COMMONWEALTH OF KENTUCKY
48TH JUDICIAL CIRCUIT
FRANKLIN CIRCUIT COURT
DIVISION ___
CIVIL ACTION NO: _____

COMMONWEALTH OF KENTUCKY **PLAINTIFF**
***ex rel.* ANDY BESHEAR, ATTORNEY GENERAL**

COMPLAINT

NOVO NORDISK, INC. **DEFENDANTS**
800 Scudders Mill Road
Plainsboro, NJ 08807

SERVE:
NOVO NORDISK, INC.
c/o The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

AND

SANOFI-AVENTIS U.S. LLC
55 Corporate Drive
Bridgewater, NJ 08807

SERVE:
SANOFI-AVENTIS U.S. LLC
c/o Corporation Service Company
251 Little Falls Drive
Wilmington, DE 19808

AND

ELI LILLY AND COMPANY
Lilly Corporate Center
Indianapolis, IN 46285

SERVE:
ELI LILLY AND COMPANY
c/o National Registered Agents, Inc

306 W. Main Street
Ste. 512
Frankfort, KY 40601

*** *** ***

Comes the Plaintiff, the Commonwealth of Kentucky *ex rel.* Andy Beshear, Attorney General, and for his Complaint against Defendants NOVO NORDISK, INC (hereinafter "Novo Nordisk"), SANOFI-AVENTIS U.S. LLC (hereinafter "Sanofi"), and ELI LILLY AND COMPANY (hereinafter "Eli Lilly") alleges the following:

PRELIMINARY STATEMENT

Hundreds of thousands of Kentuckians live with diabetes mellitus, a chronic insulin deficiency (Type I diabetes) or a resistance to insulin a person's body produces (Type II diabetes). Though the human pancreas ordinarily produces insulin, people with diabetes often do not produce enough to keep them alive. Insulin is a hormone necessary for the human body to metabolize and store glucose, the body's main energy source. Without insulin to process glucose, the human body turns to the liver to convert fat into energy in a process that literally acidifies the blood, causing ketoacidosis. Therefore, many people with diabetes must rely on other people to manufacture insulin for them and are at the mercy of these insulin manufacturers not to bilk them or exploit their need.

In 1922, the inventors of insulin sold their patent to the University of Toronto for $1 so that inexpensive and life-sustaining insulin would be available to diabetics everywhere.[1] Forsaking these humble and altruistic beginnings, Defendants—the three largest manufacturers of insulin in the world, accounting for 96% of global market volume[2]—have deceptively and greedily overpriced their insulin products in a three-party race to curry favor from the Pharmacy Benefit Managers (PBMs) who control what medications insurance health plans will cover. Their prize is increasing and maintaining their market share, but it comes at the cost of lives.

[1] White, John R., Jr., "A Brief History of the Development of Diabetes Medications," *Diabetes Spectrum*, American Diabetes Association (May 2014) *available at:* http://spectrum.diabetesjournals.org/content/27/2/82.
[2] Gotham, Dzintars, et al., "Production costs and potential prices for biosimilars of human insulin and insulin analogues," p. 1, BMJ Global Health (July 27, 2018).

Over the last 20 years, Defendants have exponentially increased the list prices of their insulin products without relationship to any appreciable changes to the insulin products themselves. While the estimated manufacturing cost of most insulin ranges from $2.28 to $6.34 per vial, the average wholesale price of insulin is now almost $300. One such product, Novolog Flex Pen, manufactured and sold by Defendant Novo Nordisk, more than doubled in price from $255.74 per package in July 2012 to $558.83 per package in July 2018 without any appreciable change to the product. This constituted an increase of 218%. Defendant Sanofi's Apidra insulin for injection increased in price 311% from December 2010 to January 2019, while its Lantus insulin increased 285% in the same time frame. Defendant Eli Lilly's Humalog Pen increased from $235.80 per package in November 2011 to $530.40 per package in May 2017.

Now, after years of falsely reporting their prices and secretly negotiating with PBMs, Defendants have admitted their list prices are a "not so relevant" sham that it "was never their intention" for individual patients to pay, but rather were meant to help "aggressively negotiate" their unreported, *actual* prices. In the meantime, whether Defendants "intended" people to pay them, the "not so relevant" prices Defendants falsely disseminated determine the market, affecting prices paid by wholesalers, pharmacies, and—most unfortunately—uninsured and underinsured people with diabetes.

Defendants' exorbitant, inflated prices have forced uninsured and underinsured people with diabetes to ration their supplies or beg for money on websites like GoFundMe.com merely to survive—and some have not. Shane Patrick Boyle died $50 short of his GoFundMe campaign to pay for his insulin after he lost his pharmacy benefits.[3] Alec Raeshawn Smith died after trying to ration his insulin because he could not afford a $1,300 insulin refill.[4]

[3] Gagliardo-Silver, Victoria, "Insulin is a human right for me, all diabetics. We need to make medications free to those who need it." USA TODAY, August 13, 2018, *available at* https://www.usatoday.com/story/opinion/voices/2018/08/13/insulin-human-right-me-all-diabetics-column/936679002/

[4] Schwers, Kaitlin, "He could afford insurance or insulin meds, and he died. His mom is speaking out." THE KANSAS CITY STAR., May 16, 2018. *available at* https://www.kansascity.com/news/nation-world/article211260394.html

As public outcry has grown louder, Defendants now claim to want to provide lower-cost "authorized generics"[5] and other alternatives[6] to help uninsured and underinsured people with diabetes bear the cost that Defendants still unapologetically and unconscionably place upon them, but only if such alternatives do not undercut Defendants' unjust profits. Defendants' acknowledgment of the harm and proposed solutions to a crisis *they created* come too little, too late. The Office of the Attorney General of Kentucky files this action against Defendants Novo Nordisk, Sanofi, and Eli Lilly to put an end to their deceptive and unconscionable pricing scheme and disgorge their unlawful profits.

I. INTRODUCTION

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

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

3. Hundreds of thousands of Kentuckians live with diabetes, a chronic condition that affects how their bodies produce or use insulin. In type 1 diabetes, the body does not produce sufficient insulin, and, in type 2 diabetes, the body is resistant to the insulin it produces.

4. Many Kentuckians must therefore regularly purchase and inject themselves with medicinal insulin to either supplement or replace their bodies' insulin, or they will die.

5. Defendants are the three largest insulin manufacturers in the world. Their products together account for 96% of the global market volume of insulin. Coupled with the vital importance

[5] Thomas Mulier, "Eli Lilly & Co. offers half-price insulin in counter to cost pressure," BLOOMBERG NEWS, March 4, 2019, *available at* https://www.bostonglobe.com/business/2019/03/04/lilly-offers-half-price-insulin-counter-cost-pressure/kmIfuIXELKY8Zwd3qidegL/story.html.

[6] "Our perspectives on pricing and affordability," Novo Nordisk US, Nov. 30, 2016, *available at* http://www.novonordisk-us.com/blog/perspectives/2016/november/our_perspectives.html.

of the insulin they produce, Defendants' oligopolistic market share grants them virtually unfettered authority to set prices.

6. This leaves Kentucky residents with diabetes at the Defendants' mercy as to how much they must regularly pay merely to stay alive, and Defendants have not been merciful.

7. Defendants set two different prices for their analog insulin products[7]: the "benchmark" or "list" price, and the "net" price. Defendants set the *list price*, which is published by price reporting services. Defendants negotiate the *net price* with pharmacy benefit managers ("PBMs") and do not publicly disclose it.

8. PBMs are companies that manage prescription drug benefits for health plans and self-insured employers. Defendants negotiate the net price of their insulin products with PBMs by beginning at the list price and then offering rebates to PBMs in exchange for the PBM including their insulin in their coverage. Ostensibly, these rebates are passed on to the PBM's health plan clients who then lower their members' or subscribers' out-of-pocket expenses. However, PBMs also retain a portion of these rebates.

9. The result of this scheme is that Defendants inflate their list prices in order to be able to offer greater rebates to PBMs without damaging their bottom line (*i.e.*, *net* price). Thus, rather than being a "benchmark," the list price is set as an opening offer to PBMs and has no bearing on the *actual* net price Defendants receive for insulin. Indeed, the CEO of Defendant Novo Nordisk admitted that the list prices are meant only to be a starting point for negotiations with PBMs and that "[i]t was never the intention that individual patients should end up paying the list price."[8]

10. However, individual patients *do* end up paying the list price or *dying* because they were unable to pay it. Defendants' cynical scheme has gravely harmed those patients whose payments for insulin are based on Defendants' deceptively advertised list prices. Those harmed

[7] Analog insulin is manufactured human insulin.
[8] James Paton, "Drug CEO Has Problem With U.S. Patients Paying His Prices," BLOOMBERG.COM, Mar. 14, 2017, *available at* https://www.bloomberg.com/news/articles/2017-03-14/drug-ceo-has-big-problem-with-u-s-patients-paying-his-prices.

include diabetic Kentuckians without insurance, with high-deductible health plans, who pay coinsurance, and who are Medicare Part D beneficiaries—all of whom have paid more for the vital, life-sustaining medication that Defendants manufacture and sell because of Defendants' unconscionable conduct.

II. PARTIES, JURISDICTION, AND VENUE

11. Plaintiff, the Commonwealth of Kentucky *ex rel*. Andy Beshear, Attorney General, is responsible for the enforcement and administration of Kentucky law, including the Kentucky Consumer Protection Act, KRS 367.110 *et seq.* (hereinafter "KCPA"). KRS 367.190 authorizes him to bring this action in the name of the Commonwealth of Kentucky, and he has determined it to be in the public interest to do so.

12. Defendant Novo Nordisk, Inc. is a foreign corporation organized under the laws of Delaware with a principal place of business located at 100 College Road West, Princeton, New Jersey 08540.

13. Defendant Sanofi-Aventis U.S. LLC is a foreign corporation organized under the laws of Delaware with a principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

14. Defendant Eli Lilly and Company is a foreign corporation organized under the laws of Indiana with a principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285.

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

16. This Court has personal jurisdiction over Defendants pursuant to KRS 454.210 because each has regularly transacted and/or solicited business in the Commonwealth and/or

derived substantial revenue from goods used or consumed or services rendered in the Commonwealth and/or contracted to supply goods or services in the Commonwealth and/or caused injury by an act or omission in the Commonwealth and/or caused injury in the Commonwealth by an act or omission outside the Commonwealth.

17. Venue is proper in Franklin County pursuant to KRS 452.450 and 452.460 because Defendants' insulin is sold therein and injuries to consumers in the Commonwealth occurred in Franklin County and pursuant to KRS 367.190(1) because Defendants' unlawful methods, acts and/or practices were committed in Franklin County.

III. FACTS

18. Plaintiff adopts, reiterates, and realleges each previous allegation as if fully alleged herein.

19. According to the American Diabetes Association, approximately 567,000, or nearly 15.3% of Kentuckians, have diabetes. This places Kentucky among the ten highest state rates of diabetes in the United States.[9] Over 1,168,000 additional adults have blood glucose levels that are higher than normal, but not high enough to be diagnosed as diabetes. Every year, an additional 135,000 new cases of diabetes are diagnosed in Kentucky. As of 2014, according to the Center for Disease Control ("CDC"), Kentucky had the 14th highest diabetes mortality rate in the United States, and diabetes was the 6th leading cause of death by disease overall and 5th leading cause of death by disease for African Americans.[10]

20. Patients diagnosed with diabetes must cope with a rigorous and invasive treatment schedule. Many have to go through daily insulin injection therapy, constant monitoring of their blood glucose levels, and adherence to a strict diet.

21. Insulin injections are a necessary, *life-sustaining* part of the daily routine for many of those who have diabetes. Insulin allows a person's body to process glucose from carbohydrates in food. However, people diagnosed with type 1 diabetes are unable to make insulin and *require*

[9] "Diabetes in the United States," The State of Obesity, *available at* https://www.stateofobesity.org/diabetes/.
[10] *2018 Kentucky Diabetes Fact Sheet*, Kentucky Department of Public Health, *available at* https://madisoncountyhealthdept.org/Documents/Community/2018KYDiabetesFactSheet.pdf

insulin injections to allow their bodies to process glucose. People diagnosed with type 2 diabetes do not respond well or are resistant to the insulin their bodies produce, and often require insulin shots to overwhelm their resistance and help process glucose to prevent long-term complications from diabetes.

22. The therapeutic benefits of insulin were first discovered in 1922, when researchers used insulin from animals to provide treatment to diabetic patients.[11] To ensure insulin would be open and available to the public, the scientists who developed this method for insulin treatments sold their patent for $1 to the University of Toronto.[12]

23. Over time, scientists discovered ways to artificially produce human insulin and developed treatments that would last longer and improve the dosage strength of their insulin products.[13] By the mid-1990s, scientists had created man-made, or "analog," insulin, which could be adjusted to allow for different absorption times and more effective management of blood sugar.[14] Analog insulins now dominate the market and are the preferred treatment for both type 1 and type 2 diabetes patients.[15]

24. There are currently two types of analog insulin available, rapid-acting and long-acting. Defendants each manufacture both types under brands they own. Rapid-acting analog insulin is often administered immediately before meals and in conjunction with long-acting insulin administered daily.

25. Long-acting insulin begins working hours after injection and lasts approximately 24 hours. Only two long-acting insulins were available until recently: Lantus, manufactured by Defendant Sanofi; and Levemir, manufactured by Defendant Novo Nordisk. Over the last two

[11] Bliss, Michael, "The Discovery of Insulin", *The Canadian Encyclopedia,* August 19, 2015, *available at:* https://www.thecanadianencyclopedia.ca/en/article/the-discovery-of-insulin.
[12] "Sir Frederick Banting," Canadian Medical Hall of Fame, *available at* http://www.cdnmedhall.org/inductees/sir-frederick-banting
[13] White, John R., Jr., "A Brief History of the Development of Diabetes Medications," *Diabetes Spectrum*, American Diabetes Association (May 2014) *available at:* http://spectrum.diabetesjournals.org/content/27/2/82
[14] *Id.*
[15] "Human Insulin", University of California San Francisco Diabetes Education Online, *available at* https://dtc.ucsf.edu/types-of-diabetes/type1/treatment-of-type-1-diabetes/medications-and-therapies/type-1-insulin-therapy/types-of-insulin/human-insulin/

years, Defendants Sanofi and Novo Nordisk have developed two new branded long-acting insulins, and Defendant Eli Lilly has developed its own.[16]

26. Since 2008, Defendants have increased the list price of their analog insulin products at least 10 times. This has meant that the list price of a 10 mL vial of Lantus went from $99.35 in 2010 to $269.54 in 2017. Levemir similarly increased from $113.81 per vial in 2008 to $293.75 today.

27. These price increases are not tied to any meaningful change or improvement to Defendants' products. Instead, these price increases are tied to Defendants' cynical and deceptive pricing scheme, publishing list prices that they mean only to use as opening offers in negotiations with PBMs, and that they claim not to have "intended" individual patients pay.

28. However, many people with diabetes have to pay these exorbitant prices. In fact, these price spikes impact those least able to afford them: the uninsured, those with high-deductible health insurance, and elderly and disabled people operating on limited budgets. The resulting financial burden is substantial. In Kentucky, diabetic patients have medical expenses approximately 2.3 times greater than those without the disease, and total direct medical expenses for people diagnosed with diabetes in Kentucky were an estimated $3.6 billion in 2017.[17]

29. Those patients that are unable to pay these high prices lose access to vital insulin products. Many patients are forced to ration the amount of insulin they take, or forgo insulin treatment altogether. According to one recent study, as many as one (1) in four (4) people with diabetes surveyed reported rationing the amount of insulin they used due to cost.[18]

30. Patients who do not take the prescribed dose of insulin face increased risks of kidney failure, heart attacks, blindness, nerve damage, infection, amputation, and ketoacidosis. They require more doctor visits, hospitalizations, and medications, further increasing their medical expenses.

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[16] *Id.*

[17] *The Burden of Diabetes in Kentucky*, American Diabetes Association, *available at* http://www.diabetes.org/assets/pdfs/advocacy/state-fact-sheets/kentucky-state-fact-sheet.pdf

[18] *Cost-related Insulin Underuse Among Patients with Diabetes*, JAMA Intern Med. 2019;179(1):112-114, Herkert, Vijayakumar, Luo, *et al*

THE OUT-OF-POCKET COST OF INSULIN

31. If a patient does not have health insurance, they must pay the entire price for the medications they purchase. Pharmacies refer to the price they charge cash-paying customers as the "usual and customary charge" or "cash price." A pharmacy's cash price for insulin is directly connected to the Defendants' *list* prices for insulin.

32. If the patient has health insurance, both the patient and their health plan may partially reimburse a pharmacy for insulin. The patient's share of the reimbursement may be a flat fee, known as a "co-pay," or a percentage of the drug's list price, known as "coinsurance." As a percentage of the drug's list price, coinsurance is a function of the list price.

33. The patient's health plan's share of the fee paid to the pharmacy is based upon its contract with the pharmacy, or its PBM's contract with the pharmacy for a net price. Patients indirectly subsidize the health plan's share by paying monthly premiums to their health plan in exchange for coverage.

34. Many patients' health plans have an annual deductible. Such plans do not provide any contribution toward the patients' pharmaceutical costs until they have paid the amount of their deductible out-of-pocket.[19] During the deductible period, patients pay cash price for their insulin. Once the patient has satisfied their deductible, the health plan will generally pay the remainder of the consumer's medical costs, minus a copay or coinsurance amount. High-deductible plans generally have lower premiums the insured and/or their employer must pay. Increasingly, employers and individuals have turned to high-deductible plans to offset the rising costs of insurance premiums. Average employer-supplied insurance deductibles in Kentucky doubled between 2006 and 2014, and more than one-third of Kentucky workers were enrolled in high-deductible plans by 2014.[20] Over 180,000 Kentucky residents are now covered by high-deductible plans, according to a survey by America's Health Insurance Plans.

[19] "Health Savings Accounts Grow as Valuable Financial Planning Tools," AHIP, April 12, 2018, *available at https://www.ahip.org/wp-content/uploads/2018/04/HSA_Report_4.12.18.pdf*.
[20] "High-Deductible Health Insurance in Kentucky" Healthy Kentucky Foundation, *available at* https://www.healthy-ky.org/res/images/resources/KY-high-deductible-brief-Final-Combined.pdf

35. If a patient has Medicare Part D, they may have a deductible during which they are subject to the "cash price." The patient may also have coinsurance, which is subject to list price. Unique to Medicare Part D beneficiaries, their coverage has a "gap" or "donut hole" when their prescription costs reach $3,820 that lasts until their out of pocket costs reach $5,100. During this time, they will pay a co-insurance of 25% for brand name insulin that is subject to list price. Medicare Part D beneficiaries meet reach their coverage gap faster and pay more during the coverage gap as a function of Defendants' false list prices.

36. Each of these patients are affected by Defendants' pricing scheme, because each of these patients must either pay the list price or pay a copayment based upon the list price.

DEFENDANTS' DECEPTIVE PRICES

37. Drug manufacturers, including Defendants, generally set a price for their products, referred to as the Wholesale Acquisition Cost ("WAC"). The WAC—also called the "list" price—is the approximate price at which a manufacturer sells a drug to a wholesale drug distributor.[21] Importantly, the WAC does not include any rebates or other discounts that the manufacturer provides to a PBM regarding the drug.

38. Defendants disseminate and publish list prices they set for their products, including insulin, with reporting services for further public dissemination. These reporting services make no independent effort to verify the price that any entity actually receives for the products, and instead rely solely on Defendants' representations about the price. Defendants know, however, that many other entities rely on the published list prices to set their own prices.

39. For instance, wholesale drug distributors typically mark up the WAC before they sell the products to pharmacies. This establishes the Average Wholesale Price ("AWP"), which is usually 20% or 25% over the WAC. In other words, the AWP is a mathematical function of the WAC, and the manufacturer setting the WAC effectively sets the AWP.

[21] Federal statute defines the WAC as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data." 42 U.S.C. 1395w-3a(c)(6)(B).

40. The "cash price"—also known as the "usual and customary price"—often charged by pharmacies, is also a function of the WAC.

41. As originally conceived, the AWP was intended to represent the average price at which drug wholesalers sell medications to pharmacies, physicians, and other customers. Today, however, the AWP is used primarily as the opening offer given to health plans (or their PBMs on their behalf) to reimburse pharmacies for prescriptions that they fill for plan members.

42. Defendants therefore set and publicly disseminate WAC/list prices knowing that they are used by PBMs, wholesalers, and pharmacies to set the prices they will charge when a Kentuckian with diabetes purchases Defendants' insulin. Accordingly, if Defendants raise their list prices, they know this will directly cause the prices paid by Kentucky patients to increase. This remains true regardless of any markups that wholesalers or pharmacies may add to the price, or any insurer's alteration of coinsurance amounts, because these list prices are the basis for the price charged during all subsequent sales of insulin.

43. Defendant Novo Nordisk admitted as much on its website's blog.[22]

PHARMACEUTICAL BENEFIT MANAGERS (PBMS)

44. PBMs create drug "formularies" for health plans. A drug formulary is a list of prescription drugs from which the health plan will reimburse pharmacies on behalf of the health plan's members. If a drug is not included on a formulary, the health plan generally will not cover it. If a doctor prescribes a drug to a patient that is not on the formulary, the patient must generally pay the entire cash price of the drug out-of-pocket.

45. For many years, PBMs included nearly all available drugs in their formularies. However, PBMs began to give particular manufacturers' drugs favorable or unfavorable treatment on their formularies, transforming PBMs into important drivers of demand for competing drugs made by different manufacturers—including Defendants' insulin products.

[22] "Our perspectives on pricing and affordability," Novo Nordisk US, Nov. 30, 2016, *available at* http://www.novonordisk-us.com/blog/perspectives/2016/november/our_perspectives.html.

46. Most PBM formularies now use a tiered structure for pharmaceuticals. A class of drugs on a formulary includes different drugs used to treat the same condition. Tier 1 drugs are generally considered "preferred" drugs and given a lower copayment or co-insurance payment for the insured patients. Patients are unlikely to use products if their health plan does not cover it or covers it at a higher co-pay or co-insurance cost. Thus, patients generally use the Tier 1 preferred drug in a class. Manufacturers sell more, and therefore earn more, when PBMs list their products as Tier 1 on their formularies.

47. Manufacturers, like Defendants, therefore bid to be the Tier 1 or preferred drug. They can bid by offering a lower net price or by offering a rebate to the PBM. Manufacturers generally bid a larger rebate to be the only Tier 1 or preferred drug for a class but may also bid a smaller rebate to be one of two Tier 1 or preferred drugs in a class. As a result, Defendants have an incentive to offer the best deals to PBMs for favorable formulary placement.

48. Manufacturer rebates are typically calculated by taking a percentage of the WAC list price and multiplying it by the number of health plan members' prescriptions purchased for the drug in a given time period. So, for example, if the drug had a list price of $100 and the manufacturer agreed to a 10% rebate, then the manufacturer would pay the PBM $10 for every health plan member prescription for the drug purchased during the relevant time period.

49. PBMs collect these rebates and retain some portion of them as compensation for their services, distributing whatever remains to their health plan clients.

50. To ensure favorable treatment by PBMs without having to reduce their net prices (*i.e.*, the price that Defendants receive for their products), Defendants increased their *list* prices so that the "spread" between their list price and their net price could be used to offer greater rebates.

51. Neither Defendants nor PBMs disclose the amount or nature of these rebates paid for favorable formulary placement, including to wholesalers and pharmacies. Instead, they treat this information as a "trade secret." In fact, even health plans often do not know the total rebate a PBM receives for a particular drug. Rather, they know the amount of the rebate passed along to them as well as the amount pharmacies are reimbursed for a given drug.

52. Under these circumstances, only the manufacturer and the PBM know the net sales price for any given drug. This price is concealed from wholesalers, pharmacies, health plans, and the public. The only prices publicly disseminated for Defendants' insulin products are the list prices.

DEFENDANTS HAVE EXPLOITED THE SYSTEM TO THEIR BENEFIT

53. The complex system by which health plans reimburse pharmacies through their PBMs and also receive a portion of any manufacturer rebate through their PBMs—with little, if any transparency into the manufacturer side of these arrangements—has resulted in a system that Defendants have exploited to their benefit.

54. Defendants' analog insulin products are largely interchangeable, and PBMs do not have to include each analog insulin product in their formularies. Typically, to satisfy their health plan clients' needs, PBMs must include one long-acting insulin and one rapid-acting insulin. Each Defendant manufactures at least one of each.

55. Defendants know that PBM revenue is based in part on the PBMs retaining a portion of the rebates Defendants pay them. Defendants know that PBMs are therefore likely to favor products on their formularies that will earn them the greatest revenue. Defendants thus focus their marketing and negotiating efforts with PBMs not on the publicly disclosed list price they set for their insulin product but rather on the amount of the *rebate*—or "spread" between Defendants' list price and the actual, net price—that the PBM can earn in exchange for including Defendants' products in the PBM's formularies.

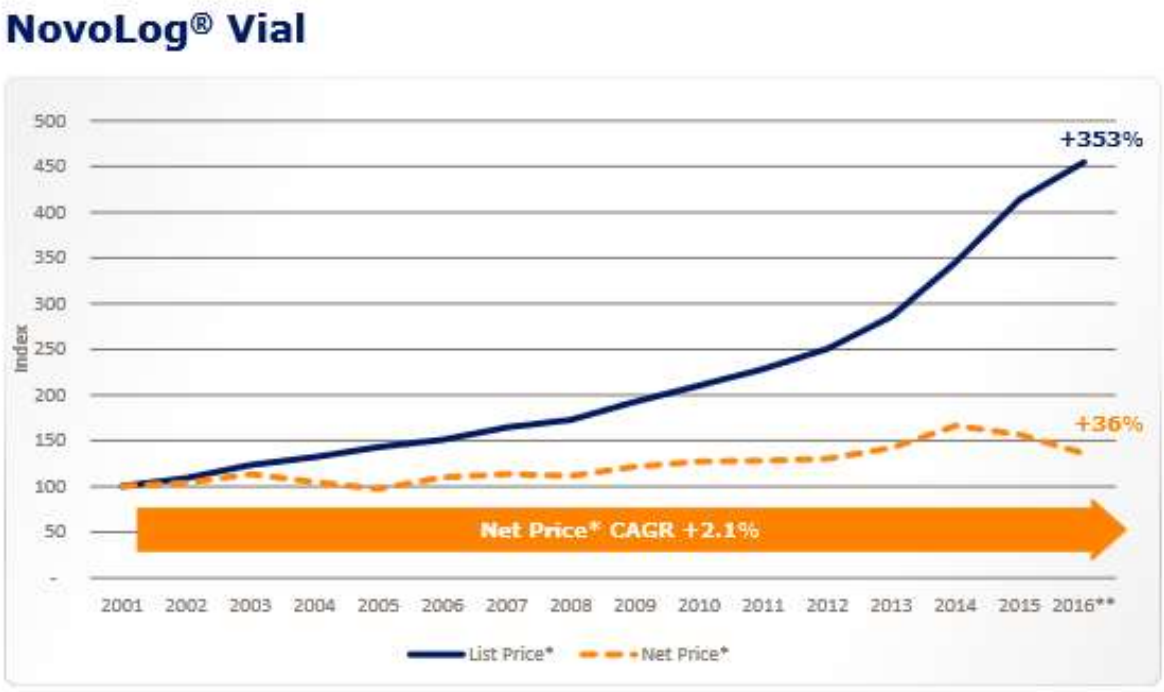
56. In order to increase their rebates without decreasing their *net* prices, Defendants have exponentially increased their *list* prices. Inflating their list prices increased the spread without affecting their net prices, permitting them to offer greater rebates to PBMs to maintain their net prices and preserve or increase their market share.

57. However, as Defendants' list prices increased with no relationship to the reality of Defendants' net prices, insulin has become less and less affordable for Kentucky patients for whom the prices they must pay are set based on list prices.

58. In response to scrutiny surrounding its drug prices, Novo Nordisk acknowledged that it inflates its list prices to protect its revenue. In a blog post on its website in November 2016, Novo Nordisk stated:

> For Novo Nordisk, those price increases were our response to changes in the healthcare system, including a greater focus on cost savings, and trying to keep up with inflation. PBMs and payers have been asking for greater savings—as they should. However, as the rebates, discounts, and price concessions got steeper, we were losing considerable revenue—revenue we use for R&D, sales and marketing, education, disease awareness activities, and medical information support. So we would continue to increase the list in an attempt to offset the increased rebates, discounts, and price concessions to maintain a profitable and sustainable business. We also monitored market conditions to ensure our prices were competitive with other medicines as part of our business model.[23]

59. Defendants have a 96% market share, with the associated power to raise their list prices at a rate ten times that of inflation without diminution of their market position. Defendant Novo Nordisk illustrated this in a chart on that same blog post:



[23] "Our perspectives on pricing and affordability," Novo Nordisk US, Nov. 30, 2016, *available at* http://www.novonordisk-us.com/blog/perspectives/2016/november/our_perspectives.html.

60. Likewise, Eli Lilly has also admitted that it increases list prices because "PBMs demand higher rebates in exchange for including the drug on their preferred drug lists."[24]

61. Despite these acknowledgements, Defendants continue to publish only their deceptive, misleading, and misrepresentative list prices.

62. Given Defendants' publication and public dissemination of their list prices, this is *not* merely a case of Defendants telling a potential buyer the price at which they are willing to sell their insulin products to that person. To the contrary, it is one where Defendants have falsely and deceptively represented to the patients, payers, and the public the price that they receive for their insulin products, and have done so knowing their misleadingly inflated pricing representations would be used to establish subsequent sale prices of their insulin products.

63. By publishing and disseminating deceptive and misleading list prices, marketing to PBMs the rebate they will earn from the sale of their products, and concealing their net prices from the public, Defendants have manufactured a marketplace where they do not have to compete with one another to set the lowest price. On the contrary, Defendants compete to offer the greatest rebates to PBMs, monitoring each other's list prices closely and increasing them in near perfect unison. Defendant Eli Lilly explained that Defendants need to monitor and match each other's list prices because they would otherwise be unable to offer the same rebates as their competitors.[25]

64. Industry observers refer to this trend as "shadow pricing." Defendants do this because they know that if a competitor raises its list prices, it can obtain greater market share by offering larger rebates to PBMs from those prices. Defendants therefore match each other's list prices so they can continue competing to offer the largest rebates without affecting the net prices of their products.

65. Today, the list prices for insulin that Defendants publish and disseminate—knowing that they will be used to set the prices charged to patients—have virtually no bearing on the price Defendants actually earn when they sell their products.

[24] Denise Roland & Peer Loftus, *Middlemen Fuel Insulin Price Rise*, WALL STREET JOURNAL, Oct. 10, 2016 at B1.
[25] Paul Barrett & Robert Langreth, *The Crazy Math Behind Drug Prices*, Bloomberg Businessweek, June 29, 2017, available at https://www.bloomberg.com/news/articles/2017-06-29/the-crazy-math-behind-drug-prices.

66. Sanofi's former chief CEO, Chris Viehbacher indicated on an October 28, 2014 earnings call that "pricing on the [WAC] basis" was "not so relevant" because it "largely followed what Levemir has done." In addition, when asked whether shadow pricing was indicative of collusion among Defendants, Defendant Eli Lilly did not even claim to compete on list prices, instead insisting it was "aggressively competing on net (or negotiated) price."[26]

67. Because of the deceptive pricing scheme that Defendants have perpetuated, the gap between their list and net prices has yawned to a chasm. The end result: the list prices that Defendants set and publish are now so removed from the actual, net prices that Defendants receive for their insulin that they are no longer an accurate approximation of the WAC that is the price which many Kentuckians must pay, and are thus falsely, deceptively, and misleadingly inflated, and unconscionable. And as prices increase, so does the suffering of these Kentuckians, who stand to lose their vision, their limbs, or even their lives to diabetes—an eminently treatable disease.

DEFENDANTS' DECEPTIVE PRICING SCHEME HARMS MOST THOSE WHO CANNOT AFFORD THEIR INSULIN

68. Since many patients lack insurance, pay coinsurance, or have to pay high deductibles before they receive pharmacy benefits of their insurance plans, Defendants' deceptive, inflated pricing causes a great deal of harm.

69. Pharmacies base the prices they charge to individual patients upon Defendants' inflated list prices, and the patients without insurance, with coinsurance, or with high deductibles—these most vulnerable patients—must pay all or at least a portion of an artificially inflated price for their life-sustaining insulin. Patients with diabetes do so without even being made aware of the fact that the list prices they must pay are dramatically and deceptively inflated.

70. However, patients cannot stop taking insulin without alarmingly increasing their risk of kidney failure, ketoacidosis, blindness, acute infection, heart disease, amputation, and death.

[26] CBS News, *Lawsuit accuses makers of conspiring to hike insulin prices* (Feb. 22, 2017), *available at* https://www.cbsnews.com/news/insulin-price-hike-lawsuit-accuses-drug-makers-of-conspiring/.

71. Approximately 5.4 % of Kentuckians had no health insurance in 2017 according to a 2018 U.S. Census report.[27] Without insurance, patients must pay the "cash price" pharmacies charge directly for medications. This usual and customary price is generally set based upon manufacturer's reported WAC. Pharmacies do not benefit from the rebates that PBMs negotiate, and do not pass any savings onto uninsured customers.

72. With high-deductible insurance, patients also often must pay the "cash price" pharmacies charge until their high deductible is met.

73. Even after the deductible is met, such plans often offer coinsurance, not a flat copayment for medication. With coinsurance, patients pay some percentage of the list price, without the benefit of the rebate offered to PBMs. Thus, patients continue to overpay as they are made to pay some percent of an artificially inflated list price the manufacturers do not even view as legitimate.

74. According to CMS, in 2017 671,437 Kentuckians were on Medicare with Part D coverage.[28] Medicare Part D beneficiaries are often subject to overpayment during their deductible and through coinsurance, but also during the "donut hole" of coverage, which they reach faster than they would in a competitive market and during which they spend more due to the inflated cash price.

75. Because Defendants compete based upon the spread, they can increase both their rebates and their list prices and hold their net prices relatively steady, preserving their own profit. If Defendants instead competed on price, the actual price of Defendants' products would be lower over time, saving all end purchasers money. However, Defendants' competition over which one can offer PBMs the biggest rebates from their list prices instead of competing on price itself is economically preferable to them because this makes it easier for Defendants to hold net prices for their insulin products relatively steady.

[27] "New Census Data Shows Progress On Health Insurance Coverage Has Stalled" BEREAONLINE.COM, Sept. 13, 2018, *available at* https://www.bereaonline.com/2018/09/new-census-data-shows-progress-on-health-insurance-coverage-has-stalled/

[28] *Id.*

76. Defendants' economic preference, therefore, is to maintain profits while the uninsured and underinsured continue to struggle to pay or watch their health deteriorate as their vital medication is priced farther and farther beyond their reach.

IV. TOLLING OF THE STATUTE OF LIMITATIONS

77. Plaintiff adopts, reiterates, and realleges each previous allegation as if fully alleged herein.

DISCOVERY RULE

78. Defendants published, or caused to be published, list prices for insulin that they knew to be inaccurate. Defendants knew that their reported list prices were not representative of the actual prices they receive for their insulin products after rebates they pay to PBMs. Defendants did not disclose the inflation of these rebates or their amount to Plaintiff.

79. Plaintiff had no way of knowing about Defendants' scheme. Indeed, the nature of Defendants' negotiations with PBMs precludes Plaintiff from discovering Defendants' scheme. No one but PBMs and Defendants knows what Defendants' real prices are, and they label these prices "trade secrets." Hence, through the exercise of reasonable diligence, a reasonable plaintiff and consumer could not discover them.

80. Plaintiff did not discover and did not know of facts that would have caused a reasonable person to suspect that Defendants were engaged in the scheme and were publishing deceptive list prices.

81. For these reasons, all applicable statutes of limitation have been tolled by operation of the discovery rule with respect to claims as to all insulin products for which Defendants falsely report list prices.

FRAUDULENT CONCEALMENT

82. Defendants knowingly, actively, and fraudulently concealed the facts alleged herein throughout the period relevant to this action.

83. Due to Defendants' fraudulent concealment of these facts, all applicable statutes of limitation have been tolled.

V. ALLEGATIONS

COUNT I

Violation of the Kentucky Consumer Protection Act (KRS 367.170)

84. Plaintiff adopts, reiterates, and realleges each previous allegation as if fully alleged herein.

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

86. KRS 367.170(2) provides that: "'unfair' shall be construed to mean unconscionable."

87. By engaging in the conduct described above, including, but not limited to, publishing and disseminating unconscionably and unreasonably inflated list prices for insulin, publishing and disseminating false and deceptive list prices for insulin, charging false and deceptive prices for insulin to uninsured and underinsured Kentuckians with diabetes, and concealing the actual price of insulin from uninsured and underinsured consumers purchasing insulin, Defendants have committed violations of KRS 367.170.

88. As a direct result of Defendants' violations of KRS 367.170, Defendants have caused damages to consumers in the Commonwealth, including, but not limited to, the charging and payment of grossly excessive prices for Defendants' insulin products.

COUNT II

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

89. Plaintiff adopts, reiterates, and realleges each previous allegation as if fully alleged herein.

90. KRS 517.030 provides that: "A person is guilty of false advertising when, in connection with the promotion of the sale of or to increase the consumption of property or services,

he knowingly makes or causes to be made a false or misleading statement in any advertisement address to the public or to a substantial number of persons."

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

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

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

COUNT III

Unjust Enrichment

94. Plaintiff adopts, reiterates, and realleges each previous allegation as if fully alleged herein.

95. Defendants have been unjustly enriched from the sales of deceptively priced insulin. Defendants received an unfair profit due to the artificially inflated list prices of their insulin. Defendants' actions caused Kentucky consumers, wholesalers, and pharmacies to overpay for their deceptively priced insulin.

96. The unjust benefit that Defendants received was at the expense of Kentucky consumers, on whose behalf Plaintiff is authorized to sue.

97. Defendants' behavior has allowed Defendants' to obtain unjust and unfair benefit from Kentucky consumers, which in turn has resulted in inequity.

98. Defendants concealed their deceit and fraud, and thus Kentucky consumers were not aware of the true value of Defendants' deceptively priced insulin and received no benefit from Defendants' transgressions.

99. Defendants knowingly accepted the unfair profits and benefits of their deceptive behavior.

100. Defendants' unjust enrichment should be disgorged and reimbursed to Kentucky consumers.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, Commonwealth of Kentucky, by counsel, Attorney General Andy Beshear, prays for Judgment against all Defendants as follows:

a) Declaring that Defendants committed repeated willful violations of KRS 367.170;

b) Declaring pursuant to KRS 446.070 that Defendants committed repeated violations of KRS 517.030;

c) Declaring that Defendants were unjustly enriched by their conduct;

d) Permanently enjoining Defendants and their employees, officers, directors, agents, successors, assigns, affiliates, merged or acquired predecessors, parent or controlling entities, subsidiaries, and any and all persons acting in concert or participation with Defendants from continuing their unlawful conduct, acts, and practices;

e) Awarding civil penalties of $2,000 for each willful violation of the Kentucky Consumer Protection Act pursuant to KRS 367.990(2);

f) Awarding civil penalties of $10,000 for each violation of the Kentucky Consumer Protection Act pursuant to KRS 367.990(2), where Defendants' conduct was directed at a person aged sixty (60) years of age or older;

g) Disgorging Defendants' unjust profits pursuant to KRS 367.200;

h) Awarding punitive damages against Defendants pursuant to KRS 411.184;

i) Awarding the Commonwealth of Kentucky its costs and attorneys' fees;

j) Awarding the Commonwealth of Kentucky prejudgment interest as permitted by law;

k) Awarding any other relief to which the Commonwealth of Kentucky is entitled or the Court deems appropriate and just.

Plaintiff demands trial by jury on all issues so triable.

Respectfully submitted,

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