBM Defendant directly manages and controls their drug formularies and the placement of the at-issue diabetes medications on those formularies.
  - C. Each PBM Defendant intentionally selects higher-priced diabetes medications for formulary placement and excludes lower priced ones in order to generate larger profits and they coordinate with each Manufacturer Defendant to increase the availability and use of higher-priced medications because they are more profitable for both groups of Defendants.
  - D. Each Manufacturer Defendant directly controls the publication of the false list prices generated by the Insulin Pricing Scheme.

- E. Each Manufacturer Defendant directly controls the creation and distribution of marketing, sales, and other materials used to inform each PBM Defendant of the profit potential from its diabetes medications.
- F. Each PBM Defendant directly controls the creation and distribution of marketing, sales, and other materials used to inform payors and the public of the benefits and cost-saving potential of their formulary and negotiations with the Manufacturers.
- G. Each PBM Defendant directs and controls each Manufacturer-PBM Enterprise's direct relationships with payors such as the Plaintiff by negotiating the terms of and executing the contracts that govern those relationships.
- H. Each PBM Defendant directs and controls each Manufacturer-PBM Enterprise's Insulin Pricing Scheme by hiding, obfuscating, and laundering Manufacturer Payments through their affiliated entities in order to retain a large and undisclosed proportion of the Manufacturer Payments to the detriment of payors, including Plaintiff.
- I. Each PBM Defendant distributes through the U.S. mail and interstate wire facilities, promotional and other materials that claim the Manufacturer Payments paid from each Manufacturer Defendant to each PBM Defendant save Plaintiff and other payors money on the at-issue drugs.

J. Each Manufacturer Defendant represented to health plan payors, including Plaintiff—by publishing and promoting false list prices without stating that these published prices differed substantially from the prices realized by each Manufacturer Defendant and each PBM Defendant —that the published prices of diabetes medications reflected or approximated the actual price realized by Defendants and resulted from transparent and competitive, fair market forces.

### F. Defendants' Pattern of Racketeering Activity.

- 409. The Manufacturer Defendants and the PBM Defendants have conducted and participated in the affairs of their respective Manufacturer–PBM Enterprises through a pattern of racketeering activity, including acts that are unlawful under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud.
- 410. The Manufacturer Defendants' and the PBM Defendants' pattern of racketeering involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of the Insulin Pricing Scheme. Each of these mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), in which the Manufacturer Defendants and the PBM

Defendants intended to defraud consumers and health plan payors, including Plaintiff.

- 411. By intentionally and falsely inflating the list prices, by misrepresenting the purpose behind both the Manufacturer Payments made from each Manufacturer Defendant to each PBM Defendant and each PBM Defendant's formulary construction, and by subsequently failing to disclose such practices to consumers and health plan payors, including Plaintiff, the Manufacturer Defendants and the PBM Defendants engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.
- 412. The Manufacturer Defendants' and the PBM Defendants' racketeering activities amounted to a common course of conduct, with similar patterns and purposes, intended to deceive Plaintiff.
- 413. Each separate use of the U.S. mails and/or interstate wire facilities employed by the Manufacturer Defendants and the PBM Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiff.
- 414. The Manufacturer Defendants and the PBM Defendants engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the respective Manufacturer–PBM Enterprises with which each of them is and was associated in fact.

### **G.** The RICO Defendants' Motive

- 415. The Manufacturer Defendants' and the PBM Defendants' motive in creating and operating the Insulin Pricing Scheme and conducting the affairs of the Manufacturer– PBM Enterprises described herein was to control the market for diabetes medications and falsely obtain sales of and profits from diabetes medications.
- 416. The Insulin Pricing Scheme was designed to, and did, encourage others, including payors such as Plaintiff, to advocate the use of each Manufacturer Defendant's products and to pay for those diabetes medications based on a falsely inflated price. Each Manufacturer Defendant used the Insulin Pricing Scheme to obtain formulary placement to sell more of its drugs without cutting into its profits. The PBM Defendants used the Insulin Pricing Scheme to falsely inflate the price payors such as Plaintiff paid for diabetes medications in order to profit off the Insulin Pricing Scheme, as discussed above.

### H. The Manufacturer–PBM Enterprises' Insulin Pricing Scheme Injured Plaintiff.

- 417. Each Manufacturer–PBM Enterprise's violations of federal law and pattern of racketeering activity have directly and proximately caused Plaintiff to be injured in its business or property.
- 418. The prices Plaintiff pays for the at-issue drugs are tied directly to the false list prices generated by the Insulin Pricing Scheme.

- 419. No other intermediary in the supply chain has control over or is responsible for the list prices on which nearly all Plaintiff's payments are based other than the Manufacturer–PBM Defendant Enterprises.
- 420. Defendants collectively set the prices Plaintiff paid for the at-issue drugs.
  - 421. During the relevant period, Plaintiff paid for the at-issue drugs.
- 422. Each Manufacturer–PBM Enterprise controlled and participated in the Insulin Pricing Scheme that was directly responsible for the false list prices upon which the price Plaintiff paid was based.
- 423. Plaintiff thus was damaged by the scheme. But for the illegal conduct of the Manufacturing-PBM Enterprises, including the misrepresentations and false prices created by the Insulin Pricing Scheme that each Manufacturer–PBM Enterprise employed, Plaintiff would have paid less for the medications.
- 424. While Defendants' scheme injured an enormous number of payors and plan members, Plaintiff's damages are separate and distinct from those of any other victim that was harmed by the Manufacturer–PBM Enterprises' Insulin Pricing Scheme.
- 425. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(c) of RICO, Defendants are jointly and severally liable

to Plaintiff for three times the damages that were sustained, plus the costs of bringing this action, including reasonable attorneys' fees.

- 426. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(a) of RICO, Plaintiff seeks injunctive relief against the Manufacturer Defendants and the PBM Defendants for their fraudulent reporting of prices, and their continuing acts to affirmatively misrepresent and/or conceal and suppress material facts concerning their false and inflated prices for diabetes medications, plus the costs of bringing this suit, including reasonable attorneys' fees.
- 427. Absent an injunction, the effects of this fraudulent, unfair, and unconscionable conduct will continue. Plaintiff continues to purchase the at-issue diabetes medications. Plaintiff will continue to pay based on the Defendants' false list prices. This continuing fraudulent, unfair, and unconscionable conduct is a serious matter that calls for injunctive relief as a remedy. Plaintiff seeks injunctive relief, including an injunction against the Manufacturer Defendants and the PBM Defendants to prevent them from affirmatively misrepresenting and/or concealing and suppressing material facts concerning their conduct in furtherance of the Insulin Pricing Scheme.

# COUNT TWO — VIOLATIONS OF RICO, 18 U.S.C. § 1962(D) BY CONSPIRING TO VIOLATE 18 U.S.C. § 1962(C) (Against All Defendants)

- 428. Plaintiff incorporates by reference all preceding paragraphs up to Section V, as well as Count I, of this Complaint as though fully set forth herein.
- 429. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b), or (c) of this section."
- 430. Defendants have violated § 1962(d) by agreeing and conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in the Insulin Pricing Scheme.
- 431. As set forth in detail above, as well as in the Civil Conspiracy count below, Defendants each knowingly agreed to facilitate the Insulin Pricing Scheme and each has engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy. Specifically, Defendants agreed to and did inflate the prices of the at-issue drugs in lockstep to achieve an unlawful purpose; Defendants agreed to and did make false or misleading statements or material omissions regarding the reasons for these price increases, the purpose of the Manufacturer Payments exchanged between Defendants and the PBMs' formulary construction; and PBMs agreed to and did, in concert, request and receive larger Manufacturer Payments and higher prices in exchange for formulary placement.

- 432. The nature of the above-described Defendant co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.
- 433. Defendants have engaged and continue to engage in the commission of overt acts, including the following unlawful racketeering predicate acts:
  - A. multiple instances of mail fraud in violations of 18 U.S.C. § 1341;
  - B. multiple instances of wire fraud in violations of 18 U.S.C. § 1343; and
  - C. multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.
- 434. Defendants' conspiracy to violate the above federal laws and the effects thereof detailed above are continuing and will continue. Plaintiff has been injured in its property by reason of these violations: Plaintiff has paid more for the at-issue drugs than it would have but for Defendants' conspiracy to violate 18 U.S.C. § 1962(c).

435. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are jointly and severally liable to Plaintiff for three times the damages Plaintiff has sustained, plus the cost of this action, including reasonable attorneys' fees.

### COUNT THREE — CIVIL CONSPIRACY (Against All Defendants)

- 436. Plaintiff incorporates by reference all preceding paragraphs up to Section V, as well as Counts I, II, and VI, of this Complaint as though fully set forth herein.
- 437. Defendants' conduct described throughout this Complaint as comprising and implementing the Insulin Pricing Scheme constituted a combination of two or more persons created and carried out for an unlawful purpose or a lawful purpose by unlawful means, further to which one or all Defendants committed an overt tortious or unlawful act.
- 438. Each and every Defendant knowingly and maliciously participated in the creation and implementation of the Insulin Pricing Scheme.
- 439. Each and every Defendant planned, assisted, and encouraged the Insulin Pricing Scheme.
- 440. Defendants aided and abetted one another to violate federal laws, including 18 U.S.C. § 1962(c) and the Washington Consumer Protection Act, as alleged herein.

- 441. Each Defendant agreed to carry out and carried out overt acts in furtherance of the Insulin Pricing Scheme that artificially inflated the price of diabetes medications to Plaintiff's detriment.
- 442. Each PBM Defendant made a conscious commitment to participate in the Insulin Pricing Scheme.
- 443. The Manufacturer Defendants agreed with each other and the PBM Defendants to intentionally raise their diabetes medication prices and then pay back a significant portion of those prices to the PBM Defendants.
- 444. In exchange for the Manufacturer Defendants inflating their prices and making large secret payments, the PBM Defendants agreed to and did grant preferred formulary status to the Manufacturer Defendants' diabetes medications.
- 445. Each Defendant shares a common purpose of perpetuating the Insulin Pricing Scheme and neither the PBM Defendants nor the Manufacturer Defendants alone could have accomplished the Insulin Pricing Scheme without their coconspirators.
- 446. The PBM Defendants need the Manufacturer Defendants to inflate the list price of their diabetes medications and to make secret payments back to the PBM Defendants in order for the PBM Defendants to profit off the Insulin Pricing Scheme.
- 447. The Manufacturer Defendants need the PBM Defendants to grant certain diabetes medications preferred formulary placement in order to maintain

access to payors and diabetics whose purchase of the at-issue drugs generated unearned and unwarranted revenue for all Defendants.

- 448. As discussed throughout this Complaint, the Insulin Pricing Scheme resulted from explicit agreements, direct coordination, constant communication, and exchange of information between the PBM Defendants and the Manufacturer Defendants.
- 449. In addition to the preceding direct evidence of an agreement, Defendants' conspiracy is also demonstrated by the following indirect evidence that infers Defendants conspired to engage in fraudulent conduct:
  - A. Defendants refuse to disclose the details of their pricing structures, agreements and sales figures in order to maintain the secrecy of the Insulin Pricing Scheme;
  - B. Numerous ongoing government investigations, hearings, and inquiries have targeted the Insulin Pricing Scheme and the collusion between the Manufacturer and PBM Defendants, including:
    - i. civil investigative demands to the Manufacturers from the States of California, Florida, Minnesota, and Washington relating to the pricing of their insulin products and their relationships with the PBM Defendants;

- ii. letters from numerous senators and representatives in recent years to the Justice Department and the Federal Trade Commission asking them to investigate potential collusion among Defendants;
- iii. 2019 hearings before the House Oversight and ReformCommittee on industry practices; and
- iv. the Senate Finance Committee's recent two-year probe into the Insulin Pricing Scheme and the conspiracy between the Manufacturers and the PBMs, resulting in the Grassley-Wyden report, first published in 2021.
- C. The astronomical rise in the price of the at-issue drugs coincides with PBM Defendants' rise in power within the pharmaceutical pricing system starting in 2003.
- 450. As a result of Defendants' unlawful and tortious acts, including violations of 18 U.S.C. § 1962(c) and the Washington Consumer Protection Act, Plaintiff has suffered actual damage and continues to be damaged by the conspiracy when it overpays for the diabetes medications.

## COUNT FOUR — COMMON LAW FRAUD (Against Defendants Express Scripts, Eli Lilly, Sanofi-Aventis, and Novo Nordisk)

- 451. Plaintiff incorporates by reference all preceding paragraphs up to Section V of this Complaint as though fully set forth herein.
- 452. As alleged extensively above, these Defendants affirmatively misrepresented and/or concealed and suppressed material facts concerning: (a) the true cost and/or price of the insulin products described herein; (b) the inflated and/or fraudulent nature of the list price(s) set and/or charged by these Defendants for the insulin products described herein; (c) the existence, amount, and/or purpose(s) of discounts and/or rebates offered and/or negotiated by these Defendants for those products; and (d) the role that these Defendants played in the price paid for the insulin products described herein, including but not limited to marketing material averring that these Defendants decrease the price of prescription drugs for consumers.
- 453. Defendants Express Scripts, Eli Lilly, Sanofi-Aventis, and Novo Nordisk valued their profits over the trust, health, and safety of Plaintiff.
- 454. Necessarily, these Defendants took steps to ensure that their employees and co-conspirators did not reveal the details of the Insulin Pricing Scheme to Plaintiff.

- 455. These Defendants' false representations and omissions were material to Plaintiff.
- 456. These Defendants knew that their representations and omissions were false and misleading. They knew, for example, that the list prices for the at-issue drugs were inflated and untethered to market price. They knew that these list prices were artificially inflated to fund kickbacks to the PBM Defendants in exchange for preferred formulary placement.
- 457. Plaintiff reasonably relied on these Defendants' deception, and these Defendants intended that they would so rely. Plaintiff had no way of discerning that these Defendants were, in fact, deceiving them because they possessed exclusive knowledge regarding the nature of insulin pricing; intentionally concealed the foregoing from Plaintiff and the public; and made incomplete or negligent representations about the pricing of the insulin products and these Defendants' role in that pricing, while purposefully withholding material facts from Plaintiff that contradicted these representations.
- 458. Plaintiff relied on these Defendants' false list prices. Because of the Insulin Pricing Scheme, list prices have skyrocketed and the spread between list price and net price has ballooned in turn. Plaintiff is injured by this list and net price divergence. Through the scheme, these Defendants have forced payors, including

Plaintiff, to pay not just for the drugs, but also for undisclosed kickbacks that are paid to PBMs.

- 459. These Defendants took steps to ensure that their employees and coconspirators did not reveal the details of the Insulin Pricing Scheme to Plaintiff.
- 460. These Defendants owed Plaintiff a duty to disclose, truthfully, all facts concerning the true cost of the at-issue medications and the inflated and fraudulent nature of their pricing; the existence, amount, flow, and purpose of rebates and discounts negotiated for those products; and the role that these Defendants played in increasing the price of the at-issue drugs.
- 461. These Defendants possessed superior knowledge of essential facts about the at-issue drugs and their prices. That information was peculiarly and exclusively in their control and not available to payors, including Plaintiff. In light of their misleading or incomplete representations, these Defendants also had an obligation to disclose facts related to the Insulin Pricing Scheme.
- 462. These Defendants' actions, representations, and misrepresentations demonstrate callous disregard for not only the rule of law but also public health. Indeed, as a direct result of these Defendants' actions, access to live-saving insulin medication has been limited, denied, or forgone.
- 463. These Defendants owed Plaintiff a duty to disclose, truthfully, all the facts concerning the true cost of the at-issue medications described herein and the

inflated and fraudulent nature of their pricing; the existence, amount, and purpose of rebates and discounts negotiated for those products; and the role that these Defendants played in increasing the price of the at-issue medications described herein.

- 464. These Defendants hatched their deceptive schemes and knew that Plaintiff did not know about (and could not reasonably discover) the manner in which they sought to artificially inflate the price of the insulin medications. These Defendants not only concealed all the facts concerning the true cost of the insulin products described herein, but went further to make affirmative misrepresentations in marketing materials and other communications, that these Defendants worked to lower the ultimate cost of prescription medications. These Defendants engaged in this fraudulent concealment at the expense of Plaintiff.
- 465. Plaintiff was not aware of the concealed and misrepresented material facts referenced above, and it would not have acted as it did, had it known the truth.
- 466. As a direct and proximate result of these Defendants' fraudulent scheme, Plaintiff sustained damages, including but not limited to paying excessive and inflated prices for the insulin products described herein.
- 467. These Defendants are liable to Plaintiff for damages in an amount to be proven at trial. Moreover, because these Defendants acted wantonly, maliciously, oppressively, recklessly, deliberately, and with intent to defraud Plaintiff for the

purpose of enriching themselves to Plaintiff's detriment, these Defendants' conduct warrants substantial damages in an amount to be determined at trial.

## COUNT FIVE — UNJUST ENRICHMENT (Against All Defendants)

- 468. Plaintiff incorporates by reference all preceding paragraphs up to Section V of this Complaint as though fully set forth herein.
  - 469. Plaintiff brings this Count on behalf of itself.
- 470. This claim is alleged in the alternative to Plaintiff's claims for legal relief.
- 471. Defendants have knowingly benefitted from the Insulin Pricing Scheme described herein, including selling, setting prices for, and negotiating discounts for insulin products marketed and sold at an artificially inflated price.
- 472. Defendants have knowingly received and retained unjust benefits from Plaintiff as a result of the Insulin Pricing Scheme described herein, including in the form of gross prescription costs paid, copayments, and coinsurance payments, and inequity has resulted.
- 473. It is inequitable and unconscionable for Defendants to retain these benefits.
- 474. Because Defendants concealed the true nature of the payments they received and the amounts they purportedly passed through to the County, Plaintiff

was not aware of the true facts concerning the Insulin Pricing Scheme described herein and did not benefit from Defendants' misconduct.

- 475. Defendants knowingly accepted the unjust benefits of their fraudulent conduct.
- 476. Equity cannot in good conscience permit Defendants to be economically enriched for their unjust actions at Plaintiff's expense and in violation of state law, and therefore restitution or disgorgement or both of such economic enrichment is required.

# COUNT SIX — WASHINGTON CONSUMER PROTECTION ACT, WASHINGTON REVISED CODE SECTION 19.86.010 ET SEQ. (Against Defendant Express Scripts)

- 477. Plaintiff incorporates by reference all preceding paragraphs up to Section V of this complaint as though fully set forth herein.
- 478. The Washington Consumer Protection Act ("Washington CPA") broadly prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Wash. Rev. Code. § 19. 86.010.
  - 479. Defendant is a "person" as defined by Wash. Rev. Code § 19.86.010.
  - 480. Plaintiff is a "person" as defined by Wash. Rev. Code § 19.86.010.
- 481. Defendant committed the acts complained of herein in the course of "trade" or "commerce" within the meaning of Wash. Rev. Code. § 19.86.010.

- 482. The Washington State Legislature has enacted Chapter 48.200 to regulate pharmacy benefit managers and health care benefit managers. Wash. Rev. Code. § 48.200. In doing so, it found that the "regulatory oversight of health care benefit managers" is critical to "protect and promote the health, safety, and welfare of Washington residents." Wash. Rev. Code. § 48.200.010(3).
- 483. Under this statute, a pharmacy benefit manager "[m]ay not cause or knowingly permit the use of any advertisement, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading." Wash. Rev. Code. § 48.200.280(2)(h).
- 484. Defendant thus violated the Washington CPA, at a minimum by taking the following actions.
  - A. Making material misrepresentations regarding the true cost of the insulin products described herein that had the tendency to mislead consumers and health plan payors, such as Plaintiff, including, but not limited to, by publishing, setting, or distributing the list price of the insulin products described herein;
  - B. Engaging in advertising concerning the role that Defendant played in setting the price paid for the insulin products described herein, including but not limited to marketing material averring that PBM Defendants make efforts to decrease the price of prescription drugs for consumers;

- C. Using the inflated list prices to determine the prices paid by health plan payors, including Plaintiff, and failing to disclose the inflated nature of the list price(s) set and/or charged by Manufacturer Defendants for the insulin products described herein, with the knowledge, consent, and cooperation of the PBM Defendant(s);
- D. Making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by the Manufacturer Defendants to the PBM Defendants and/or negotiated by the PBM Defendants in exchange for inclusion and/or tier placement of the Manufacturer Defendants' products on the PBM Defendants' formularies;
- E. Making material misrepresentations regarding or failing to disclose the portion of discounts, rebates, and/or other payments from the Manufacturer Defendants that the PBM Defendants keep;
- F. Misleading health plan payors, including Plaintiff, as to the true nature of the value of the services provided and reaping illicit profits exponentially greater than the fair market value of the products and services provided;

- G. Confusing and misleading health plan payors, including Plaintiff, regarding each Defendant's respective role in the Insulin Pricing Scheme in an attempt to evade liability;
- H. Hiding, obfuscating, and laundering the Manufacturer Payments through the PBM Defendants' affiliated entities in order to retain a large and undisclosed proportion of the Manufacturer Payments to the detriment of health plan payors, including Plaintiff; and/or
- I. Engaging in misleading, false, unfair and/or deceptive acts or practices by selling and/or facilitating the sale of the insulin products described herein at grossly inflated and/or fraudulently obtained price points.
- 485. Defendant continues to make misrepresentations and publish false prices generated by the Insulin Pricing Scheme, and consumers and health plan payors, including Plaintiff, continue to purchase diabetes medications at inflated prices, notwithstanding the Manufacturer Defendants' price caps. The foregoing violations caused harm to Plaintiff, and are likely to harm Plaintiff in the future if Defendant's practices are not stopped.
- 486. Each at-issue purchase Plaintiff made of diabetes medications at the prices generated by the Insulin Pricing Scheme constitutes a separate violation of the Washington Consumer Protection Act.

- 487. Defendant's acts and practices in violation of the Washington Consumer Protection Act caused Plaintiff to suffer injuries alleged herein, including but not limited to paying excessive and inflated prices for diabetes medications as described herein.
- 488. Furthermore, Clark County brings this cause of action in its sovereign capacity for the benefit of the State of Washington. The Washington Consumer Protection Act expressly authorizes local governments to enforce its provisions and to recover damages for violations of the Act, and this action is brought to promote the public welfare of the state and for the common good of the state.
- 489. Defendant is liable to Plaintiff for damages in amounts to be proven at trial, including attorneys' fees, costs, and treble damages, as well as any other remedies the Court may deem appropriate under Wash. Rev. Code. § 19.86.090.

### VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for entry of judgment against the Defendants for all the relief requested herein and to which the Plaintiff may otherwise be entitled, specifically including, but without limitation, to wit:

A. A determination that Defendants have violated the Washington Consumer Protection Act, violated RICO, conspired to violate RICO, engaged in a civil conspiracy, and have been unjustly enriched;

- B. Judgment in favor of Plaintiff and against the Defendants for damages in excess of the minimum jurisdictional requirements of this Court, in a specific amount to be proven at trial;
- C. Injunctive relief in accordance with the Washington Consumer Protection Act (Wash. Rev. Code § 19.86.010 et seq.), 18 U.S.C. § 1964(a), and 18 U.S.C. § 1962(c), to the effect that Defendants, their affiliates, successors, transferees, assignees, and the officers, directors, partners, agents, and employees thereof, and all other persons acting or claiming to act on their behalf or in concert with them, be enjoined and restrained from in any manner continuing, maintaining or renewing the conduct, contract, conspiracy, or combination alleged herein in violation of Washington law and RICO, or from entering into any other contract, conspiracy, or combination having a similar purpose or effect, and from adopting or following any practice, plan, program, or device having a similar purpose or effect;

### D. That Plaintiff:

- i. be awarded restitution, damages (including but not limited to treble damages as permitted by Wash. Rev. Code § 19.86.010 *et seq.* and 18 U.S.C. §§ 1962(c) and 1964(a)), disgorgement, penalties, and all other legal and equitable relief to which Plaintiff may be entitled;
  - ii. be awarded 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 initial Complaint in this action;

- iii. recover its costs of this action, including its reasonable attorneys' fees; and
- iv. be awarded such other further relief as the case may require and the Court may deem just and proper under the circumstances.

### VIII. JURY DEMAND

Plaintiff demands trial by jury on all issues so triable.

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### RESPECTFULLY SUBMITTED this 30th day of May, 2024.

### **CLARK COUNTY**

By: s/ Amanda Migchelbrink
Amanda Migchelbrink
Senior Deputy Prosecuting Attorney
Clark County Prosecutor's Office
Civil Division

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#### KELLER ROHRBACK L.L.P.

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Attorneys for Plaintiff

### JS 44 (Rev. 04/21) Case 2:24-cv-06568 Document 2-0 Vilad St/20/24 Page 1 of 1 PageID: 177

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

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(c) Attorneys (Firm Name, Address, and Telephone Number) David J. Ko				Attorneys (If Kno	own)					
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IF ANY	(See insu actions).	JUDGE Hon. B	rian R.	Martinotti		_DOCK	ET NUMBER N	1DL No. 30	080	
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05.30.2024		s/ David J. Ko								
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