United States Senate
Senate Finance Committee

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Ron Wyden, Ranking Member

Insulin:

Examining the Factors Driving the Rising Cost of a Century Old Drug

Staff Report

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I. Introduction

On January 22, 2019, Chairman Grassley and Ranking Member Wyden sent a letter to Sanofi, Eli Lilly, and Novo Nordisk requesting information relating to the process by which they price their insulin products.[1] A few months later, on April 2, 2019, Chairman Grassley and Ranking Member Wyden sent letters to CVS Caremark, OptumRx, and Express Scripts requesting information about how their role within the insulin market impacts the cost of insulin drugs.[2] These letters began the Chairman's and Ranking Member's insulin investigation. This investigation aimed to shed light on how drug manufacturers price insulin medication, the role played by pharmacy benefit managers (PBMs), and the financial and contractual relationships between these entities.

Relatively little is publicly known about these financial relationships and the impact they have on insulin costs borne by consumers, even though PBMs play a major role in the drug supply and payment chain by negotiating drug rebates and discounts with manufacturers and managing drug benefits for health care payers, including private insurers, employers, and entities that provide coverage under Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). The Senate Finance Committee has jurisdiction over these Federal health care programs and thus has an obligation to inform other members of Congress and the public of these interactions and how they affect drug prices.

This investigation builds on work that Chairman Grassley and Ranking Member Wyden have conducted in recent years to shed light into the prescription drug supply chain, and their joint and individual efforts to bring accountability to those responsible for rising drug prices.[3] For almost two years, investigative staff reviewed more than 100,000 pages of internal company documents produced by Sanofi, Novo Nordisk, Eli Lilly, CVS Caremark, Express Scripts,

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[1] Press release, Grassley, Wyden Launch Bipartisan Investigation into Insulin Prices (Feb. 22, 2019), https://www.grassley.senate.gov/news/news-releases/grassley-wyden-launch-bipartisan-investigation-insulin-prices.

[2] Press release, Grassley, Wyden Question Role of Middlemen in Skyrocketing Insulin Prices (Apr. 2, 2019), https://www.grassley.senate.gov/news/news-releases/grassley-wyden-question-role-middlemen-skyrocketing-insulin-prices.

[3] In 2015, Ranking Member Wyden and Senator Grassley, who was then-Chairman of the Senate Judiciary Committee, released the findings of an 18-month long investigation into the pricing of Sovaldi and Harvoni, new "blockbuster" hepatitis C therapies whose price caused an international uproar. *See* Press release, Wyden-Grassley Solvaldi Investigation Finds Revenue-Driven Pricing Strategy Behind $84,000 Hepatitis Drug (Dec. 2015), https://www.finance.senate.gov/ranking-members-news/wyden-grassley-sovaldi-investigation-finds-revenue-driven-pricing-strategy-behind-84-000-hepatitis-drug. In 2018, Ranking Member Wyden released a report detailing a year-long Minority staff investigation that used public documents to explain the path that a prescription drug takes from the lab bench to the medicine cabinet or doctor's office. *See* Press Release, Wyden Releases Report on High Drug Prices in Medicare (June 2018), https://www.finance.senate.gov/ranking-members-news/wyden-releases-report-on-high-drug-prices-in-medicare. In 2019, the Senate Finance Committee held three hearings on drug pricing, bringing executives from drug companies and PBMs to testify before Congress and released the Prescription Drug Price Reduction Act (PDPRA) of 2019 in an effort to shed light on drug manufacturers pricing practices and bring down drug costs for seniors. In 2020, Chairman Grassley and Ranking Member Wyden released a bipartisan report to Finance Committee colleagues detailing how opioid manufacturers use tax-exempt organizations as extensions of their sales and marketing strategy. *See* Press release, Grassley, Wyden Call for Greater Drug Industry Transparency in Report Exposing Opioid Makers' Ties to Tax-Exempt Groups (Dec. 2020), https://www.finance.senate.gov/chairmans-news/grassley-wyden-call-for-greater-drug-industry-transparency-in-report-exposing-opioid-makers-ties-to-tax-exempt-groups.

OptumRx as well as documents and data produced by the Centers for Medicare and Medicaid Services (CMS). Investigative staff also met with experts with knowledge of the United States' drug pricing system and interviewed individuals within OptumRx and Express Scripts who have direct knowledge of how insulin is priced within their respective companies.

Information and documents collected during the course of this investigation suggest that a combination of factors contributed to consumers facing higher costs for insulin over the last 15 years. First and foremost, pharmaceutical manufacturers have complete control over setting the list price (the Wholesale Acquisition Cost (WAC)) for their products. This investigation found that manufacturers aggressively raised the WAC of their insulin products absent significant advances in the efficacy of the drugs.[4] These price increases appear to have been driven, in part, by tactics PBMs employed in the early 2010s. At that time, PBMs began to more aggressively pit manufacturers against each other by implementing formulary exclusions in the insulin therapeutic class, which effectively stopped manufacturers from reaching large blocks of patients. While insulin manufacturers had been increasing prices for their products prior to formulary exclusions being employed, this tactic appears to have been more effective in boosting the size of rebates than suppressing the upward march of WAC prices. As a result, pharmaceutical manufacturers continued to raise WAC prices aggressively—increases that were often closely timed with price changes made by competitors (a practice that has been referred to as "shadow pricing").

The Finance Committee found that drug manufacturers increased insulins' WAC in part to give them room to offer larger rebates to PBMs 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. In some cases, manufacturers appear to have been concerned that decreasing WAC prices would be viewed negatively by PBMs, since PBMs capture a portion of rebate revenue and are also paid administrative fees based on a percentage of WAC.

This report describes how Sanofi, Novo Nordisk, and Eli Lilly set the price for their insulin drugs and how those decisions were affected not only by their competitors' pricing decisions, but also by their perceived need to offer large rebates, discounts, and other fees to PBMs such as CVS Caremark, OptumRx and Express Scripts and other payers. In addition, this report also discusses and analyzes the financial and budgetary impacts of insulin on both private and public payers, including Medicare and Medicaid. Lastly, this report discusses and analyzes rebate agreements executed between manufacturers and PBMs, and seeks to shed light on the role PBMs play in the U.S. drug pricing system.

[4] Insulin manufacturers appear to focus their R&D efforts on new insulin-related devices, equipment, and other mechanical parts which are separate from insulin's formulation. For example, in response to the Committee's request for information, Sanofi listed all patents received by the company since January 1, 2014. Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019). Most, if not all, of these are patents for pen-type injectors or drive mechanisms used in drug delivery devices. (Sanofi's patent on insulin expired in 2014, paving the way for others to utilize Sanofi's insulin glargine formulation). This suggests that manufacturers' R&D spending is primarily focused on insulin-related devices, rather than insulin itself.

II. Key Findings

1. **The WAC prices of long- and short-acting insulins have risen steeply.** Sanofi's long-acting insulin pens, Lantus SoloStar, increased from $303 in 2014 to $404 in 2019. The WAC price of Novo Nordisk's long-acting insulin pens, Levemir FlexTouch, increased from $303 in May 2014 to approximately $462 in January 2019, representing an increase of $159—or 52%— in a little more than five years. Eli Lilly's rapid-acting insulin, Humalog 50-50 Kwikpen, had a WAC of $530 in 2017 compared to $323 in 2013—an increase of $207 or 64% in four years. Sanofi's rapid-acting insulin, Apidra Solostar, also increased—from $302 in 2014 to $521 in 2019—while Novo Nordisk's rapid-acting insulin, Novolog FlexPen, rose from $324 in 2013 to $558 in 2018, representing a more than 70% WAC price hike for both companies during this time period.

2. **Spending on insulin products has increased significantly for the Medicare program and its beneficiaries.** Based on data collected from CMS, annual spending on insulin has increased by billions of dollars over the last decade. Between 2010 and 2018, Medicare Part D spent $78.4 billion on insulin, prior to rebates, the majority of which was spent on Lantus ($27.4 billion), Novolog ($16.5 billion), Humalog ($12.3 billion), and Levemir ($11 billion). The growth of CMS's pre-rebate spending on insulin also significantly outstripped the growth rate of beneficiaries utilizing insulin from 2010 to 2018. For instance, the number of Part D beneficiaries using insulin increased 51%, from over 2.1 million in 2010 to approximately 3.2 million in 2017, whereas spending on insulin prior to rebates increased more than 470%, from over $3 billion in 2010 to roughly $14.3 billion in 2018.

3. **Sanofi aggressively increased its list price between 2012 and 2014 in response to market pressure and competition.** From 2001 to 2012, Sanofi increased list price as much as 18% annually, raising its price from $34 to $131 by the end of 2012. However, in 2013 and 2014, Sanofi embarked on much more aggressive increases, nearly doubling the drug's WAC to $248 by the end of 2014. Internal documents suggest that Sanofi did this for three reasons: (1) to lock in price increases in advance of introducing a new insulin product called Toujeo and anticipated market competition from Eli Lilly, (2) to respond to aggressive rebate and discount activity from Novo Nordisk, and (3) to respond to increased pressure from PBMs and payers to offer large rebates and discounts.

4. **Novo Nordisk repeatedly tracked Sanofi's price increases in a practice known as "shadow pricing."** Rather than seeking to undercut its competitors' pricing, from 2014 on Novo Nordisk engaged in a cat-and-mouse strategy of pricing that followed Sanofi's price increases closely, sometimes mirroring them within days or even hours. In 2015, Novo Nordisk changed its pricing strategy in advance of launching Tresiba, its next generation basal insulin (also known as long-acting insulin). Instead of following Sanofi, it led with a list price increase in order to set a high basal insulin price floor from which to launch Tresiba's initial list price. However, in 2017 and

2018, Novo Nordisk resumed increasing its list price to respond to Sanofi's pricing actions. According to internal memoranda, on October 1, 2017, Sanofi increased Lantus's list price by 3% and Toujeo's list price by 5.4%. Roughly three weeks later, Novo Nordisk recommended that the company make a 4% list price increase on January 1, 2018 in response to Sanofi, which was approved as recommended on November 3, 2017. Novo Nordisk would make at least one more list price increase in response to Sanofi in 2018.

5. **Novo Nordisk's board of directors voted down a proposed insulin price decrease due to financial downsides, risk of backlash from PBMs and payers, and expected pressure to take similar action on other products.** PBMs and payer backlash appeared to be of particular concern to Novo Nordisk. The company believed that its decision to decrease list price could upset payers, and that many in the drug supply chain (e.g., wholesaler distributors, PBMs, and health insurers) would be negatively impacted financially and could retaliate against Novo Nordisk.

6. **Insulin R&D spending was a fraction of manufacturers' revenue and sales and marketing expenses.** Eli Lilly reported spending $395 million on R&D costs for Humalog, Humulin, and Basaglar between 2014 and 2018, during which time the company spent nearly $1.5 billion on sales and marketing expenses for its insulins. These three drugs generated $22.4 billion in revenue during that period. Similarly, Sanofi reported net sales of nearly €31 billion (approximately $37 billion based on current currency conversion rates)[5] between 2014 and 2018 for its five insulin products, during which time the company reported spending $902 million on insulin R&D. Novo Nordisk failed to provide requested R&D spending information to the Committee.

7. **Rebates for insulins have increased exponentially since 2013.** In July 2013, Sanofi offered rebates between 2% and 4% for preferred placement on CVS Caremark's client's commercial formulary. Five years later, in 2018, Sanofi rebates were as high as 56% for preferred formulary placement. Similarly, in 2017, Novo Nordisk offered Express Scripts up to a 47% rebate for Levemir for preferred formulary placement on their client's commercial formulary compared to 25% in 2014.

8. **Manufacturers are retaining more revenue from insulin than in the 2000s.** Data and documents produced to the Committee show that the amount of revenue pharmaceutical manufacturers are retaining from insulin has risen. The increased revenue is taking place even as the net price—the revenue after rebates and discounts—has declined in recent years, although it appears to remain significantly higher than in the first decade of the 21st Century. For example, Eli Lilly reported that the average net price for Humalog KwikPen had declined slightly from $28 per pen in 2015 to $24 per pen in 2018, despite the WAC price nearly doubling during that same period. 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. An internal Sanofi presentation shows that while the average Lantus net price of $87.48 in 2016 was $32

[5] Sanofi reported net sales in Euros to the Securities and Exchange Commission.

lower than the drug's net price in 2014, it was roughly double the drug's net price of $46.92 in 2005.

9. **The three largest PBMs—CVS Caremark, Express Scripts, and OptumRx—command significant market power when negotiating rebates in comparison to smaller rivals.** PBMs and health plans with more bargaining power (i.e., those with more plan members) generally command higher rebates than those with less bargaining power (i.e., fewer members). For example, in 2014, Novo Nordisk offered WellPoint, the largest for-profit managed health care company with over 40 million members, a larger rebate (40.625%) for Novolin vials for preferred formulary placement as 1 of 2 manufacturers on their client's commercial formulary compared to North Carolina State Employees (27.625%). Similarly, Eli Lilly prepared widely divergent rebate bids within a few months of each other for Humulin and Humalog to a commercial health plan in Puerto Rico called SIS (22%), Cigna (45%-55% depending on formulary placement), a PBM in Puerto Rico called Abarca Health (up to 54%), and Optum's Part D business (68%).

10. **PBM contracting practices did little to discourage higher list prices for insulin.**

    a. **Exclusion lists.** When a drug is not included on a health plan's formulary, it is "excluded." Over the past decade, payers and PBMs have increased their use of formulary exclusion lists. Exclusion can have significant consequences for patients and manufacturers. For patients, if the drug is excluded, they are forced to either switch to a new product, which could affect adherence and health outcomes, or pay significantly more to stay on their preferred medication. For manufacturers, exclusion can result in significant financial loss and reduced market share. On the contrary, being the exclusive therapy on a formulary can also be advantageous for the manufacturer's market share and revenue, which incentivizes manufactures to offer larger discounts to maintain preferred status. This investigation found several instances where manufacturers increased their rebate offers significantly following the threat of exclusion. Furthermore, in instances when manufacturers considered decreasing the list price of their products, they ultimately decided against it in part because they believed PBMs and payers would react negatively to receiving smaller rebates and administrative fees by excluding their product.

    b. **Administrative Fees.** PBMs earn administrative fees from manufacturers each time a drug is dispensed at the pharmacy. Administrative fees vary by contract, ranging up to 5% of the WAC price for the insulin therapeutic class. These fees are a significant revenue stream for PBMs and likely act as a countervailing force against lower list prices—PBMs may be reluctant to push for lower WAC prices since it would reduce their administrative fee-based revenue. The Committee's investigation found several instances in which manufacturers decided against lowering their list price in fear of retaliation from PBMs and payers for this very reason.

c. **Price Protection.** In addition to rebates and administrative fees, PBMs negotiate contract terms in which payers receive an additional rebate when manufacturers increase their price beyond a certain percentage cap—referred to as price or inflation protection. Price protection terms vary from contract to contract. For example, they can cap the annual increase of a drug's WAC price increase (i.e. prior to rebates) or its net price (after rebates). The Committee found examples of annual price caps ranging from 0% to 12% in one contract alone. The Committee's investigation also found examples of manufacturers seeking to and succeeding in efforts to avoid paying these additional rebates by timing their WAC price increases to exploit the terms in PBM contracts.

III. Diabetes: The Disease and How It's Treated

Diabetes is among the most pervasive, deadly, and costly diseases in the United States. According to the Centers for Disease Control and Prevention (CDC), diabetes is the 7th leading cause of death in the U.S. and more than 34 million people in the country live with the disease.[6] Of these, 7.3 million adults were not even aware of, or reported, having diabetes.[7] The CDC also estimates that 88 million Americans have prediabetes, a health condition that can lead to type 2 diabetes.[8] Unfortunately, this trend does not appear to be slowing: the CDC estimates that 1.5 million Americans will be diagnosed with diabetes this year alone.[9]

The number of diabetes patients in the U.S. has grown steadily since 1958, when approximately 1.6 million people were diagnosed with the disease.[10] According to the International Diabetes Foundation, the U.S. has one of the highest per capita rates of diabetes in the world, and spends heavily on the disease in comparison to other countries.[11] Moreover, as the prevalence of diabetes continues to increase in the U.S., so does spending on the disease. According to the American Diabetes Association (ADA), the U.S. spent approximately $327 billion on diabetes in 2017, of which $237 billion represented direct health care expenditures related to the disease.[12] By comparison, the U.S. spent approximately $205 billion on diabetes in 2007 (in inflation-adjusted dollars).[13]

However, the disease burden of diabetes is not equally distributed in the United States. Diabetes has a major impact on Federal health care programs within the Finance Committee's jurisdiction, as well as the health and financial well-being of program enrollees. For instance, diabetes disproportionally impacts individuals enrolled in Federal health care programs, as the growth of diabetes is primarily among those 65 and older.[14] According to CMS, diabetes affects approximately 1 in 5 individuals enrolled in Medicare compared to about 1 in 10 in the general population.[15] Medicare beneficiaries with diabetes also "reported worse general health, more inpatient admissions, and higher out-of-pocket health care costs than those without diabetes."[16]

Diabetes prevalence also varies by geography, economic status, education level, and by ethnicity. Diabetes is significantly more prevalent in impoverished regions of the U.S. that have high rates of Medicaid enrollment such as Appalachia and the Mississippi Delta, as well as

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[6] CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL DIABETES STATISTICS REPORT (2020), https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.
[7] *Id.*
[8] *Id.*
[9] *Id. See also Statistics About Diabetes*, AMERICAN DIABETES ASSOCIATION (ADA), https://www.diabetes.org/resources/statistics/statistics-about-diabetes (last viewed Nov. 18, 2020).
[10] CENTERS FOR DISEASE CONTROL AND PREVENTION, LONG TERM TRENDS IN DIABETES (2017), https://www.cdc.gov/DIABETES/statistics/slides/long_term_trends.pdf.
[11] International Diabetes Foundation Atlas, Table 3.5, Table 3.23 (2019), https://www.diabetesatlas.org/upload/resources/material/20200302_133351_IDFATLAS9e-final-web.pdf.
[12] American Diabetes Association, *Economic Costs of Diabetes in the U.S. in 2017*, 41 DIABETES CARE 917 (May 2018), https://care.diabetesjournals.org/content/41/5/917.
[13] *Id.*
[14] *Id.*
[15] *Diabetes Occurrence, Costs, and Access to Care among Medicare Beneficiaries Aged 65 Years and Over*, CTRS. FOR MEDICARE AND MEDICAID (Sept. 2017), https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/MCBS/Downloads/Diabetes_DataBrief_2017.pdf.
[16] *Id.*

among people who are eligible for both Medicare and Medicaid (so called "dual eligible" beneficiaries).[17] Adults with less than a high school education are also more likely to be diagnosed with diabetes than those who have attained a high school education or greater.[18] Lastly, minority communities are also disproportionally affected by this disease, with American Indians, Hispanics, Black Americans, and Asian Americans representing more than 45% of those diagnosed with the disease,[19] despite these groups making up 39% of the U.S. population.[20] According to the CDC, 15.1% of American Indians, 12.7% of Hispanics, 12.1% of Black Americans, and 8% of Asian Americans have been diagnosed with diabetes.[21]

Rising insulin prices negatively impact Federal health care programs, private payers, and the health system as a whole, as payers bear the costs of inadequate treatment. (Proper glycemic control, achieved through medication use, can reduce health care costs of individual patients as well as hospital admissions.)[22] They also harm patient health by reducing access to this life-saving medication. Therefore, it is incredibly important for Congress to continue to study the root cause of diabetes and how the list price of insulin can serve as a barrier for diabetics to access the very medication that allows them to survive.

a. Diabetes: The Disease

Even though diabetes is the 7th leading cause of death in the U.S. (as of 2017), it is a treatable disease and has been for almost a century.[23] Prior to the discovery of insulin in 1921,

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[17] CTRS. FOR DISEASE CONTROL AND PREVENTION, DIABETES 2019 REPORT CARD (2019), https://www.cdc.gov/diabetes/pdfs/library/Diabetes-Report-Card-2019-508.pdf; CTRS. FOR MEDICARE AND MEDICAID SERVS., RACIAL AND ETHNIC DISPARITIES IN DIABETES PREVALENCE, SELF-MANAGEMENT, AND HEALTH OUTCOMES AMONG MEDICARE BENEFICIARIES (Mar. 2017), https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/information-products/data. *See also* Heather Landi, *Lessons Learned From the Mississippi Delta, Tackling Chronic Disease Through Remove Monitoring Technology*, HEALTHCARE INNOVATION (Oct. 3, 2016), https://www.hcinnovationgroup.com/population-health-management/.

[18] *Addressing Health Disparities in Diabetes*, CDC, https://www.cdc.gov/diabetes/disparities.html (last reviewed Apr. 15, 2019).

[19] CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL DIABETES STATISTICS REPORT (2020), https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.

[20] *Quick Facts*, U.S. CENSUS BUREAU, https://www.census.gov/quickfacts/fact/table/US/PST045219 (last viewed Nov. 16, 2020).

[21] *Addressing Health Disparities in Diabetes*, CDC, https://www.cdc.gov/diabetes/disparities.html (last reviewed Apr. 15, 2019).

[22] *Cost-effectiveness of Intensive Glycemic Control, Intensified Hypertension Control, and Serum Cholesterol Level Reduction for Type 2 Diabetes*, JAMA NETWORK (May 15, 2002), https://jamanetwork.com/journals/jama/fullarticle/194927; *Medicaid Eligibility Expansions May Address Gaps In Access To Diabetes Medications*, HEALTH AFFAIRS (Aug. 2018), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2018.0154.

[23] CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL DIABETES STATISTICS REPORT (2020), https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf. *See also The History of A Wonderful Thing We Call Insulin*, ADA (July 1, 2019), https://www.diabetes.org/blog/history-wonderful-thing-we-call-insulin. Despite being patented more than a century ago, insulin lacks a less expensive alternative in the United States that would introduce downward price pressure in the marketplace. In addition to list price and rebate dynamics discussed throughout this report, another reason for this situation is that insulin is a biologic—a product derived from living cells (e.g., plant, animal, human cells)—which makes it a complex drug molecule and difficult to manufacturer on a mass scale. For further reading, *see* Jeremy A. Greene & Kevin R. Riggs, *Why Is There No Generic Insulin? Historical Origins of a Modern Problem*, 372 N. ENG. J. MED. 1171 (2015). *See also What Are*

diabetes was difficult to manage, and was treated primarily with highly restrictive diets, which compromised immune systems, stunted growth, and could lead to death by starvation.[24] It wasn't until the late 19th and early 20th century that scientists began to understand the role that insulin and the pancreas play in diabetes.[25]

Diabetes occurs when the body cannot produce insulin (type 1) or use insulin properly (type 2), resulting in higher-than-normal levels of sugar in the bloodstream.[26] Insulin injections are the cornerstone of treatment for many people with diabetes, and patients depend on them to avoid severe health complications and death. The body uses carbohydrates, proteins and fats as sources of energy to function. Primarily, the body breaks down carbohydrates for energy, producing glucose.[27] As glucose levels rise in the bloodstream, the pancreas releases the hormone, insulin. Insulin moves glucose from the blood into the cells, where it can be used as a source of energy.[28] Without insulin, glucose accumulates in the blood stream leading to high blood sugar (or hyperglycemia).

More than 90% of people with diabetes are diagnosed with type 2.[29] Type 2 diabetes is a disease that can often be prevented and managed through diet and exercise.[30] However, if these interventions fail, medication is required for proper glycemic control. And, while this type of diabetes is often associated with older adults, children, teens, and young adults with obesity and other risk factors are also susceptible.[31] For type 2 diabetes, patients are treated with a variety of medications to manage their disease, most of which work by stimulating insulin production, improving the way the body absorbs sugar and uses insulin.[32] In contrast, Type 1 diabetes is an autoimmune endocrine disorder that can be diagnosed at any age, but more often presents in children, teens, and young adults.[33] Unlike Type 2 diabetes, Type 1 diabetes cannot be prevented

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"Biologics" Questions and Answers, FDA, https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers (last viewed Oct. 6, 2020).

[24] *The History of A Wonderful Thing We Call Insulin*, ADA (July 1, 2019), https://www.diabetes.org/blog/history-wonderful-thing-we-call-insulin.

[25] CONG. RES. SERV., INSULIN PRODUCTS AND THE COST OF DIABETES TREATMENT (Nov. 19, 2018), https://fas.org/sgp/crs/misc/IF11026.pdf. *See also* Jeremy A. Greene & Kevin R. Riggs, *Why Is There No Generic Insulin? Historical Origins of a Modern Problem*, 372 N. ENG. J. MED. 1171, 1171 (2015). *See also The History of A Wonderful Thing We Call Insulin*, ADA (July 1, 2019), https://www.diabetes.org/blog/history-wonderful-thing-we-call-insulin.

[26] *Diabetes, Symptoms & Causes*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/diabetes/symptoms-causes/syc-20371444 (last viewed Sept. 15, 2020).

[27] *Carbohydrates*, THE AMERICAN HEART ASSOCIATION https://www.heart.org/en/healthy-living/healthy-eating/eat-smart/nutrition-basics/carbohydrates (last reviewed Apr. 16, 2018).

[28] *Id.*

[29] Diabetes Fast Facts, CDC, https://www.cdc.gov/diabetes/basics/quick-facts.html (last viewed Nov. 16, 2020).

[30] *Type 2 Diabetes*, CDC, https://www.cdc.gov/diabetes/basics/type2.html (last reviewed May 30, 2019). *See also The Nutrition Source: Simple Steps to Preventing Diabetes*, HARVARD SCHOOL OF PUBLIC HEALTH, https://www.hsph.harvard.edu/nutritionsource/disease-prevention/diabetes-prevention/ (last viewed Nov. 11, 2020).

[31] *Type 2 Diabetes*, CDC, https://www.cdc.gov/diabetes/basics/type2.html (last reviewed Nov. 16, 2020).

[32] The most common of these medications is metformin, a drug that decreases the amount of sugar the liver makes and increases the body's sensitivity to insulin. Metformin is often the first medication prescribed to Type 2 diabetes patients, and is often combined with other diabetes medications. Metformin was the 4th most commonly prescribed prescription drug in 2019. Sarah Lewis, *The Top 50 Drugs Prescribed in the United States*, HEALTHGRADES (Sept. 5, 2019), https://www.healthgrades.com/right-care/patient-advocate/the-top-50-drugs-prescribed-in-the-united-states.

[33] *Type 1 Diabetes*, CDC, https://www.cdc.gov/diabetes/basics/type1.html (last reviewed Jan. 3, 2021).

and can only be treated with insulin, through multiple daily insulin injections or a continuous insulin pump.[34]

As noted above, Type 1 and Type 2 diabetic patients use a combination of short-acting, rapid-acting, intermediate-acting, and long-acting insulin analogs (e.g., Lantus, Levemir, Toujeo, Tresiba, and Basaglar) to control glucose levels.[35] Today, insulin analogs are widely prescribed by physicians and are the standard of care for people with type 1 diabetes. Insulin can also be one component of care for people with type 2 diabetes, even though insulin analogs are more expensive than other types of insulin.[36]

While type 1 and type 2 diabetes are different in some respects, these diseases share one commonality: significant health risks. If left untreated or under-treated, diabetes can lead to hyperglycemia, cardiovascular disease, kidney disease, blindness, and diabetic ketoacidosis—a build-up of acids in the blood—which may result in a coma or even death.[37] According to the CDC, in 2016, 1.7 million people with diabetes were hospitalized for major cardiovascular disease, such as heart disease or stroke, 188,000 were hospitalized for diabetic ketoacidosis, and 130,000 were hospitalized for lower-extremity amputation.[38] Recently, and as a result of the COVID-19 global pandemic, those with pre-existing conditions, like diabetes, face greater risks of disease complications than the general population.[39] Initial observations also suggest that COVID-19 may be linked to patients developing diabetes or experiencing metabolic complications related to existing diabetes.[40] In addition, diabetes deaths have also been above average in 2020, according to an analysis of estimates from the CDC.[41]

b. How the High Cost of Insulin Negatively Affects Individuals with Diabetes

Approximately 7.4 million Americans use insulin, of which about 1.4 million have type 1 diabetes.[42] However, high-list prices, health plan structures, and high out-of-pocket costs make it

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[34] *Id.*
[35] Cigna-SFC-00011177; Cigna-SFC-00011229.
[36] American Diabetes Association, *Pharmacological Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes*, 43 DIABETES CARE 98, 99 (Jan. 2020), https://care.diabetesjournals.org/content/43/Supplement_1/S98.
[37] *Hyperglycemia in diabetes*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/hyperglycemia/symptoms-causes/syc-20373631 (last viewed Nov. 16, 2020); *High blood sugar with type 1 diabetes*, UNIV. OF IOWA STEAD FAMILY CHILDREN'S HOSPITAL, https://www.uichildrens.org/health-library/high-blood-sugar-type-1-diabetes (last viewed Nov. 16, 2020).
[38] CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL DIABETES STATISTICS REPORT (2020), https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.
[39] *New-Onset Diabetes in COVID-19*, 383 N. ENG. J. MED. 789 (Aug. 2020), https://www.nejm.org/doi/10.1056/NEJMc2018688; Elizabeth Cooney, *Why people with diabetes are being hit so hard by COVID-19*, STAT NEWS (Oct. 1, 2020), https://www.statnews.com/2020/10/01/why-people-with-diabetes-are-being-hit-so-hard-by-covid-19/; Chad Terhune et al., *Why COVID-19 is killing U.S. diabetes patients at alarming rates*, Reuters (July 24, 2020), https://www.reuters.com/article/us-health-coronavirus-diabetes-insight/why-covid-19-is-killing-u-s-diabetes-patients-at-alarming-rates-idUSKCN24P1B4.
[40] *New-Onset Diabetes in COVID-19*, 383 N. ENG. J. MED. 789 (Aug. 2020), https://www.nejm.org/doi/10.1056/NEJMc2018688.
[41] Denise Lu, *2020 Was Especially Deadly. COVID Wasn't the Only Culprit*, N.Y. TIMES (Dec. 13, 2020), https://www.nytimes.com/interactive/2020/12/13/us/deaths-covid-other-causes.html.
[42] American Diabetes Association, *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, 44 DIABETES CARE 1, 2 (Jan. 2020),

more difficult for patients to adhere to their medications, resulting in avoidable complications and higher costs for the U.S. health care system overall.[43] An ADA working group recently noted that "people with high cost-sharing are less adherent to recommended dosing, which results in short- and long-term harm to their health," and further detailed issues that lead to insulin accessibility issues for diabetic patients:

> Formulary exclusions and frequent formulary changes increase financial costs for patients. In addition, patients are bearing more of the cost of medications because of high-deductible plans, increased use of coinsurance, growing number of formulary tiers, and fewer medications covered per tier . . . Since negotiated discounts or rebates are usually not passed directly to people with diabetes, their financial obligations for purchasing insulin are often based on the list price. Clearly, this varies depending on the type of insurance the person has and the type of insulin purchased . . . but specifically impacts those with a high deductible, those who have to pay coinsurance, or those who are in the Medicare Part D coverage gap. People without insurance are often required to pay list price for insulins.[44]

It has been reported that some patients even cross the border into Canada to purchase insulin at lower prices.[45] Some diabetes patients have also resorted to rationing, which can be particularly dangerous to the health of a diabetic and can lead to a variety of complications such as diabetic ketoacidosis—a complication that results in tens of thousands of hospitalizations annually—and can even lead to death.[46] A survey conducted at the Yale Diabetes Center in 2017 found that 1 in 4 people reported rationing their insulin due to financial reasons, contributing to negative health outcomes and poor glycemic control.[47] If this rate of rationing was applied on a national scale, as many as 1.6 million Americans may ration their medication because of cost—highlighting the urgent need to address insulin affordability.

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https://care.diabetesjournals.org/content/early/2018/05/03/dci18-0019. *See also* CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL DIABETES STATISTICS REPORT (2020), https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.

[43] American Diabetes Association, *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, 44 DIABETES CARE 1, 8 (Jan. 2020), https://care.diabetesjournals.org/content/early/2018/05/03/dci18-0019.

[44] *Id.*

[45] Emily Rauhala, *As the price of insulin soars, American's caravan to Canada for lifesaving medication*, WASH. POST (July 31, 2019), https://www.washingtonpost.com/world/the_americas/as-price-of-insulin-soars-americans-caravan-to-canada-for-lifesaving-medicine/.

[46] American Diabetes Association, *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, 44 DIABETES CARE 1, 8 (Jan. 2020), https://care.diabetesjournals.org/content/early/2018/05/03/dci18-0019. *See also Hyperglycemia in diabetes*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/hyperglycemia/symptoms-causes/syc-20373631 (last viewed Nov. 16, 2020). *See also* Tiffany Stanley, *Life, Death and Insulin, As the costs of lifesaving medication skyrockets, some desperate diabetics are rationing – and risking their lives. Was Alec Raeshawn Smith one of them?*, WASH. POST (Jan. 7, 2019), https://www.washingtonpost.com/news/magazine/wp/2019/01/07/feature/insulin-is-a-lifesaving-drug-but-it-has-become-intolerably-expensive-and-the-consequences-can-be-tragic/?utm_term=.7d6e15666caa&itid=lk_inline_manual_18.

[47] Darby Herkert, et al., *Cost-related Insulin Underuse Among Patients with Diabetes,* JAMA NETWORK (Jan. 2019), https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2717499.

The COVID-19 pandemic has further compounded these problems, as the loss of work and income has made it more difficult for individuals and families to afford their insulin medications.[48] Earlier this year, the ADA conducted a survey of 5,000 people with diabetes nationwide since the start of the pandemic.[49] The ADA found that about 1 in 3 people with diabetes who were employed prior to COVID-19 had lost some or all of their income—rates higher than the general population.[50] The survey also found that, "24% of people with diabetes have used savings, loans or money from stimulus checks to pay for diabetes care in the past three months."[51] A quarter of people with diabetes also reported that they turned to rationing to cut costs whereas others have resorted to underground networks of people who share extra insulin, often free of charge.[52]

While insulin is the focus of the Committee's investigation, it's important to remember that diabetics often have other comorbidities associated with their disease and take other medications to treat conditions such as heart disease, high cholesterol, and hypertension.[53] Often, a large portion of medical costs associated with diabetes is for related comorbidities. For example, in 2017, the ADA estimated that $37 billion in cardiovascular-related spending was associated with diabetes, stating that "the presence of diabetes is associated with greater use of health care services in general." [54] According to the Government Accountability Office (GAO), these services can include "periodic test for blood glucose, eye and foot exams, medical nutrition therapy, and diabetes education . . . [and] services, such as cholesterol tests, smoking cessation tests, smoking cessation services, and influenza immunizations."[55] Taken together, these drugs and preventative measures greatly increase health care costs for diabetic patients in comparison to people who live without the disease.

II. Examining the Flow of Goods and Money in the U.S. Pharmaceutical Supply Chain

The path a drug takes from the manufacturer to the patient is complex and involves multiple financial exchanges. This complexity is caused, in part, by the many different players in the drug supply chain, including drug manufacturers, wholesalers, pharmacies, health insurers, PBMs, employers, and the Federal government.[56] Each link in the supply chain affects the price

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[48] Serena Gordon, *Pandemic Means Financial Hardship for Many with Diabetes*, U.S. NEWS (Aug. 19, 2020), https://www.usnews.com/news/health-news/articles/2020-08-19/pandemic-means-financial-hardship-for-many-with-diabetes.

[49] *Diabetes and COVID-19: New Data Quantifies Extraordinary Challenges Faced by Americans with Diabetes During the Pandemic*, ADA, https://www.diabetes.org/sites/default/files/2020-07/7.29.2020_dQA-ADA%20Data%20Release.pdf.

[50] *Id.*

[51] *Id.*

[52] *Id. See also* Markian Hawryluk, *Not pandemic-proof: Insulin copay caps fall short, fueling underground exchanges*, PITTSBURGH POST-GAZETTE (Oct. 11, 2020), https://www.post-gazette.com/news/insight/2020/10/11/Not-pandemic-proof-Insulin-copay-caps-fall-short-fueling-underground-exchanges/stories/202010110029.

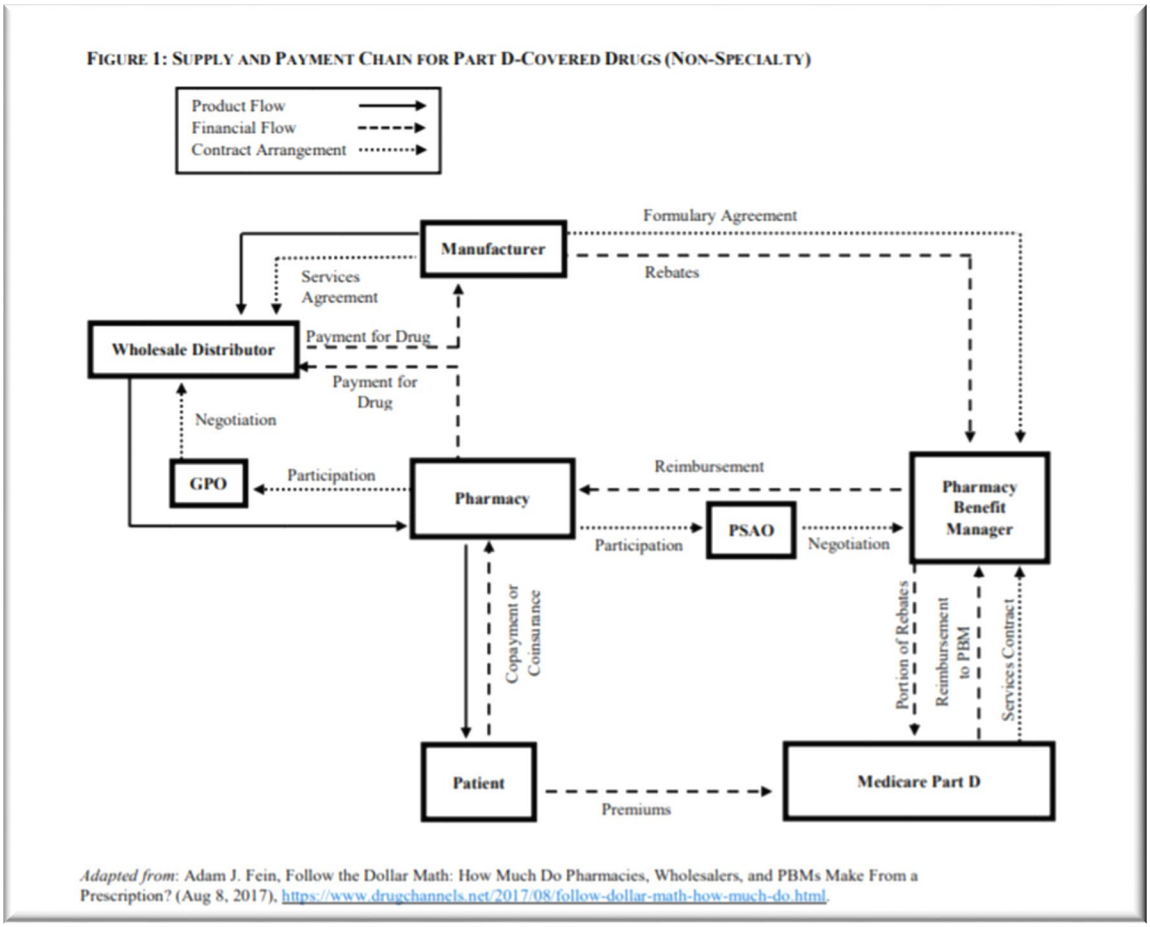
[53] American Diabetes Association, *Economic Costs of Diabetes in the U.S. in 2017*, 41 DIABETES CARE 917, 924 (May 2018), https://care.diabetesjournals.org/content/41/5/917.

[54] *Id.* at 927.

[55] GOV'T ACCOUNTABILITY OFF., MANAGING DIABETES, HEALTH PAN COVERAGE OF SERVICES AND SUPPLIES (Feb. 2005), https://www.gao.gov/new.items/d05210.pdf.

[56] Greg Brown, *The Insulin-Pricing Machine*, BEYOND TYPE 1 (June 18, 2018), https://beyondtype1.org/the-insulin-pricing-machine/.

the patient and payer eventually pays for the drug. This section will briefly explore how drugs are priced and the role of the various players in the drug supply chain.



a. Drug Manufacturers

There are two types of drug manufacturers—those that manufacture brand-name drugs and those that manufacture generic drugs.[57] While brand-name and generic manufacturers share similarities, "the branded drug business model requires very heavy investments in R&D and marketing [whereas] … the generic drug model requires particularly strong competence in manufacturing, channel management and patent litigation."[58] This report focuses on three brand-name insulin manufacturers: Sanofi, Novo Nordisk, and Eli Lilly. Therefore, it will not discuss generic manufacturers in depth. However, it's important to distinguish between these two business models because it affects the price manufacturers initially set for their product, known as the wholesale acquisition cost (WAC), which is colloquially known as the "list price."

Drug manufacturers are solely responsible for determining the WAC of their products. Internal documents produced to the Committee show that companies set their WAC price for insulin based on competitive considerations in the insulin market, maximizing revenue, and

[57] Samuel H. Kina and Marta Wosinska, *Pharmaceutical pricing*, IN HANDBOOK OF PRICING RESEARCH AND MARKETING 488, 490 (2009).
[58] *Id.*

maximizing market share. In response to the Committee, Sanofi asserted that R&D, marketing, and patent status factor into WAC.[59] However, documents produced to the Committee did not fully support the company's assertion. In fact, it appears that the only instance in which R&D costs appear to have been considered by one of the three manufacturers in relation to WAC price or rebate offers was when an Eli Lilly executive asked subordinates whether a requested bid from the Department of Veterans Affairs would result in too much of the company's manufacturing capacity being used for business that generated low margins.[60]

i. Research & Development, Sales & Marketing

1. Eli Lilly

During this investigation, the Committee requested that Sanofi, Novo Nordisk, and Eli Lilly "provide an itemized accounting of [insulin] R&D costs that breaks out costs by activity (e.g., basic research, clinical trials for marketing approval, post-marketing research and surveillance, etc.)" and "how each activity directly supports R&D for insulin products."[61] In response, Eli Lilly estimated that:

> [B]etween 2014 and 2018, it has spent approximately $244 million on research and development related to Humalog globally, $66 million on research and development related to Humulin globally, and $85 million on research and development related to Basaglar globally."[62]

However, this spending represents a fraction of the $22.4 billion in revenue Eli Lilly reported for these therapies during the same five-year period—$14.3 billion for Humalog, $6.8 billion for Humulin, and $1.3 billion for Basaglar.[63]

[59] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 29, 2019).
[60] LLY-SFCOM-UR-00003543, at LLY-SFC-UR-00003543-44.
[61] Letter from Senator Grassley and Senator Wyden to Lars Fruergaard Jorgensen, President and Chief Executive Officer, Novo Nordisk (Feb. 22, 2019).
[62] Letter from Reginald Brown, Counsel, WilmerHale, on Behalf of Eli Lilly, to Senator Grassley and Senator Wyden (Mar. 8, 2019).
[63] Revenue derived from Forms 10-K that Eli Lilly filed with the Securities and Exchange Commission for years 2014-2018. According to Eli Lilly, the company does not maintain net revenue at the NDC level on a consistent and audited basis. The company therefore produced gross revenue at the NDC level and net revenue at the consolidated product family level. *See* Letter from Reginald Brown, Counsel, WilmerHale, on Behalf of Eli Lilly, to Senator Grassley and Senator Wyden (Mar. 8, 2019). *See also* LLY-SFCOM-00000002. *Eli Lilly 10-k (2018)*, SEC, https://www.sec.gov/Archives/edgar/data/59478/000005947819000082/lly-20181231x10xk.htm; *Eli Lilly 10-k (2016)*, SEC, https://www.sec.gov/Archives/edgar/data/59478/000005947817000098/lly-20161231x10xk.htm.

Net Sales of Eli Lilly Insulin Products in Millions of Dollars (2014-2018)						
	2014	**2015**	**2016**	**2017**	**2018**	**Total**
Humalog	$2,785.2	$2,841.9	$2,768.8	$2,865.2	$2,996.5	**$14,257.6**
Humulin	$1,400.1	$1,348.3	$1,365.9	$1,335.4	$1,331.4	**$6,781.1**
Basaglar	--	$11.1	$86.1	$432.1	$801.2	**$1,330.5**
Total	**$4,185.3**	**$4,201.3**	**$4,220.8**	**$4,632.7**	**$5,129.1**	**$22,369.2**
Source: Eli Lilly Form 10-K, Securities and Exchange Commission						

Eli Lilly further explained that it could not provide a full breakdown of its R&D spending because "certain costs, such as local medical expenses and billable hours for training and administrative activities are not allocated by product."[64] R&D spending also represents a fraction of the money Eli Lilly spent on marketing the drugs. Eli Lilly reported spending nearly $1.5 billion on sales and marketing expenses on the drugs, which the company cautioned may not capture all such expenses.[65]

[64] Letter from Reginald Brown, Counsel, WilmerHale, on Behalf of Eli Lilly, to Senator Grassley and Senator Wyden (Mar. 8, 2019).

[65] LLY-SFCOM-00000045. Eli Lilly noted that "Marketing and Advertising expenses not tracked at SKU level (Pen, vial, Mixes, etc.) . . . For purposes of this report, all expenses shown at a consolidated 'Total Insulins' level . . . Certain marketing and advertising expenses incurred at Diabetes portfolio level (i.e., Requiring an allocation to the brands) are not included in this report." *Id.*

Sales Expenses for Eli Lilly Insulins (Humalog, Humulin, Basaglar), 2014-2018						
	2014	**2015**	**2016**	**2017**	**2018**	**Total**
Sales Force[1]	$136,086,445	$94,518,702	$83,835,211	$79,667,141	$87,511,840	**$481,619,340**
Market Research[2]	$8,672,584	$7,638,121	$7,147,827	$3,584,742	$2,799,660	**$29,842,934**
Samples[3]	$17,814,969	$12,817,014	$9,776,947	$8,399,706	$11,313,803	**$60,122,440**
3rd Party Vendors[4]	$61,909,679	$54,371,417	$89,351,175	$94,728,535	$82,725,285	**$383,086,091**
Medical Conference Sponsorships[5]	$227,961	$155,092	$47,512	$187,850	$37,172	**$655,587**
Other[6]	$4,874,300	$7,154,787	$6,645,130	$2,864,632	$2,514,864	**$24,053,713**
Total	**$229,585,940**	**$176,655,133**	**$196,803,802**	**$189,432,606**	**$186,902,624**	**$979,380,105**

Source: LLY-SFCOM-00000045; LLY-SFCOM-00002499.

[1] *Compensation and Benefits of Lilly Sales force for Humalog, Humulin, Basaglar. Includes meal, travel, meetings, etc.*

[2] *Includes IMS Health secondary (physician prescribing) data purchases, analytics charges.*

[3] *Includes cost of sample only, no distribution/packing costs.*

[4] *Digital Media, agency fees, patient support programs, etc.*

[5] *Exhibition fees for congress/conferences.*

[6] *Includes Compensation and Benefits of Lilly Marketing team.*

Marketing Expenses for Eli Lilly Insulins (Humalog, Humulin, Basaglar), 2014-2018						
	2014	**2015**	**2016**	**2017**	**2018**	**Total**
Consumer Marketing[1]	$22,286,002	$15,931,892	$21,679,235	$22,686,366	$23,371,480	**$105,954,975**
Prescriber Marketing[2]	$22,779,532	$15,279,295	$36,251,278	$44,687,503	$34,404,984	**$153,402,592**
Other[3]	$47,838,126	$49,391,585	$54,498,308	$38,566,312	$25,914,074	**$216,208,405**
Patient Support[4]	$595,834	$1,533,658	$539,770	$3,825,284	$15,700,246	**$22,194,793**
Total	**$93,499,494**	**$82,136,431**	**$112,968,591**	**$109,765,465**	**$99,390,784**	**$497,760,765**

Source: LLY-SFCOM-00002499.

[1] Consumer expenses reflect promotional activities designed to support patients initiating insulin treatment whom already received an insulin prescription from their Health Care Provider. Examples include branded paid search advertising and printed materials for patients. Also, included are unbranded disease state education digital content sponsored by LillyUSA, LLC. This may also include branded advertising presented alongside unbranded content. These expenses, including the unbranded content, are classified as promotional advertising by Eli Lilly & Co.

[2] Prescriber expenses reflect marketing programs designed to educate health care professionals prescribing insulin about Lilly products. These expenses include peer to peer programs (physicians educating other physicians) and Lilly's presence at medical conferences. Prescriber expenses do not include any costs for Lilly Sales force.

[3] Samples, Market Research, Analytics, Payer, Cover My Meds.

[4] Patient Support expenses reflect the operating expenses to administer insulin affordability programs. Expenses in this line do not include actual dollars spent on copay assistance (as such figures are accounted for as Gross to Net Sales adjustments in accordance with Generally Accepted Accounting Principles).

According to internal memoranda prepared for Eli Lilly's executive committee, in November 2016, the company assumed its "core insulins" would earn revenue of $3.3 billion in 2017 ($4 billion worldwide).[66] In order to achieve these results, Eli Lilly sought to improve its competitive position with respect to its key brands and planned to devote a majority of its R&D spending on clinical trials for existing Type 2 diabetes drugs—Jardiance,[67] Tranjenta,[68] and Trulicity[69]—the last of which was Eli Lilly's "largest growth driver."[70] Indeed, according to Eli Lilly, "Trulicity has been a catalyst . . . with growth driven by investments in [direct to consumer], sales force reach, and access."[71] These post-marketing clinical trials were intended to show that the therapy helped reduce incidence of cardiovascular disease which allowed Eli Lilly to seek an expansion of its FDA label indication.[72] However, even with these significant studies, the company's R&D spending for its entire diabetes franchise was budgeted to be just one-third of its sales, goods and administrative expenses, and, in fact, less than the cost of a single line item—Eli Lilly's global diabetes salesforce.[73] The following table details Eli Lilly's funded initiatives and sales force spending between 2017 and 2018.[74]

[66] LLY-SFCOM-UR-00006920; LLY-SFCOM-UR-00006921; LLY-SFCOM-UR-00006924, at LLY-SFCOM-UR-00006925.

[67] Press Release, Eli Lilly, Jardiance meets primary endpoint in reducing risk of cardiovascular death or hospitalization for heart failure in phase III clinical trial in adults with and without diabetes (July 2020), https://investor.lilly.com/news-releases/news-release-details/jardiancer-meets-primary-endpoint-reducing-risk-cardiovascular.

[68] Press Release, Eli Lilly, Boehringer Ingelheim and Lilly full results of Tradjenta's CARMELINA cardiovascular outcome trial (Oct. 4, 2018), https://investor.lilly.com/news-releases/news-release-details/boehringer-ingelheim-and-lilly-present-full-results-tradjentars.

[69] Press Release, Eli Lilly, Trulicity significantly reduced major cardiovascular events for broad range of people with type 2 diabetes (Jul. 9, 2019), https://investor.lilly.com/news-releases/news-release-details/trulicityr-dulaglutide-significantly-reduced-major.

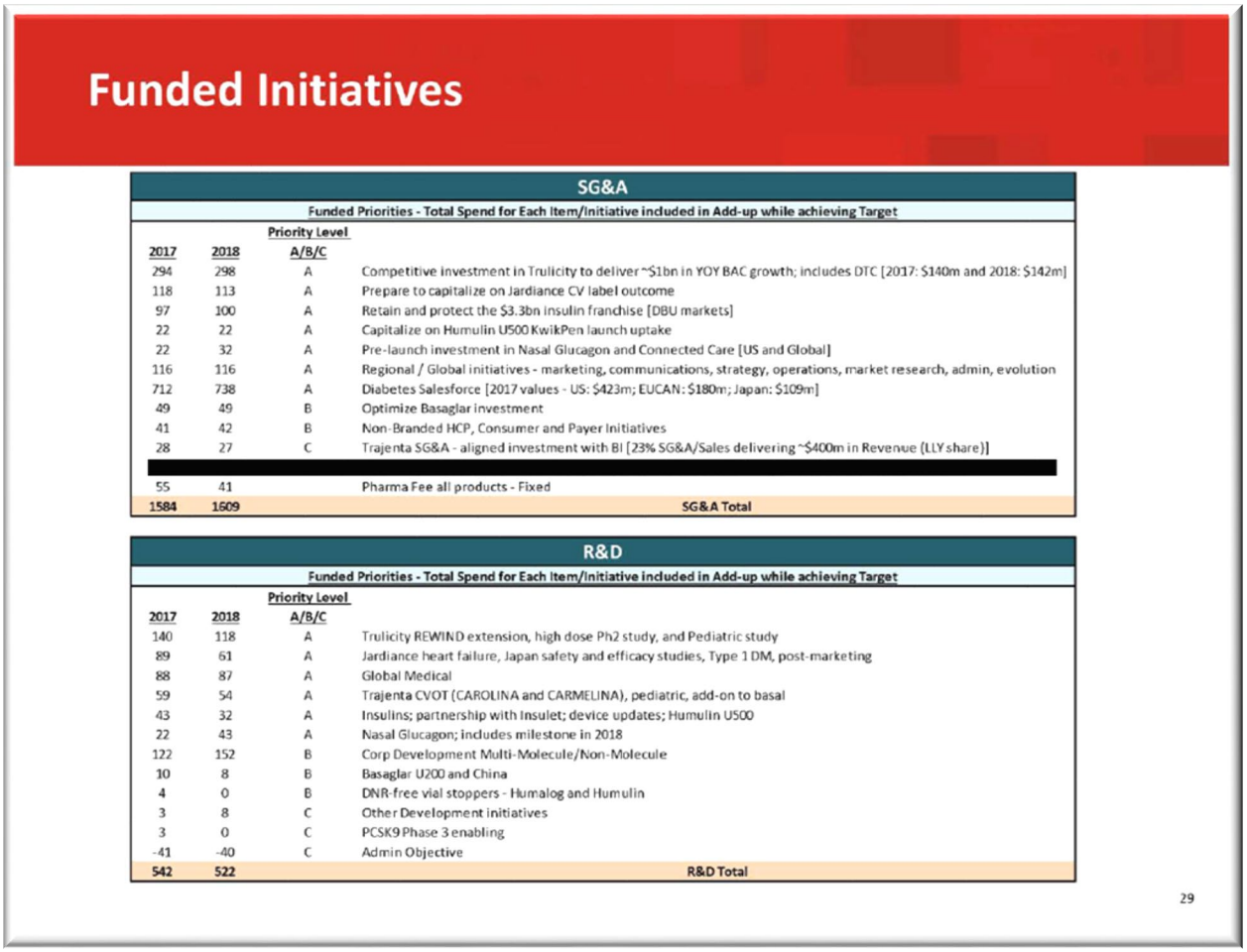
[70] LLY-SFCOM-UR-00006924, at LLY-SFCOM-UR-00006952.

[71] LLY-SFCOM-UR-00006921, at LLY-SFCOM-UR-00006922. Trulicity, Jaridance and Trajenta are marketed and manufactured in partnership with Boehringer Ingelheim.

[72] For example, in February 2020, Eli Lilly announced that the FDA approved Trulicity for the reduction of major adverse cardiovascular events in adults with type 2 diabetes. According to Eli Lilly, this new indication makes Trulicity the only type 2 medicine approved to reduce these risks. *See* Press Release, Eli Lilly, Trulicity is the first and only type 2 diabetes medicine approved to reduce cardiovascular events in adults with and without established cardiovascular disease (Feb. 21, 2020), https://investor.lilly.com/news-releases/news-release-details/trulicityr-dulaglutide-first-and-only-type-2-diabetes-medicine. LLY-SFCOM-UR-00006921; LLY-SFCOM-UR-00006924, at LLY-SFCOM-UR-00006952.

[73] LLY-SFCOM-00000045; LLY-SFCOM-00002499; LLY-SFCOM-UR-00006921; LLY-SFCOM-UR-00006924, at LLY-SFCOM-UR-00006952.

[74] LLY-SFCOM-UR-00006924, at LLY-SFCOM-UR-00006952.



Funded Initiatives

SG&A

Funded Priorities - Total Spend for Each Item/Initiative included in Add-up while achieving Target

2017	2018	Priority Level A/B/C	
294	298	A	Competitive investment in Trulicity to deliver ~$1bn in YOY BAC growth; includes DTC [2017: $140m and 2018: $142m]
118	113	A	Prepare to capitalize on Jardiance CV label outcome
97	100	A	Retain and protect the $3.3bn insulin franchise [DBU markets]
22	22	A	Capitalize on Humulin U500 KwikPen launch uptake
22	32	A	Pre-launch investment in Nasal Glucagon and Connected Care [US and Global]
116	116	A	Regional / Global initiatives - marketing, communications, strategy, operations, market research, admin, evolution
712	738	A	Diabetes Salesforce [2017 values - US: $423m; EUCAN: $180m; Japan: $109m]
49	49	B	Optimize Basaglar investment
41	42	B	Non-Branded HCP, Consumer and Payer Initiatives
28	27	C	Trajenta SG&A - aligned investment with BI [23% SG&A/Sales delivering ~$400m in Revenue (LLY share)]
[redacted]			
55	41		Pharma Fee all products - Fixed
1584	**1609**		**SG&A Total**

R&D

Funded Priorities - Total Spend for Each Item/Initiative included in Add-up while achieving Target

2017	2018	Priority Level A/B/C	
140	118	A	Trulicity REWIND extension, high dose Ph2 study, and Pediatric study
89	61	A	Jardiance heart failure, Japan safety and efficacy studies, Type 1 DM, post-marketing
88	87	A	Global Medical
59	54	A	Trajenta CVOT (CAROLINA and CARMELINA), pediatric, add-on to basal
43	32	A	Insulins; partnership with Insulet; device updates; Humulin U500
22	43	A	Nasal Glucagon; includes milestone in 2018
122	152	B	Corp Development Multi-Molecule/Non-Molecule
10	8	B	Basaglar U200 and China
4	0	B	DNR-free vial stoppers - Humalog and Humulin
3	8	C	Other Development initiatives
3	0	C	PCSK9 Phase 3 enabling
-41	-40	C	Admin Objective
542	**522**		**R&D Total**

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2. Sanofi

In response to the Committee's request, Sanofi estimated that it had invested approximately $4.5 billion in diabetes, which includes both insulin and non-insulin products, between 2012 and 2018, noting that it spent $800 million in 2018 on diabetes alone.[75] Sanofi only provided R&D product-specific data for 2014 to 2018, and limited the data to five insulin products.[76] Therefore, the Committee was unable to confirm Sanofi's total R&D spending on its diabetes franchises. However, R&D spending (which was reported to the Committee in dollars) on these five diabetes products accounted for a fraction of the company's reported revenue from its diabetes franchise, as reported to the U.S. Securities and Exchange Commission.[77] From 2014 to 2018, the company's diabetes franchise generated nearly €31 billion in net sales

[75] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019).
[76] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 29, 2019).
[77] *Id.* Sanofi produced data regarding gross sales, net sales, and gross units by product line, which is how Sanofi tracks this information. *Id.*

(approximately $37 billion based on current currency conversion rates), [78] whereas R&D spending for these five insulin products was approximately $902 million.[79]

Net Sales of Sanofi Diabetes Products in Millions of Euros (2014-2018)

	2014	2015	2016	2017	2018	Total
Admelog					€ 93	**€ 93**
Apidra	€ 336	€ 376	€ 367	€ 286	€ 357	**€ 1,722**
Lantus	€ 6,344	€ 6,390	€ 5,714	€ 4,761	€ 3,565	**€ 26,774**
Soliqua					€ 73	**€ 73**
Toujeo		€ 164	€ 649	€ 630	€ 840	**€ 2,283**
Total	**€ 6,680**	**€ 6,930**	**€ 6,730**	**€ 5,677**	**€ 4,928**	**€ 30,945**

Source: Securities and Exchange Commission. According to Sanofi, "[n]et sales comprise revenue from sales of pharmaceutical products, consumer healthcare products, active ingredients and vaccines, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities." (Sanofi, 20-F, 2019)

Sanofi R&D Spending by Product in Millions of Dollars (2014-2018)

	2014	2015	2016	2017	2018	Total
Admelog	$ 24.45	$ 54.53	$ 38.25	$ 11.26	$ 6.15	**$ 134.64**
Apidra	$ 2.31	$ 5.47	$ 3.64	$ 1.36	$ 1.04	**$ 13.82**
Lantus	$ 42.79	$ 21.95	$ 20.76	$ 16.44	$ 8.24	**$ 110.18**
Soliqua	$ -	$ 1.03	$ 40.94	$ 70.76	$ 68.74	**$ 181.47**
Toujeo	$ 67.53	$ 72.45	$ 150.25	$ 117.84	$ 54.43	**$ 462.50**
Total	**$ 137.08**	**$ 155.43**	**$ 253.84**	**$ 217.66**	**$ 138.60**	**$ 902.61**

Source: Letter to Senator Grassley and Senator Wyden from Jeffrey Handwerker, Counsel, Sanofi (March 29, 2019).

3. Novo Nordisk

Novo Nordisk failed to provide a detailed accounting of its R&D expenditures to the Committee. However, on its annual report submitted to the SEC, the company reported that it spent approximately 36 million Danish krone related to diabetes and obesity R&D between 2017 and 2019.[80]

b. Wholesale Distributors and Pharmacies

Drugs are purchased directly by wholesale distributors and delivered to a variety of customers, including pharmacies, physicians, hospitals, and other medical facilities. Wholesale distributors negotiate with drug manufacturers for discounts off a drug's list price, often referred

[78] Sanofi reported net sales in Euros to the Securities and Exchange Commission.
[79] *Id.*
[80] *See Novo Nordisk Annual Report 2019*, NOVO NORDISK at 52 (2019), https://www.novonordisk.com/content/dam/nncorp/global/en/annual-report/pdfs/2019/Novo-Nordisk-Annual-Report-2019.pdf.

to as the wholesale acquisition cost (WAC).[81] Examples of discounts include volume discounts, inventory claw backs, and prompt pay discounts. The wholesale distributor then sells the product to a pharmacy, hospital, or other medical facility at WAC plus some negotiated percentage.[82]

The outcome of these negotiations is critical to a drug's success because wholesale distributors help connect pharmacies, hospitals, and other medical facilities to drug manufacturers. However, over the past 30 years, the wholesale distribution industry has become highly consolidated. In 2018, the three largest wholesale distributors—AmerisourceBergen, McKesson, and Cardinal Health—covered 95% of the market.[83] This consolidation allows wholesale distributors to use aggressive disruption techniques to secure favorable agreements, such as the refusal to stock new product, reduce service levels on certain drugs, or ordering the slowdown of drug distribution in non-U.S. countries.[84]

At the pharmacy level, payers and PBMs reimburse pharmacies for the drugs they disburse to patients. However, payments vary.[85] For example, contracts typically set pharmacy reimbursement as the lesser of (1) the over-the-counter cash price, (2) the drug cost plus a dispensing fee, (3) the contractual rate, or (4) if a generic drug, the Maximum Allowable Cost (MAC) on a MAC list.[86] Insulin drugs are not included on MAC lists because it is regulated as a biologic and has no generic alternatives.

c. Health Insurance

In the United States today, a majority of Americans receive coverage through a private health insurer. Most of these Americans—about 158 million people, or 49% of the country—receive coverage through an employer, while a smaller portion—nearly 19 million people—receive private coverage directly from an insurer, including through the Affordable Care Act's (ACA) marketplaces.[87] The remaining insured population is generally divided between Medicaid and Medicare, which covered approximately 20% and 14% of the country, respectively, in 2019.[88] That same year, nearly 29 million nonelderly Americans were uninsured.[89] Notably, the COVID-19 pandemic has altered this coverage landscape as job losses and lost income led many Americans to seek coverage through Medicaid and the marketplace.[90] For the purposes of this

[81] Samuel H. Kina and Marta Wosinska, *Pharmaceutical pricing*, IN HANDBOOK OF PRICING RESEARCH AND MARKETING 488, 500 (2009).
[82] *Id.* at 500-01.
[83] Adam Fein, *The Big Three Wholesalers: Revenues and Channel Share Up, Profits Down*, DRUG CHANNELS (Oct. 2, 2019), https://www.drugchannels.net/2019/10/the-big-three-wholesalers-revenues-and.html.
[84] SANOFI_SFC_00013920.
[85] Samuel H. Kina and Marta Wosinska, *Pharmaceutical pricing*, IN HANDBOOK OF PRICING RESEARCH AND MARKETING 488, 502 (2009).
[86] ORX_Sen_Fin_0009800. *See also* Samuel H. Kina and Marta Wosinska, *Pharmaceutical pricing*, IN HANDBOOK OF PRICING RESEARCH AND MARKETING 488, 502 (2009).
[87] *Health Insurance Coverage of Total Population*, KFF https://www.kff.org/other/state-indicator/total-population/ (last viewed July 7, 2020).
[88] *Id.*
[89] Jennifer Tolbert and Kendal Orgera, *Key Facts About the Uninsured Population*, KFF (Nov. 6, 2020), https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/.
[90] M. Karpman and S. Zuckerman, *ACA Offers Protection as the COVID-19 Pandemic Erodes Employer Health Insurance Coverage*, URBAN INSTITUTE (Nov. 6, 2020), https://www.rwjf.org/en/library/research/2020/11/aca-offers-protection-as-the-covid-19-pandemic-erodes-employer-health-insurance-coverage.html.

discussion, we will provide a brief overview of how Medicare, Medicaid, and employer-sponsored insurance generally pays for insulin products.

i. Medicare Part D

Medicare provides optional prescription drug coverage through its Part D benefit, which is provided through private plans that are approved by the Federal government.[91] Beneficiaries can choose Medicare Part D stand-alone prescription drug plans (PDPs) or enroll in Medicare Advantage (MA-PD) plans that offer drug coverage in addition to all other Medicare benefits.[92] In 2020, over 75% of Medicare beneficiaries were enrolled in Part D plans.[93] PDPs and MA-PD plans must offer enrollees the *standard drug benefit* or alternative coverage that is the *actuarially equivalent* in value. Part D plan formularies must include a minimum of two chemically distinct drugs in each drug class and are required to cover all drugs in the six protected classes: immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics.[94]

The Part D standard drug benefit provides different levels of coverage and cost-sharing at different phases of the benefit. These phases include a deductible, an initial coverage phase, a coverage gap, and catastrophic coverage.[95] For 2020, the standard drug benefit included a $435 deductible and a 25% coinsurance until the enrollee and plan reached $4,020 in total drug spending.[96] After this point, the enrollee enters the coverage gap phase (also referred to as the *doughnut hole*) and continues to pay a 25% coinsurance for both brand-name and generic drugs. For brand-name drugs, manufacturers pay a 70% discount on the drug while the plan pays 5%.[97] Whereas, for generic drugs, the plan pays 75%.[98] Once the enrollee's out-of-pocket costs exceeded $6,350 (an estimated $9,719 in total spending by the plan and enrollee), they reach what is known as the catastrophic phase of the Medicare Part D benefit. In this phase, Medicare pays 80%, plans pay 15%, and the enrollee must pay the greater of 5% in coinsurance or $3.60 for a generic drug and $8.95 for a brand-name drug.[99] Updated coverage parameters for 2021 are reflected in the figure below.[100]

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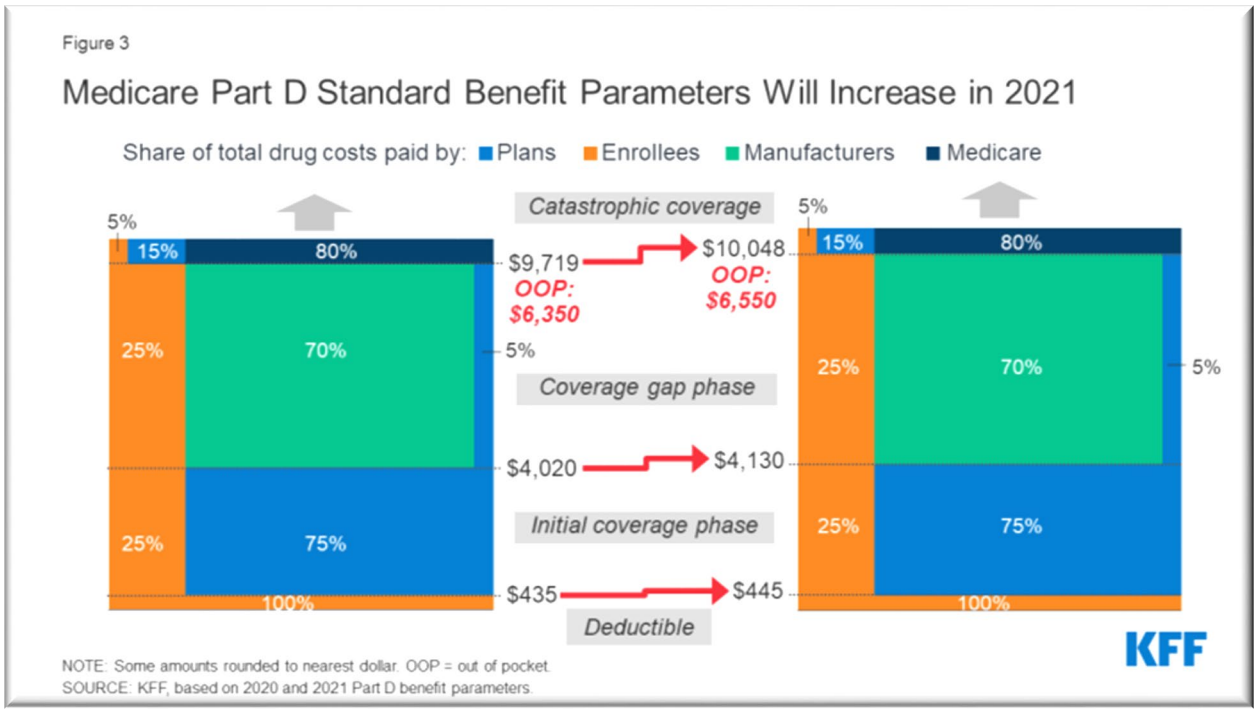
[91] CONG. RES. SERV., MEDICARE PRIMER, at 23 (May 21, 2020), https://fas.org/sgp/crs/misc/R40425.pdf.
[92] *An Overview of the Medicare Part D Prescription Drug Benefit,* KFF (Oct. 14, 2020), https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/.
[93] *Id.*
[94] *Id.*
[95] *Id.*
[96] CONG. RES. SERV., MEDICARE PRIMER, at 23 (May 21, 2020), https://fas.org/sgp/crs/misc/R40425.pdf.
[97] *Id.* at 23-24.
[98] *Id.*
[99] *Id.* at 24. *See An Overview of the Medicare Part D Prescription Drug Benefit*, KFF (Oct. 14, 2020), https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/.
[100] *An Overview of the Medicare Part D Prescription Drug Benefit*, KFF (Oct. 14, 2020), https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/.



In addition to paying nearly all drug costs above the catastrophic threshold of the standard drug benefit (*reinsurance*), Medicare also pays plans monthly *direct subsidies* to Part D plans for each enrollee. Every year, Part D plan sponsors submit bids to CMS estimating the cost to provide drug coverage to beneficiaries. The Federal government then pays Part D sponsors a risk-adjusted amount based on the nationwide average of all plan bids (*direct subsidies*).[101] In addition, Medicare also pays Part D plan sponsors an additional subsidy for providing drug benefits to low-income beneficiaries. For example, if a beneficiary is dual-eligible (meaning they qualify for both Medicare and Medicaid) or if they meet certain income benchmarks, Medicare pays additional subsidies to help cover the beneficiary's out-of-pocket costs, including premiums, deductibles, and lowered cost-sharing for prescriptions.[102] Dual-eligible beneficiaries and certain other low-income beneficiaries are also automatically enrolled in a PDP if they do not choose a plan on their own.[103]

According to the Congressional Budget Office (CBO), Medicare Part D spending will total $96 billion in 2021, or approximately 13% of total Medicare spending.[104] CBO further estimates that Part D spending will total $192 billion by 2030.[105] This dramatic rise in spending is due in part to the availability of more expensive drugs—many of which cost more than $7,500

[101] *Part D Payment System,* MedPAC (Oct. 2016), http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_16_partd_final.pdf?sfvrsn=0.
[102] CONG. RES. SERV., MEDICARE PRIMER, at 25 (May 21, 2020), https://fas.org/sgp/crs/misc/R40425.pdf
[103] *An Overview of the Medicare Part D Prescription Drug Benefit*, KFF (Oct. 14, 2020), https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/.
[104] *Id.*
[105] CONG. BUDGET. OFF., MEDICARE—CBO'S MAY 2020 BASELINE (Mar. 2020), https://www.cbo.gov/system/files/2020-03/51302-2020-03-medicare.pdf.

annually—causing the Federal government to pay higher reinsurance subsidies to plans.[106] Additionally, for Medicare beneficiaries, there is no cap on individual out-of-pocket spending, so individual costs can be quite high.[107] High costs can be especially problematic for people with diabetes who tend to have comorbidities, such as hypertension, obesity, or hyperlipidemia (or excess fat in the blood), and must use several drugs to stay healthy.[108]

ii. Medicaid Drug Rebate Program

Medicaid is a joint Federal-state program that provides health insurance coverage for low-income individuals and families. Though states are not required to cover prescription drugs, all state Medicaid programs currently provide this benefit.[109] Medicaid spending for prescription drugs is largely shaped by the Medicaid Drug Rebate Program (MDRP), which requires drug manufacturers to enter into rebate agreements with the Federal government in exchange for having nearly all of their drugs covered by the Medicaid program. Under the MDRP, for each drug administered to a Medicaid beneficiary, a manufacturer must provide a rebate to the state, which shares a portion of the drug rebate with the Federal government.[110] The formula for these rebates is set by statute and differs for generic and brand name drugs. For generic drugs, the rebate is 13% of the Average Manufacturer Price (AMP), which is the average price paid to drug manufacturers by wholesalers and pharmacies.[111] For brand name drugs, manufacturers pay 23.1% of the AMP or the difference between AMP and the "best price," whichever is greater.[112] The "best price" is defined as the lowest price at which the manufacturer sold a drug to any wholesaler, retailer, provider, or other entity within or outside of Medicaid, excluding certain government programs.[113] In this way, the best price requirement ensures that Medicaid receives the lowest price available *to any purchaser in any state* for a brand name drug.[114]

The MDRP plays a key role in reducing Federal and state spending on prescription drugs. In 2017, Medicaid spent approximately $64 billion on prescription drugs and collected more than half of that in rebates (nearly $35 billion), reducing net spending to just over $29 billion.[115] However, the MDRP also places some limits on states' ability to negotiate lower prices directly with manufacturers, which can increase Medicaid's exposure to new high-cost blockbuster drugs. For example, in the case of Sovaldi, Medicaid programs found themselves unable to extract additional, supplemental rebates from Gilead Sciences until the company was forced to offer more generous rebates in response to market competition in the therapeutic class. The high

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[106] Mike McCaughan, *Medicare Part D*, HEALTH AFFAIRS (Aug. 10, 2017), https://www.healthaffairs.org/do/10.1377/hpb20171008.000172/full/.
[107] *Id.*
[108] Helena Rodboard, et al., *Impact of type 2 diabetes mellitus on prescription medication burden and out-of-pocket healthcare expenses*, DIABETES RES. CLIN. PRACT. (Mar. 2010), https://pubmed.ncbi.nlm.nih.gov/20047768/.
[109] *Prescription Drugs*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/prescription-drugs/index.html (last viewed Dec. 29, 2020).
[110] *Understanding the Medicaid Prescription Drug Rebate Program,* KFF (Nov. 12, 2019), https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/.
[111] *Id.*
[112] *Id.*
[113] 42 U.S.C. § 1396r-8(c)(1)(C)(i).
[114] *Medicaid Payment for Outpatient Prescription Drugs*, MACPAC (May 2018), https://www.macpac.gov/wp-content/uploads/2015/09/Medicaid-Payment-for-Outpatient-Prescription-Drugs.pdf.
[115] *Medicaid Drug Spending Trends*, MACPAC (Feb. 2019), https://www.macpac.gov/wp-content/uploads/2019/02/Medicaid-Drug-Spending-Trends.pdf.

cost of Sovaldi initially led some states to restrict access to the drug to the sickest patients, reducing access to program beneficiaries.[116] Furthermore, as will be discussed below, the MDRP may influence drug spending outside of Medicaid by leading some drug manufacturers to inflate their launch prices and avoid setting new and lower "best prices" for their products.[117]

iii. Employer-sponsored health insurance

Collectively, employers are another major payer of prescription drugs. Employer-sponsored health insurance is health coverage offered by employers to employees, and sometimes their dependents, as a benefit of employment. Nearly all covered workers have prescription drug coverage through their plans.[118] However, many enrollees can still face significant cost-sharing in the form of high deductibles or coinsurance.[119] Approximately 30% of adults with employer-sponsored plans are enrolled in high-deductible-health-plans (HDHP).[120] In 2021, HDHPs (as defined by the Internal Revenue Service) require a deductible of at least $1,400 for an individual and $2,800 for a family.[121] HDHPs are often touted as a way to mitigate rising premiums, but for individuals with lifelong illnesses like diabetes, the financial exposure fundamental to HDHPs may contribute to their decision to delay medical treatment.

For example, several studies have found that diabetics who enroll in HDHPs often do not refill branded medications or delay treatment altogether, contributing to problems with adherence.[122] Delaying treatment can be disastrous to one's health or even deadly, and from an economic perspective, delayed treatment leads to increased health care costs for patients and payers in the long-term. The Internal Revenue Service sought to address this issue in July 2019 when it released guidance that expanded the list of preventative services that a HDHP can cover below the deductible to include insulin.[123]

d. The PBM Industry

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[116] *See* Press release, Wyden-Grassley Solvaldi Investigation Finds Revenue-Driven Pricing Strategy Behind $84,000 Hepatitis Drug (Dec. 2015), https://www.finance.senate.gov/ranking-members-news/wyden-grassley-sovaldi-investigation-finds-revenue-driven-pricing-strategy-behind-84-000-hepatitis-drug.
[117] Rachel Dolan, *Understanding the Medicaid Prescription Drug Rebate Program*, KFF (Nov. 12, 2019), https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/.
[118] Adam Fein, *Employer Pharmacy Benefits in 2019: High Deductibles and Greater Coinsurance Expose Even More Patients to Prescription List Prices*, DRUG CHANNELS (Nov. 13, 2019), https://www.drugchannels.net/2019/11/employer-pharmacy-benefits-in-2019-high.html.
[119] *Id.*
[120] *2019 Employer Health Benefits Survey*, KFF (Sept. 25, 2019), https://www.kff.org/report-section/ehbs-2019-section-8-high-deductible-health-plans-with-savings-option/#figure85.
[121] INTERNAL REVENUE PROCEDURE 2020-32, https://www.irs.gov/pub/irs-drop/rp-20-32.pdf (Total out-of-pocket expenses for the year are capped at $7,000 for individuals and $14,000 for families). *See also* A. Mark Fendrick et al*., Association between Switching to a high-deductible health plan and discontinuation of Type 2 diabetes treatment*, JAMA Network (Nov. 1, 2019), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2753788.
[122] A. Mark Fendrick et al*., Association between Switching to a high-deductible health plan and discontinuation of Type 2 diabetes treatment*, JAMA Network (Nov. 1, 2019), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2753788; J. Frank Wharam, *et al*., *High-Deductible Insurance and Delay in Care for the Microvascular Complications of Diabetes*, ANNALS OF INTERNAL MEDICINE (Dec. 18, 2018), https://www.acpjournals.org/doi/10.7326/M17-3365.
[123] Press release, IRS expands list of preventive care for HSA participants to include certain care for chronic conditions (July 17, 2019), https://www.irs.gov/newsroom/irs-expands-list-of-preventive-care-for-hsa-participants-to-include-certain-care-for-chronic-conditions.

PBMs administer prescription drug benefits on behalf of health insurers and payers, including employers, state Medicaid agencies, and commercial insurers that provide employer-sponsored insurance and coverage through Medicare, Medicaid, or CHIP.[124] The largest PBMs administer drug benefits for health plans that insure tens of millions of people (often referred to as "covered lives"), giving these PBMs tremendous bargaining power in negotiations with pharmaceutical manufacturers seeking access to, and favorable placement on, health insurers' formularies. PBMs use this power to negotiate with drug manufacturers, ostensibly to lower drug costs for their clients.

Manufacturers have a strong financial incentive to gain access to a plan sponsor's formulary, particularly national formularies administered by the three largest PBMs on behalf of hundreds or thousands of health plan clients. PBMs also negotiate formularies on behalf of individual clients. As Eli Lilly explained to its investors in 2019, failing to secure formulary placement can "lead to reduced usage of a drug for the relevant patient population due to coverage restrictions, such as prior authorizations and formulary exclusions, or due to reimbursement limitations which result in higher consumer out-of-pocket cost, such as non-preferred co-pay tiers, increased co-insurance levels, and higher deductibles."[125] This is why pharmaceutical manufacturers compete fiercely for formulary placement, particularly in therapeutic areas such as diabetes where there are multiple branded products with similar clinical attributes. They also seek to balance drug price increases and price concessions—primarily rebates and price protection clauses—to compete against each other for favorable formulary placement with health plans represented by PBMs and health plans that choose to negotiate with manufacturers directly.[126]

The PBM industry has grown and consolidated rapidly in recent decades. As an example, in 1989, roughly 60 million people had their prescription drug coverage administered by PBMs.[127] A few years later, just five companies controlled roughly 80% of a 100 million person market[128] and, by 2014, health care experts estimated three companies—CVS Caremark, Express Scripts, and OptumRx—served over 180 million people, representing roughly 80% of people whose pharmacy benefits were administered by PBMs (as of 2014).[129] However, PBMs have only continued to grow and expand their operations.

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[124] *See Pharmacy Benefit Managers: Practices, Controversies, and What Lies Ahead*, COMMONWEALTH FUND (Mar. 2019), https://www.commonwealthfund.org/sites/default/files/2019-03/Seeley_pharmacy_benefit_managers_ib_v2.pdf; Kathleen Gifford et al., *How State Medicaid Programs are Managing Prescription Drug Costs: Resulting from a State Medicaid Pharmacy Survey for State Fiscal Years 2019 and 2020*, KFF (Apr. 29, 2020), https://www.kff.org/report-section/how-state-medicaid-programs-are-managing-prescription-drug-costs-pharmacy-benefit-administration/.

[125] *Eli Lilly Form 10-K*, SEC at 35, https://www.sec.gov/ix?doc=/Archives/edgar/data/59478/000005947820000057/lly-20191231x10xk.htm.

[126] For example, Eli Lilly boosted its rebate offer to one PBM after it learned of a competitor offering a 54% rebate, 6% annual price protection, and "covering the cost of 'transitioning lives away from Lilly products.'" LLY-SFCOM-UR-00003520, at LLY-SFCOM-UR-00003521; LLY-SFCOM-UR-00003532. *See also* LLY-SFCOM-UR-00002612; LLY-SFCOM-UR-00002644; LLY-SFCOM-UR-00003325.

[127] *Pharmacy Benefit Managers, Early Results on Ventures with Drug Manufacturers*, GAO at 3 (Nov. 1995), https://www.gao.gov/assets/230/221921.pdf.

[128] *Id* at 3.

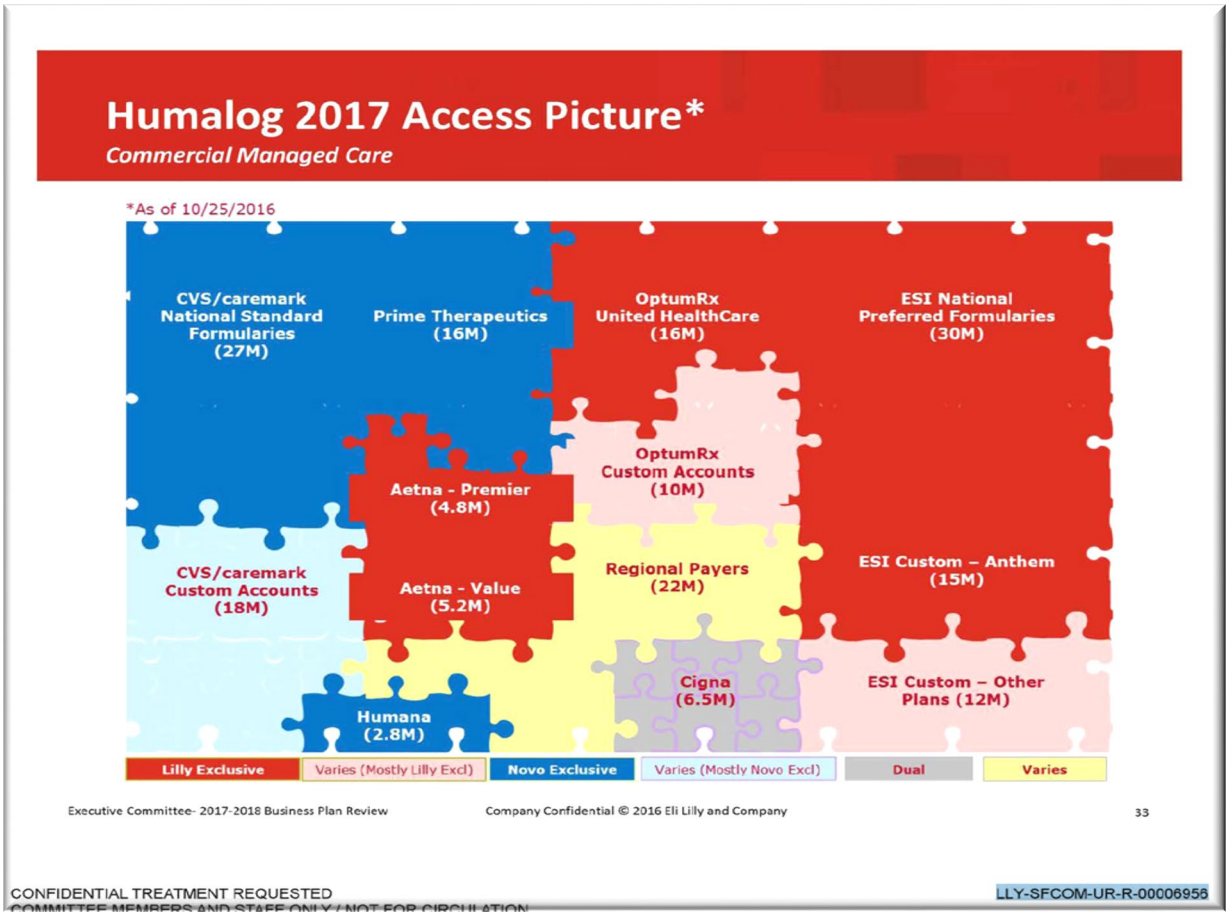
[129] Cole Werble, *Pharmacy Benefit Managers*, HEALTH AFFAIRS (Sept. 14, 2017), https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/full/.

Company	History and Market Position	Proposed Mergers and Partnerships	Total Lives Covered (as of 2019)
CVS Caremark	CVS Health acquires Aetna in November 2018 in a deal worth nearly $70 billion.[130]		105 million.[131]
Express Scripts	In 2018, Cigna acquired Express Scripts in a deal worth approximately $67 billion.[132] In 2012, Express Scripts acquired rival Medco Health Solutions for $29 billion.[133]	In December 2019, Express Scripts announced a partnership with Prime Therapeutics, a PBM collectively owned and operated by 18 Blue Cross Blue Shield health plans, to enhance "pharmacy networks" and "pharmaceutical manufacturer value"—essentially meaning that the PBM will handle negotiations between the health insurer and drug manufacturers.[134]	More than 80 million.[135]
OptumRx	A subsidiary of UnitedHealth Group. In 2015, UnitedHealth Group acquired PBM Catamaran Corp. for		More than 65 million.[137]

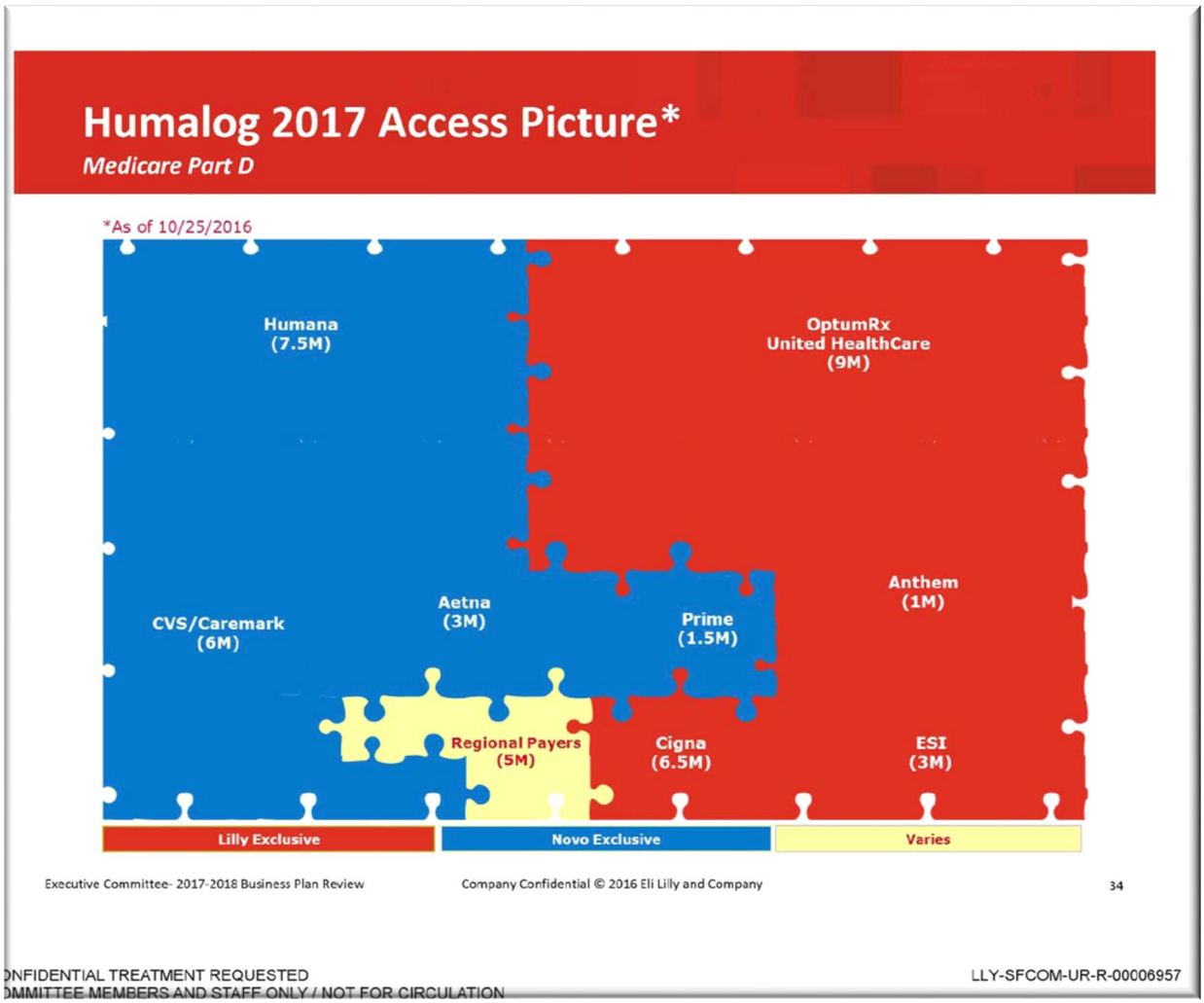
[130] Anna Wilde Mathews and Aisha Al-Muslim, *CVS Completes $70 Billion Acquisition of Aetna*, WALL ST. J. (Nov. 28, 2018), https://www.wsj.com/articles/cvs-completes-70-billion-acquisition-of-aetna-1543423322.
[131] *2019 Annual Report*, CVS HEALTH at 58, https://www.annualreports.com/HostedData/AnnualReports/PDF/NYSE_CVS_2019.pdf.
[132] Press Release, Cigna, Cigna to Acquire Express Scripts for $67 Billion (Mar. 8, 2018), https://www.cigna.com/about-us/newsroom/news-and-views/press-releases/2018/cigna-to-acquire-express-scripts-for-67-billion.
[133] Jaimy Lee, *Express Scripts Buys Medco for $29 Billion*, MODERN HEALTH CARE (Apr. 2, 2012), https://www.modernhealth care.com/article/20120402/NEWS/304029961/express-scripts-buys-medco-for-29-billion.
[134] Press Release, Prime Therapeutics, Express Scripts and Prime Therapeutics Collaborate to Deliver More Affordable Care to More Than 100 Million Americans (Dec. 19, 2019), https://www.primetherapeutics.com/en/news/pressreleases/2019/release-prime-express-scripts-collaboration.html.
[135] Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Apr. 16, 2019).
[137] *How Did UnitedHealth's OptumRx Revenues Increase in Q3 Despite A Drop in Retail Prescriptions*, FORBES (Nov. 28, 2019), https://www.forbes.com/sites/greatspeculations/2019/11/28/how-did-unitedhealths-optumrx-revenues-increase-in-q3-despite-a-drop-in-retail-prescriptions/?sh=751ad7c42547.

	approximately $13 billion.[136]		

In addition to being the largest PBMs in the country, these companies are also vertically integrated with health insurance companies and operate specialty pharmacies through acquisitions and mergers. For example, OptumRx is a subsidiary of UnitedHealth Group, CVS Caremark is a subsidiary of CVS Health, which acquired the health insurer Aetna in a $69 billion deal in 2018, and Express Scripts merged with health insurer Cigna in 2018.[138] An Eli Lilly presentation prior to the Cigna-Express Scripts and CVS-Aetna mergers suggested that the companies, once combined, would represent 172 million or about 75% of the nearly 228 million people in Part D and commercial markets, alone.[139] Adding the Express Scripts-Prime Therapeutics partnership brings the number to 189.5 million or roughly 83% of those markets.[140] Excerpts from this presentation are shown below.[141]



[136] Anna Wilde Mathews and Joseph Walker, *UnitedHealth to Buy Catamaran for $12.8 Billion in Cash*, WALL ST. J. (Mar. 30, 2015), https://www.wsj.com/articles/unitedhealth-to-buy-catamaran-for-12-8-billion-in-cash-1427709601.
[138] Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Apr. 16, 2019).
[139] LLY-SFCOM-UR-R-00006924, at LLY-SFCOM-UR-R-00006956-57.
[140] LLY-SFCOM-UR-R-00006924, at LLY-SFCOM-UR-R-00006956-57.
[141] LLY-SFCOM-UR-R-00006924, at LLY-SFCOM-UR-R-00006956-57.



As PBMs have grown, they have faced significant legal scrutiny, including paying millions of dollars in damages, settlements, and fines connected to kickback schemes, fraud allegations, and false claims.[142] Members of Congress and industry groups have expressed

[142] Nate Raymond, *Ohio accuses UnitedHealth's OptumRx of drug overcharges in lawsuit*, REUTERS (Mar. 18, 2019) (emphasizing the significance of current legal scrutiny), https://www.reuters.com/article/us-ohio-drugprices-lawsuit/ohio-accuses-unitedhealths-optumrx-of-drug-overcharges-in-lawsuit-idUSKCN1QZ1UH. *See also 2017 Annual Report*, CVS HEALTH, https://s2.q4cdn.com/447711729/files/doc_financials/annual/annual-report-2017.pdf (last visited Mar. 29, 2019) (noting that CVS reported receiving a civil investigative demand in 2017 from the Attorney General for Washington. The state informed the company that information provided in response to the demand would be shared with California, Florida, Minnesota, New Mexico, and the District of Columbia.); *Express Scripts Form 10-K*, SEC at 32 (Feb. 27, 2018), https://www.sec.gov/Archives/edgar/data/1532063/000153206318000004/esrx-12312017x10k.htm (noting "[Express Scripts] has received inquiries from various state Attorneys General offices in connection with pending investigations into potential unfair and deceptive acts or practices related to the pricing, reimbursement and rebates for insulin and epinephrine products and possible contracts, combinations or conspiracies in restraint of trade in the setting of prices for insulin and epinephrine products" and "[o]n March 29, 2017, the Company received a Civil Investigative Demand from the Office of the Attorney General of Washington related to insulin products."). *Id. See also The State of Competition in the Pharmacy Benefits Manager and Pharmacy Marketplaces, Hearing Before the House Judiciary Comm., Subcomm. on Regulator Reform, Commercial and Antitrust Law*, 114th Cong.

concern that consolidation in the health care sector harms patients and discourages competition. During the Committee's April 9, 2019 hearing titled *Drug Pricing in America: A Prescription for Change, Part III*, Senator Grassley and Senator Wyden questioned CVS Caremark, Express Scripts, and OptumRx executives on anti-competitive behavior and asked that they respond to their concerns that vertical integration may actually harm patients and consumers.[143] In response to Senator Grassley's question, the witnesses pointed to the highly competitive nature of their industry and alluded that vertical integration was required to keep costs low for patients and insurers.[144]

Information collected during this investigation demonstrates that smaller PBMs and rival health insurers with less bargaining power (generally those with fewer patients or "covered lives" served by the company) are offered less generous rebates, discounts, and other fees by drug manufacturers when compared to larger competitors.[145] An example of this dynamic is on display in an internal Sanofi memo regarding its rebate negotiations with a small company, WellDyneRx, LLC, as the company considered offering lower rebates for Lantus and Toujeo, which represented an "opportunity to retain glargine business at WellDyneRx at a lower rebate rate than the national PBM rates."[146] A September 27, 2017 email further elaborated on the company's view:[147]

(2015)(statement of David A. Balto), https://docs.house.gov/meetings/JU/JU05/20151117/104193/HHRG-114-JU05-Wstate-BaltoD-20151117.pdf; Press Release, U.S. Dep't of Justice, Medco to Pay $7.9 Million to Resolve Kickback Allegations, (May 20, 2015), https://www.justice.gov/opa/pr/medco-pay-79-million-resolve-kickback-allegations; Press Release, U.S. Dep't of Justice, U.S. Attorney's Office, Southern District of New York, Manhattan U.S. Attorney Announces $60 Million Civil Fraud Settlement With Accredo Health Group Over Kickback Scheme Involving Prescription Drug (May 1, 2015), https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-60-million-civil-fraud-settlement-accredo-health-group; Press Release, Attorney General McKenna Announces Caremark To Pay $41 Million To Resolve Multistate Consumer Protection Claims (Feb. 14, 2008), https://www.atg.wa.gov/news/news-releases/attorney-general-mckenna-announces-caremark-pay-41-million-resolve-multistate; Press Release, U.S. Dep't of Justice, Medco to Pay U.S. $155 Million to Settle False Claims Act Cases (Oct. 23, 2006), https://www.justice.gov/archive/opa/pr/2006/October/06_civ_722.html; Press Release, U.S. Dep't of Justice, Justice Department Recovers $1.4 Billion in Fraud & False Claims in Fiscal Year 2005; More Than $15 Billion Since 1986 (Nov. 7, 2005), https://www.justice.gov/archive/opa/pr/2005/November/05_civ_595.html.

[143] *Drug Pricing in America: A Prescription for Change, Part III: Hearing Before S. Comm. on Finance*, 116th Cong. (Apr. 2019) (Question for the record of Sen. Charles E. Grassley, Chairman, S. Comm. Finance).

[144] *Id.*

[145] *See* Press Release, American Medical Association, AMA urges DOJ to challenge CVS-Aetna merger (Aug. 8, 2018), https://www.ama-assn.org/press-center/press-releases/ama-urges-doj-challenge-cvs-aetna-merger.

[146] SANOFI_SFC_00010641.

[147] SANOFI_SFC_00010655.

From: Fondaco, Michael /US
Sent: Wednesday, September 27, 2017 9:32 PM
To: Borys, Margaret /US; Halenar, Lori /US
Subject: RE: Preliminary PRB Agenda 9/28/17

Margaret,

In a nutshell, WellDyneRx is a PBM with ~1M lives. They currently use Gateway as their claims aggregator under ESI. WellDyne believes they can better negotiate rebates on their own instead of getting their rates nipped by both Gateway and ESI. Much more information to be presented tomorrow but the bottom line is the proposed rates are less than the ESI rate so it's a savings to the brand.

Feel free to call me if you have any questions.

Thanks.

Mike

Little more than a month after this email was sent, Sanofi considered offering WellDyneRx rebates between 42% and 50% off WAC for Lantus, and between 40% and 48% off WAC for Toujeo.[148] In comparison, Sanofi prepared a much better offer for CVS's Part D portfolio, which covered 12.8 million lives at the time and was preparing to merge with Aetna, adding another 3.1 million lives. According to internal pricing review board memoranda, on November 30, 2017, Sanofi sought approval to offer rebates up to 72% for Lantus and 67% for Toujeo in addition to administrative fees and deferred payments.[149] A "bid tracker" with rebates Sanofi offered to different payers similarly shows that companies with more "lives" typically received larger discounts than smaller competitors.[150]

What follows is a brief overview of PBM operations based on information collected during the course of the investigation.

i. Formulary Development Process

One of the primary functions that PBMs perform is developing lists of covered drugs for plan sponsors, known as formularies. A formulary is "[a] list of prescription drugs covered by a prescription drug plan or another insurance plan offering prescription drug benefits."[151] Drugs listed on a formulary are typically less expensive for a plan beneficiary to purchase, since they are subject to the plan's drug benefit. In turn, a manufacturer typically provides a rebate to a health plan when a drug is placed on a formulary, saving the plan money on the cost of the medication. A product's formulary placement can also affect a patient's out-of-pocket spending, as demonstrated by an internal Sanofi analysis of Part D formularies operated by CVS Caremark that found co-pays for Lantus could "range . . . from $236 (34% co-ins) to as high as $348 (50% co-ins)" depending on its formulary tier.[152]

[148] SANOFI_SFC_00010641.
[149] SANOFI_SFC_00009950, at SANOFI_SFC_00009954.
[150] SANOFI_SFC_00010668, at SANOFI_SFC_00010671.
[151] *Formulary*, HEALTHCARE.GOV, https://www.healthcare.gov/glossary/formulary/ (last viewed Dec. 29, 2020).
[152] SANOFI_SFC_00009811, at SANOFI_SFC_00009815.

There are many different types of formularies with different cost-sharing tiers.[153] While each PBM has different names and particular practices for each of its formularies, they all offer their clients a range of options that vary in the amount of restrictions placed on patients (such as step-therapy and prior authorizations), the number of therapies available, and the cost. However, the development of a health plan's formulary is relatively similar across PBMs in that it follows a multi-step process involving several distinct committees within the respective PBMs.

Pharmacy & Therapeutics Committee. The Pharmacy & Therapeutics Committee (P&T Committee) is an independent advisory committee comprised of actively practicing physicians, pharmacists, and other experts who are responsible for evaluating clinical evidence to assess a medication's clinical value.[154] In determining a medication's clinical value, the P&T Committee reviews scientific evidence, medical literature, and standards of practice to assess a medication's safety and efficacy.[155] It then assigns a clinical designation for the drug and makes formulary recommendations for the PBM's "national" formularies (a type of formulary that is designed by the PBM and offered to multiple, sometimes thousands of, plan sponsors) or for an individual client's custom formulary.[156] According to CVS Caremark, Express Scripts, and OptumRx, the P&T Committee neither has access to, nor does it consider, financial factors such

[153] For example, CVS Caremark has several different formularies it offers clients. One such formulary, the "Standard Opt-Out" is the least restrictive, and includes the greatest number of products, with the CVS website noting that it does "not include formulary removals." Troy Brennen, *2018 Formulary Strategy*, CVS CAREMARK (Aug. 1, 2017), https://payorsolutions.cvshealth.com/insights/2018-formulary-strategy. Meanwhile, the "Standard Control" formulary "offers the broadest coverage of generic, brand and specialty medications of [CVS Caremark's] formularies. Updates are made at the beginning of the year with potential quarterly exclusions for hyperinflation and specialty products. It offers savings of 1 to 2 percent on pharmacy spending." *Formulary Management*, CVS CAREMARK, https://payorsolutions.cvshealth.com/programs-and-services/cost-management/formulary-management (last viewed Dec. 29, 2020). The "Value" formulary purports to include only the lowest-cost medications, with CVS Caremark noting it "covers most generics, and select brands, including specialty medications, with tier exceptions or higher copays for non-formulary brands. Drug list and management strategies are updated quarterly. Value Formulary can deliver pharmacy spend savings of up to 8 percent and an increase in generic dispensing of up to 5 percent or more." *Id.* As formularies have become more restrictive, they cost clients less money. CVS Caremark estimated costs for clients with a custom formulary who opted-out of exclusions to be $113.62 per-member per-month (PMPM) whereas the "Value" formulary, which had the highest generic dispensing rate of CVS's various formularies, had the lowest baseline cost at $81.86 per-member-per-month. Jon Roberts, *Trend Drops to the Lowest Level in 4 years, Despite the Headlines, Prescription Spending Growth Slowed for Our Clients*, CVS CAREMARK (Mar. 15, 2017), https://payorsolutions.cvshealth.com/insights/trend-drops-lowest-level-4-years.

[154] *See* Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Apr.16, 2019); Letter from Michael Bopp, Counsel, Gibson Dunn ,Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (June 21, 2020); Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Sept. 25, 2019); Letter from Enu Mainigi, Counsel, Williams & Connolly, on Behalf of CVS Health Corp., to Senator Grassley and Senator Wyden (Apr. 26, 2019); Letter from Enu Mainigi, Counsel, Williams & Connolly, on Behalf of CVS Health Corp., to Senator Grassley and Senator Wyden (Aug. 27, 2019); Cigna-SFC-0008830; ORX_Sen_Fin_00001935.

[155] Based on information collected during the Committee's interview with Andy Behm, Vice President of the Office of Clinical Evaluation and Policy, Express Scripts (Nov. 7, 2019). *See also* ORX_Sen_Fin_0005329. (This document, produced by OptumRx, is an example of the type of evidence reviewed by the P&T Committee in making their determination.)

[156] ORX_Sen_Fin_00001935.

as rebates, discounts, or net costs.[157] However, with regard to insulin, the P&T Committee, from a clinical perspective, considers these drugs to be mostly interchangeable.[158]

The P&T Committee also meets annually to review final formulary recommendations.[159] This is often an opportunity to ensure that formularies include products for a wide-range of therapeutic classes and, if necessary, to make final adjustments to plan formularies.[160]

Formulary Development. PBMs also maintain internal committees that determine which therapies are placed on formularies. The development of drug formularies has a major financial impact not only on pharmaceutical companies, but on health insurers and the PBMs. Formulary development committees appear to be at the center of developing these lists. These committees are comprised of company personnel, which may include representatives from formulary management, product management, trade relations, human resources, and clinical account management.[161] PBMs differ in what they call this committee. For example, Express Scripts refers to this committee as the *Value Assessment Committee*, CVS Caremark refers to this Committee as the *Formulary Review Committee*, and OptumRx refers to this committee as the *Formulary Management Committee*.[162] Regardless, their purpose and composition remains similar. What follows is a summary of the operations of OptumRx's Formulary Management Committee (FMC).

OptumRx's FMC meets on a monthly basis and is responsible for reviewing evidence transmitted by the P&T Committee to make formulary placement decisions.[163] The FMC also reviews the "P&T Committee Drug Classification Designations" to make decisions or recommendations about the formulary structure."[164] The P&T Committee can assign one of seven different drug designations, including "essential drug," "essential class," and "optional inclusion" based on clinical evidence.[165] Subject to the clinical designations and recommendations of the P&T Committee, the formulary development committee makes

[157] Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (June 21, 2019); Letter to Senator Grassley and Senator Wyden from Enu Mainigi, Counsel, CVS Caremark (Aug. 27, 2019); ORX_Sen_Fin_00001935, at ORX_Sen_Fin_00001936.
[158] *See* Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Sept. 25, 2019).
[159] *See* Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (June 21, 2019).
[160] Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (June 21, 2019).
[161] Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Sept. 25, 2019); Letter from Enu Mainigi, Counsel, Williams & Connolly, on Behalf of CVS Health Corp., to Senator Grassley and Senator Wyden (Apr. 26, 2019); ORX_Sen_Fin_0005387.
[162] Letter from Enu Mainigi, Counsel, Williams & Connolly, on Behalf of CVS Health Corp., to Senator Grassley and Senator Wyden (Apr. 26, 2019); Cigna-SFC-00008830; ORX_Sen_Fin_0005377.
[163] ORX_Sen_Fin_0005377, at ORX_Sen_Fin_0005379.
[164] ORX_Sen_Fin_0005377, at ORX_Sen_Fin_0005378, ORX_Sen_Fin_0005383.
[165] ORX_Sen_Fin_0005377, at ORX_Sen_Fin_0005378, ORX_Sen_Fin_0005383.

formulary recommendations for drugs that are deemed interchangeable[166] by evaluating net cost, rebates, discounts, plan sponsor costs, utilization trends, and business benefit considerations.[167]

Several presentations collected during this investigation demonstrate how the FMC considers the financial impact to OptumRx's business. For example, a FMC presentation dated April 25, 2018, refers to the financial evaluation of different insulin products, such as the net cost and per-member-per-month impact of Humalog;[168] the annual impact on rebates by moving Tresiba to a different formulary tier;[169] the net cost and incremental cost of every insulin product in the long-acting class,[170] and the net WAC of multiple insulin products.[171] This presentation also refers to an FMC vote that was conducted by email,[172] states that "[t]he basal insulin class was evaluated as part of 2019 recontracting (sic) effort to leverage competition and reduce the overall cost of the category,"[173] stresses the need for a "[r]eevaluation of the Humalog brand … to address market dynamics … [and mentions with respect to Humalog that] [a]dditional rebate opportunities [are] available for the various benefit designs."[174]

The materials used for these meetings are provided to, and maintained by, FMC members.[175] The FMC's policies also suggest that the FMC engages in several other types of communications that would have been responsive to the Committee's April 2nd request for information, but that the company failed to produce. For example, OptumRx's FMC policy states:[176]

[166] Some PBMs assign designations to drugs that are clinically similar to other available drug alternatives. For example, Express Scripts' P&T Committee designates insulins as *optional* and forwards this information to the Value Assessment Committee, which evaluates net cost, market share, and drug utilization trends of clinically similar medications. *See* Cigna-SFC-00008330, at Cigna-SFC-00008831. Express Scripts' P&T Committee considers insulins interchangeable. Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Sept. 25, 2019).

[167] *See* Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (June 21, 2020)(stating that Cigna's Value Assessment Committee considers the value of the drug by evaluating net cost, market share, and drug utilization trends of clinically similar medications); Letter from Enu Mainigi, Counsel, Williams & Connolly, on Behalf of CVS Health Corp., to Senator Grassley and Senator Wyden (Apr. 26, 2019)(stating that CVS Caremark's Formulary Review Committee considers net-cost, clinical guidance, marketplace dynamics, and the potential for patient disruption); ORX_Sen_Fin_0005387 (stating that OptumRx's Formulary Management Committee considers net-cost, economic, pharmacoeconomic, and business/benefit considerations as well as factors that are "attractive to current and potential clients, particularly by providing clients with the lowest possible net cost of drugs.")

[168] ORX_Sen_Fin_0007468, at ORX_Sen_Fin_0007489.

[169] ORX_Sen_Fin_0007468, at ORX_Sen_Fin_0007479.

[170] ORX_Sen_Fin_0007468, at ORX_Sen_Fin_0007480

[171] ORX_Sen_Fin_0007468, at ORX_Sen_Fin_0007490.

[172] ORX_Sen_Fin_0007468, at ORX_Sen_Fin_0007490.

[173] ORX_Sen_Fin_0007468, at ORX_Sen_Fin_0007479.

[174] ORX_Sen_Fin_0007468, at ORX_Sen_Fin_0007489.

[175] ORX_Sen_Fin_0005377, at ORX_Sen_Fin_0005378.

[176] ORX_Sen_Fin_0005377, at ORX_Sen_Fin_0005380.

COMMUNICATION
FMC will deliver all approved decisions to SVP of Clinical, and SVP of Industry Relations, for their reference.

FMC will deliver final decisions to the Benefit Implementation Committee ("BIC") for implementation and communication to internal and external stakeholders. Refer to BIC Charter.

PBM clients can also receive documentation concerning formulary recommendations from OptumRx, if their agreement allows for it. (The Finance Committee did not attempt to determine if plans are in fact allowed to review these agreements. However, the Office of Inspector General for the Department of Health and Human Services found that, while some Part D plans have certain contractual rights to audit agreements between their PBMs and manufacturers, they are not always allowed to do so.)[177] The FMC also provides its clients with guidance about how to structure their formularies:[178]

- Clinical Program Strategy: FMC also provides economic guidance into the type of utilization management tools ("UM") for use with particular drugs or a particular Formulary, including, but not limited to, prior authorizations, quantity limits, step therapies, and provider education. FMC makes these decisions by considering clinical, economic and pharmacoeconomic evidence (as available) provided by the P&T Committee, OptumRx staff, and other supporting financial, business and benefit strategy analyses. FMC reviews and considers recommendations and other information, including, but not limited to:

Trade Relations Group. The Trade Relations Group is an internal committee comprised of PBM personnel who are responsible for negotiating or approving rebate agreements with drug manufacturers.[179] PBMs differ in what they call this committee. For example, OptumRx refers to this committee as the Industry Relations Group whereas CVS Caremark and Express Scripts refer to this committee as the Trade Relations Group.[180] For the purposes of this discussion, "Trade Relations Group" will be used. The Trade Relations Group utilizes the PBM's purchasing power and other market forces to negotiate rebates, discounts, and other fees with drug manufacturers.[181] The Trade Relations Group also seeks to obtain the lowest net cost for its clients—regardless of the list price set by manufacturers—and uses certain tactics (e.g., formulary exclusions) to meet its goal.[182]

ii. Rebates, Discounts, and Other Fees

[177] DEP'T HEALTH AND HUMAN SERVS., OFF. OF INSPEC. GEN., CONCERNS WITH REBATES IN THE MEDICARE PART D PROGRAM at 22 (Mar. 11, 2011), https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf.
[178] ORX_Sen_Fin_0005387.
[179] *See* Letter from Enu Mainigi, Counsel, Williams & Connolly, on Behalf of CVS Health Corp., to Senator Grassley and Senator Wyden (Aug. 27, 2019).
[180] Letter from Enu Mainigi, Counsel, Williams & Connolly, on Behalf of CVS Health Corp., to Senator Grassley and Senator Wyden (Apr. 26, 2019); ORX_Sen_Fin_0004991.
[181] *See* ORX_Sen_Fin_0004991.
[182] ORX_Sen_Fin_0057558.

Rebates are payments made by drug manufacturers to PBMs after the point of sale,[183] and are calculated as a percentage of WAC. Drug manufacturers negotiate rebates with PBMs and health insurers to secure preferred formulary placement for their products.[184] These negotiations can be of such great financial importance to pharmaceutical companies that senior executives up to and including the chief executive officer are often personally involved in the process.[185] Typically, PBMs pass on the majority of these rebates to health insurers,[186] who use rebates to lower premiums, lower cost-sharing, or fund wellness programs for beneficiaries.[187] However, plan sponsors have not always been sufficiently transparent as to how they use rebates, discounts, and other fees they receive from their contracted PBM or from drug manufacturers.[188]

There is limited publicly available information about the contractual arrangements between manufacturers and PBMs. The lack of public understanding stems from the commercial sensitivity of these contracts, and the broad confidentiality clauses that limit their disclosure.[189] The lack of transparency even extends to health plans. While some health plans have certain contractual rights to conduct audits of agreements between their contracted PBM and manufacturers, HHS OIG found that manufacturers can and do refuse such audits.[190]

Moreover, Federal law restricts the dissemination of price and rebate information that companies disclose to the Federal government for Medicaid and Part D plans. Until recently, such information could only be reviewed by the Secretary of the Department of Health and Human Services (HHS), the Comptroller General, Congressional Budget Office, and States (in regards to Medicaid). However, the Consolidated Appropriations Act of 2021 expanded the dissemination of price and rebate information to the Executive Directors of the Medicare Payment Advisory Commission and Medicaid and CHIP Payment and Access Commission—an

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[183] *See* Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Apr. 16, 2019). CVS Caremark, Express Scripts, and OptumRx all have rebate contracts with the three major insulin manufacturers—Eli Lilly, Novo Nordisk, and Sanofi. Letter Wyden from Michael Bopp, Counsel, Cigna to Senator Grassley and Senator (June 21, 2019); Letter Wyden from Enu Mainigi, Counsel, CVS Caremark to Senator Grassley and Senator (May 24, 2019); ORX_Sen_00001935; ORX_Sen_Fin_0005305.
[184] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (May 24, 2019); ORX_Sen_Fin_0005389. For an example of a rebate agreement, *see* Cigna-SFC-00009847.
[185] e.g., LLY-SFCOM-UR-00005146; LLY-SFCOM-UR-00003868; LLY-SFCOM-UR-00003699; LLY-SFCOM-UR-00003445, LLY-SFCOM-UR-00003449. For example, Eli Lilly's chief executive officer and chief financial officer were personally involved in the approval of multiple rebate offers. At one point, the company's chief financial officer "requested LillyUSA implement a more structured process for executive review of material payer deals (requiring CFO and CEO approval)." *See* LLY-SFCOM-UR-00003445. In another instance, diabetes unit employees were chastised for providing management insufficient time to review rebate deals. *See* LLY-SFCOM-UR-00005146.
[186] In 2019, GAO reported that "PBMs passed nearly all rebates received from manufacturers through to Part D plan sponsors in 2016. Part D plan sponsors reported to CMS that, of the approximately $18 billion in rebates that PBMs negotiated with pharmaceutical manufacturers that year, PBMs retained $74.3 million, or about 0.4%, and passed through the remaining 99.6% to plan sponsors." GOV. ACCT. OFFICE, MEDICARE PART D, USE OF PHARMACY BENEFIT MANAGERS AND EFFORTS TO MANAGE DRUG EXPENDITURES AND UTILIZATION, at 16 (July 2019), https://www.gao.gov/assets/710/700259.pdf .
[187] Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Apr. 16, 2019); ORX_Sen_Fin_00001935.
[188] *See generally* DEP'T HEALTH AND HUMAN SERVS., OFF. OF INSPEC. GEN., CONCERNS WITH REBATES IN THE MEDICARE PART D PROGRAM (Mar. 11, 2011), https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf.
[189] SANOFI_SFC_00007985, at SANOFI_SFC_00007994.
[190] DEP'T HEALTH AND HUMAN SERVS., OFF. OF INSPEC. GEN., CONCERNS WITH REBATES IN THE MEDICARE PART D PROGRAM (Mar. 11, 2011), https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf.

expansion proposed in the Prescription Drug Pricing Reduction Act of 2019 that was introduced by Chairman Grassley and Ranking Member Wyden. And, with regard to public disclosure, the Secretary of HHS is allowed to "disclose (through a website accessible to the public) the weighted average of the most recently reported monthly average manufacturer prices and the average retail survey price determined for each multiple source drug."[191]

The Committee's investigation found that manufacturers negotiate contracts directly with health plans or their PBM representatives. These contracts contain terms for drug-specific rebates, price protection clauses (designed to dissuade manufacturers from implementing large year-over-year WAC increases), and administrative fees charged by PBMs, among other items. The investigation also found that these contracts and subsequent amendments can stretch over hundreds of pages and cover multiple therapies offered by a manufacturer. The base contracts and subsequent amendments are updated frequently—sometimes multiple times a year—often over the course of a decade or more.

Contracts between PBMs and manufacturers provide a menu of options from which their health plans clients can choose certain terms and conditions. Rebates can vary significantly based on utilization and the plan's benefit design. Manufacturers will also typically make multiple rebate offers for each drug, with the size of each offer typically tied to formulary access and competition within a therapeutic class. Often, a higher rebate is offered for preferred formulary placement which may include few, if any, utilization restrictions (i.e., lower cost-sharing for patients or plans agreeing not to implement prior authorization). Manufacturers will also pay higher rebates, and sometimes even an additional rebate, if the health plan agrees to make their drugs the only therapy on a given formulary tier. As this investigation has shown, the size of rebates for the insulin therapeutic class has risen rapidly, with some PBMs securing rebates as high as 70% in recent years. However, it's the PBM or health plan who ultimately decide a drug's formulary placement and the patient's cost-sharing responsibility. (PBMs generate revenue from these negotiations. For example, Cigna retains approximately 5% of these negotiated discounts, since it reported passing on "approximately 95% of rebates, discounts, and price reductions back to our clients.")[192]

In addition to rebates, PBMs negotiate with drug manufacturers for other discounts and fees. One such example is the use of inflationary protection fees (often referred to as price protection). If drug manufacturers raise the WAC beyond a certain agreed upon percentage, price protection is triggered, and manufacturers must pay additional rebates to plan sponsors in addition to rebates and other discounts.[193] As stated previously, plan sponsors use these fees to lower premiums, lower cost-sharing, or fund wellness programs for beneficiaries.[194] (This investigation did not examine the financial relationships between PBMs and plan sponsors.) However, in 2011, HHS OIG raised concerns that Part D sponsors "commonly had complex

[191] *See* 42 U.S.C. 1396r-8(b)(3)(D)(cross-referenced at 42 U.S.C. 1395w-102(d)(2) and 42 U.S.C. 1396r-8(b)(3)(D)).
[192] Letter from Kristin Julason Damato, Vice President, Global Public Policy & Government Affairs, Cigna Corporation, to Senator Grassley and Senator Wyden (Dec. 7, 2020).
[193] Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Apr. 20, 2019); Letter from Enu Mainigi, Counsel, Williams & Connolly, on Behalf of CVS Health Corp., to Senator Grassley and Senator Wyden (May 24, 2019); ORX_Sen_Fin_00001935; ORX_Sen_Fin_0005389.
[194] Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Apr. 16, 2019); ORX_Sen_Fin_00001935.

relationships with their PBMs, and in some cases, these relationships lacked transparency," which "raises concerns that sponsors may not always have enough information to oversee the services and information provided by PBMs."[195] HHS OIG added:

> Five sponsors had limited information about the rebate contracts and the rebate amounts negotiated by their PBMs. One PBM reported that it does not share the manufacturer rebate contracts with its sponsors because they contain confidential information and there is a chance that the sponsor may one day become a PBM itself. Another PBM specifically stated that the sponsor would 'not be permitted to copy or retain' any portion of the contract. As a result of these practices, most of the selected sponsors were unaware of all of the contract terms that determine the rebates they receive from drug manufacturers.[196]

The following information details the Committee's findings based on internal documents and memoranda collected from manufacturers (Sanofi, Novo Nordisk, and Eli Lilly) and PBMs (CVS Caremark, Express Scripts, and OptumRx), and seeks to shed further light on these contractual relationships, the negotiations that take place between these two groups, and how rebates, discounts, and fees contribute to insulin's rising list price.

III. The Cost of Insulin to Patients, Medicare, and Private Payers

Increases in insulin's list price have dramatically exceeded rates of inflation and health care inflation,[197] leading to concerns about affordability and access for patients. Indeed, during the Committee's hearing titled: *Drug Pricing in America: A Prescription for Change Part I*, the Committee heard from Kathy Sego, a resident of Indiana and a mother whose son has Type 1 diabetes.[198] Ms. Sego told the Committee how, unbeknownst to her, her son rationed his insulin so that their family could afford the $1,700 price tag of his monthly insulin medication. It wasn't until he stopped eating, lost 20 pounds, and seemed depressed that she realized that something was wrong. Unfortunately, Ms. Sego's family is not alone in this struggle. Therefore, as Congress considers common sense policy solutions to address this growing crisis, it is critically important to understand how insulin's list price has evolved over time, and the various factors and players that have caused it to increase exponentially in the past decade.[199]

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[195] DEP'T HEALTH AND HUMAN SERVS., OFF. OF INSPEC. GEN., CONCERNS WITH REBATES IN THE MEDICARE PART D PROGRAM, at 17 (Mar. 11, 2011), https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf.
[196] Id. AT 17-18.
[197] *National Health Expenditure Projections, 2019-2028*, CTRS. MEDICARE AND MEDICAID SERVS., https://www.cms.gov/files/document/nhe-projections-2019-2028-forecast-summary.pdf (last viewed Dec. 28, 2020) (The rate of personal health care inflation is projected to grow 1.9% in 2020 up from 1.5% in 2019). According to the Keiser Family Foundation: "Among the 22 insulin therapies that have been on the market since 2013, 16 products had average annual increases of more than 10% between 2014 and 2018 . . . which far exceeded the 1.5% rate of inflation over the same time period." *Insulin Costs and Coverage in Medicare Part D*, KFF (June 2020), https://www.kff.org/report-section/insulin-costs-and-coverage-in-medicare-part-d-issue-brief/.
[198] *Drug Pricing in America: A Prescription For Change Part I, Hearing Before the S. Fin. Comm*., 116th Cong. (2019) (statement of Kathy Sego), https://www.finance.senate.gov/imo/media/doc/29JAN2019SEGOSTMNT.pdf.
[199] The *Prescription Drug Price Reduction Act of 2020* (co-authored by Senator Grassley and Senator Wyden) is one such piece of legislation that would reduce prescription drug costs for Americans. *See* Press Release, Grassley, Colleagues Introduce Updated Bipartisan Prescription Drug Pricing Bill (July 2, 2020), https://www.grassley.senate.gov/news/news-releases/grassley-colleagues-introduce-updated-bipartisan-prescription-drug-pricing-bill.

a. Insulin List and Net Price Trends: 2013 to 2019

Drug manufacturers independently set the price for their medications—referred to as wholesale acquisition cost, WAC, or list price—based on a number of factors.[200] Documents reviewed during this investigation show that the primary factors considered by companies were the competitive environment, the need to provide rebates, discounts, and other fees to health insurers and their PBMs, and the importance of maintaining market access to preserve sales volume and revenue. When manufacturers set the WAC price for a given product, it is applicable to all payer contracts in its book of business. However, the WAC price is not the amount the manufacturer receives, nor is it the amount paid by the Federal government, health insurers, or employers. The WAC price is the starting point that manufacturers use to negotiate with wholesale distributers, who resell the medication to pharmacies.[201] Instead, manufacturers receive what is known as "net price," which is the amount of money remaining after the manufacturer pays for rebates, discounts, and other fees to health insurers or PBMs, Federal and state health care programs, employers, and other entities.[202]

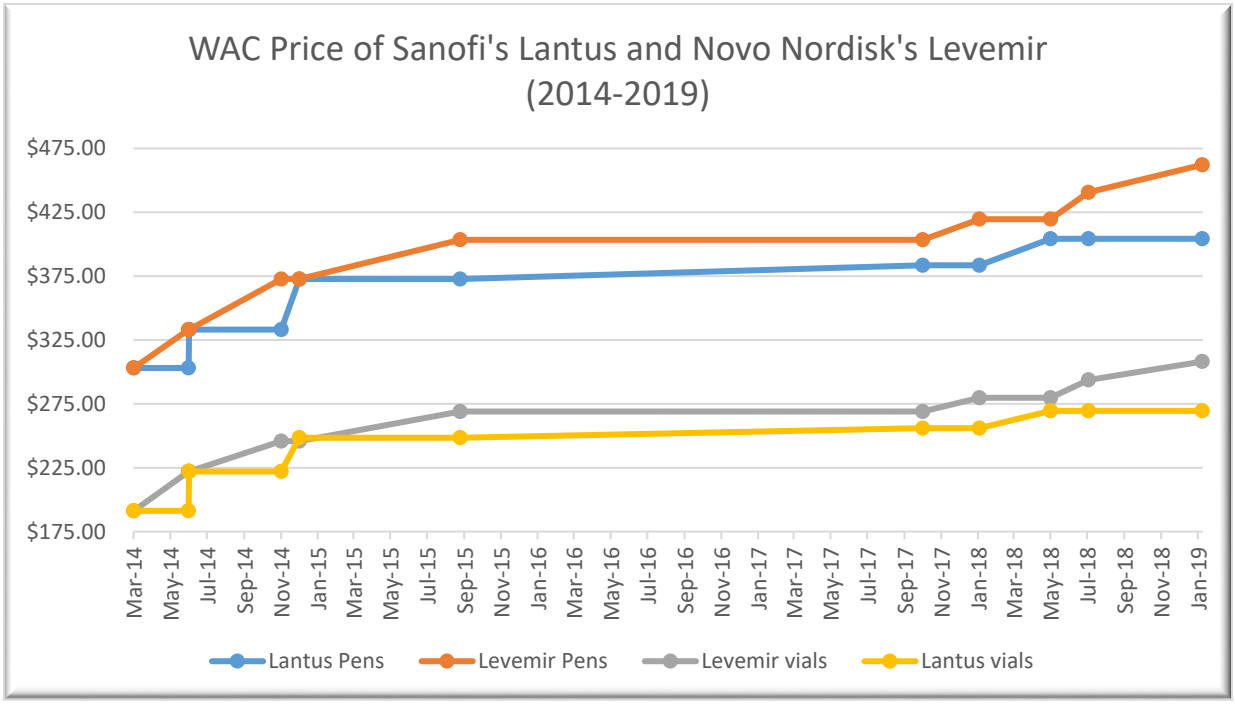
The following tables refects the WAC price of Sanofi's Lantus and Novo Nordisk's Levemir between 2014 and 2019.[203]

[200] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019); Letter from Raphael Prober, Counsel, Akin Gump, on Behalf of Novo Nordisk, to Senator Grassley and Senator Wyden (Mar. 8, 2019); Letter from Joseph B. Kelley, Vice President, Global Government Affairs, Eli Lilly, to Senator Grassley and Senator Wyden (Mar. 8, 2019).

[201] Letter from Joseph B. Kelley, Vice President, Global Government Affairs, Eli Lilly, to Senator Grassley and Senator Wyden (Mar. 8, 2019).

[202] *Id.* The practical effect of rebates is substantial. For example, Novo Nordisk reported net sales of DKK 122 billion (Danish krone) in 2019, noting in its annual report, "the provision for sales rebates and discounts amounted to DKK 30,878 million as of December 31, 2019, *of which a significant portion relates to the US business*." *2019 Annual Report*, NOVO NORDISK, https://www.novonordisk.com/content/dam/nncorp/global/en/annual-report/pdfs/2019/Novo-Nordisk-Form-20-f-2019.pdf (last viewed Dec. 29, 2020).

[203] Calculated using WAC data produced by Sanofi and Novo Nordisk. Sanofi produced WAC data for insulin products per milliliter. In order to calculate the WAC total, Committee staff multiplied price per milliliter by the amount of mL in the vial or in the box. *See* Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019) (attachment 1(a) and (b)). NNI-FINANCE-0002-03.



This investigation primarily focused on the change in WAC price between three long-acting insulins[204]—Lantus, Levemir, and Basaglar—that are in direct competition with each other. Sanofi and Novo Nordisk have steadily increased Lantus' and Levemir's WAC since 2005.[205] Based on WAC data tracked in internal documents, between 2013 and 2019, Lantus' and Levemir's WAC prices increased rapidly.[206] For example:

- Sanofi's Lantus SoloStar (pens) increased from a WAC of $303 in January 2014 to approximately $404 in January 2019—an increase of over 33% in 5 years.[207]

- Novo Nordisk's Levemir Flextouch (pens) increased from a WAC of $303 in May 2014 to approximately $462 in January 2019—an increase of over 52% in 5 years.[208]

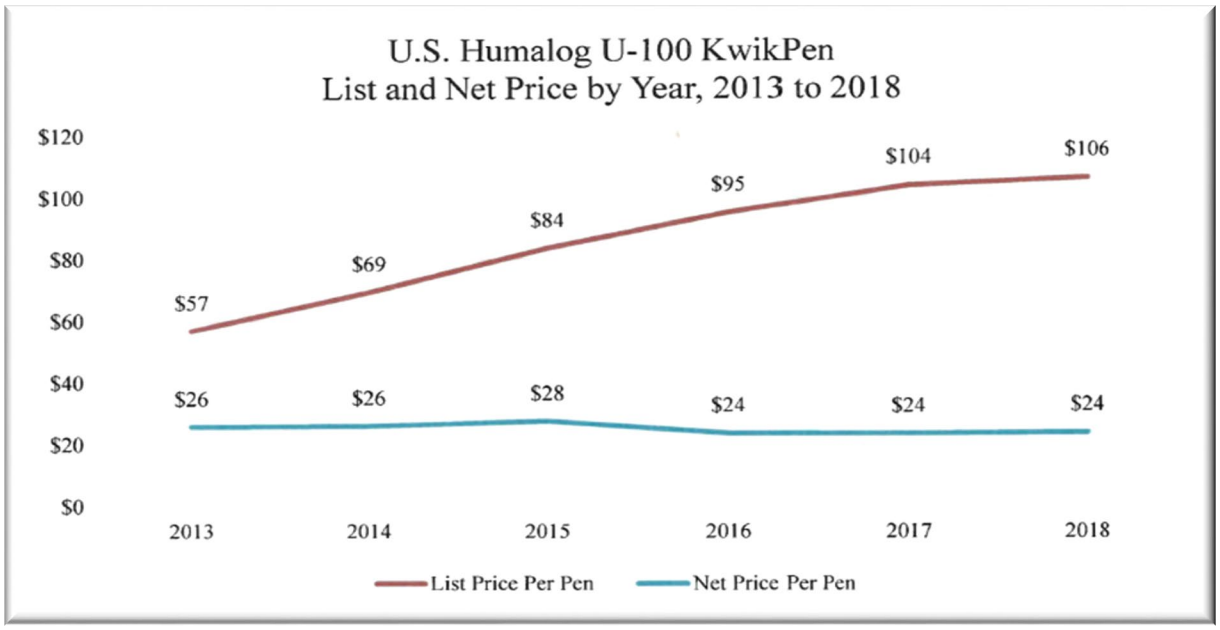
[204] According to the ADA, "long-acting insulin reaches the blood stream several hours after injection" and keeps glucose levels stable in the body for up to 24 hours. *See Insulin Basics*, ADA, https://www.diabetes.org/diabetes/medication-management/insulin-other-injectables/insulin-basics (last visited Dec. 29, 2020).
[205] E.g., Sanofi increased Lantus's WAC by almost 250% from 2005 to 2015, while retaining higher average net prices. *See* SANOFI_SFC_00009556. (On file with Committee). *See also* SANOFI_SFC_00009527.
[206] *See* Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019) (attachment 1(a) and (b)). NNI-FINANCE-0002-03.
[207] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019) (attachment 1(a) and (b)).
[208] NNI-FINANCE-0002-03.

- Eli Lilly's Basaglar launched in November 2016 with a WAC price 23% lower than Lantus at $316.85.[209] However, Basaglar's WAC price increased to $326.36 the following year.[210]

List prices for short-acting and rapid-acting insulins have also risen dramatically during this time period.[211] For example, in 2017, Eli Lilly's Humalog 50-50 Kwikpen[212] had a WAC of $530.40 compared to $323.95 in 2013—representing an increase of approximately 64% in 4 years.[213] Sanofi's rapid-acting insulin, Apidra, increased from $302 in 2014 to $521 in 2019, and Novo Nordisk's rapid acting insulin, Novolog Mix 70/30 FlexPen, increased from $324 in 2013 to $558 in 2018, over a 70% WAC increase for both companies during this time.[214]

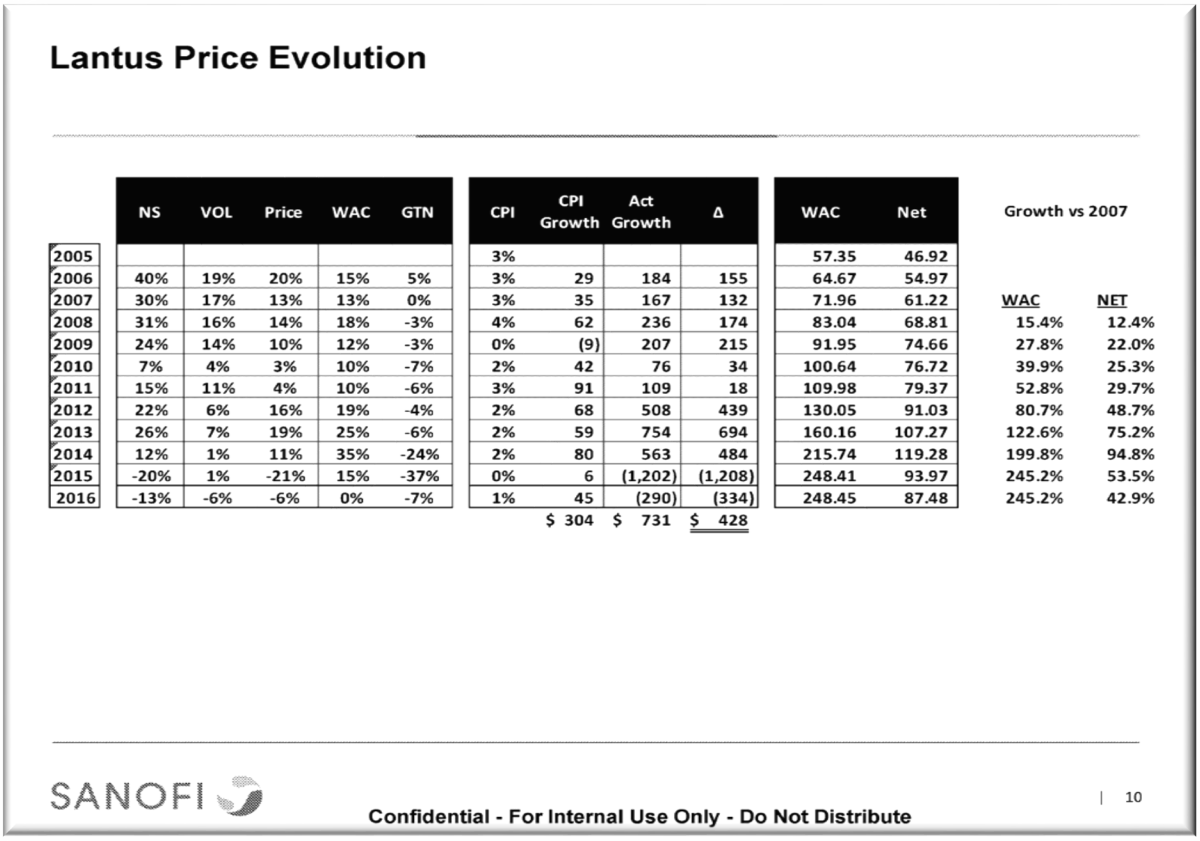
While insulin manufacturers set a single WAC price for each product across their entire book of business, it is important to note that there is no "single" net price for insulin.[215] As discussed above, manufacturers negotiate contracts with PBMs that provide participating health plans with a range of rebates and other discounts based on, and subtracted from, the product's WAC price. The contracts stipulate terms the plans must follow regarding factors such as formulary placement and competition from other drugs in the therapeutic class. As such, a manufacturer can actually receive multiple net prices from a single payer if the payer operates multiple plans that, in turn, place the product in different formulary positions.[216]

[209] LLY-SFCCOM-00000001. *See also* Letter from Joseph B. Kelley, Vice President, Global Government Affairs, Eli Lilly, to Senator Grassley and Senator Wyden (Mar. 8, 2019).
[210] LLY-SFCCOM-00000001.
[211] As discussed above, there are several different kinds of insulin products. According to the ADA, rapid-acting insulins begin to work about 15 minutes after injection (e.g., Fiasp, NovoLog, Apidra, Admelog, and Humalog). Short-acting insulins on the other hand reach the bloodstream within 30 minutes after injection (e.g., Humulin R, Novolin R). *See Insulin Basics*, ADA, https://www.diabetes.org/diabetes/medication-management/insulin-other-injectables/insulin-basics (last viewed Dec. 29, 2020).
[212] Specifically, Humalog Kwikipen U-100.
[213] LLY-SFCCOM-00000001.
[214] *See* Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019) (attachment 1(a) and (b)). NNI-FINANCE-0002-03.
[215] *See* Letter from Reginald Brown, Counsel, WilmerHale, on Behalf of Eli Lilly, to Senator Grassley and Senator Wyden (Mar. 8, 2019).
[216] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019); Letter from Raphael Prober, Counsel, Akin Gump, on Behalf of Novo Nordisk, to Senator Grassley and Senator Wyden (Mar. 8, 2019); Letter from Joseph B. Kelly, Vice President, Global Government Affairs, Eli Lilly, to Senator Grassley and Senator Wyden (Mar. 8, 2019).



Data and documents produced to the Committee suggest that the net prices of insulin manufacturers' products has declined in recent years, but remained significantly higher than they were in the first decade of the 21st Century. For example, in a letter to the Committee, Eli Lilly provided data showing that its average net price for Humalog KwikPen had declined slightly from $28 per pen in 2015 to $24 per pen in 2018, despite the WAC price nearly doubling during that same period (see figure above).[217] On the other hand, an internal Sanofi presentation shows that while the average Lantus net price of $87.48 in 2016 was $32 lower than the drug's net price in 2014, it was roughly double the drug's net price of $46.92 in 2005.[218] Net price growth was also significantly greater than the Consumer Price Index growth the company tracked.[219] An excerpt of Sanofi's internal presentation is shown below.[220]

[217] Letter from Joseph B. Kelly, Vice President, Global Government Affairs, Eli Lilly, to Senator Grassley and Senator Wyden (Mar. 8, 2019).
[218] SANOFI_SFC_00011407, at SANOFI_SFC_00011416.
[219] SANOFI_SFC_00011407, at SANOFI_SFC_00011416.
[220] SANOFI_SFC_00011407, at SANOFI_SFC_00011416.



Lantus Price Evolution

	NS	VOL	Price	WAC	GTN	CPI	CPI Growth	Act Growth	Δ	WAC	Net
2005						3%				57.35	46.92
2006	40%	19%	20%	15%	5%	3%	29	184	155	64.67	54.97
2007	30%	17%	13%	13%	0%	3%	35	167	132	71.96	61.22
2008	31%	16%	14%	18%	-3%	4%	62	236	174	83.04	68.81
2009	24%	14%	10%	12%	-3%	0%	(9)	207	215	91.95	74.66
2010	7%	4%	3%	10%	-7%	2%	42	76	34	100.64	76.72
2011	15%	11%	4%	10%	-6%	3%	91	109	18	109.98	79.37
2012	22%	6%	16%	19%	-4%	2%	68	508	439	130.05	91.03
2013	26%	7%	19%	25%	-6%	2%	59	754	694	160.16	107.27
2014	12%	1%	11%	35%	-24%	2%	80	563	484	215.74	119.28
2015	-20%	1%	-21%	15%	-37%	0%	6	(1,202)	(1,208)	248.41	93.97
2016	-13%	-6%	-6%	0%	-7%	1%	45	(290)	(334)	248.45	87.48
							$ 304	$ 731	$ 428		

Growth vs 2007	
WAC	NET
15.4%	12.4%
27.8%	22.0%
39.9%	25.3%
52.8%	29.7%
80.7%	48.7%
122.6%	75.2%
199.8%	94.8%
245.2%	53.5%
245.2%	42.9%

It is clear that WAC prices have not kept up with the growing size of rebates, discounts, and other fees, putting pressure on pharmaceutical manufacturers' margins. The Committee found examples of manufacturers recognizing this market dynamic and seeking to make up for lost revenue elsewhere. For example, in 2014, senior officials in Eli Lilly's diabetes business unit were preparing to warn company executives "that the ability to pull the US price lever for Humalog to cover a gap in the overall corporate plan does not exist."[221] Another employee in the exchange observed, "[t]his is an interesting picture –list prices going way up and so are rebates– after these major changes … our net prices are flat."[222] His colleague responded, "Exactly. And to expect it to grow again in a meaningful way would be a huge planning risk."[223]

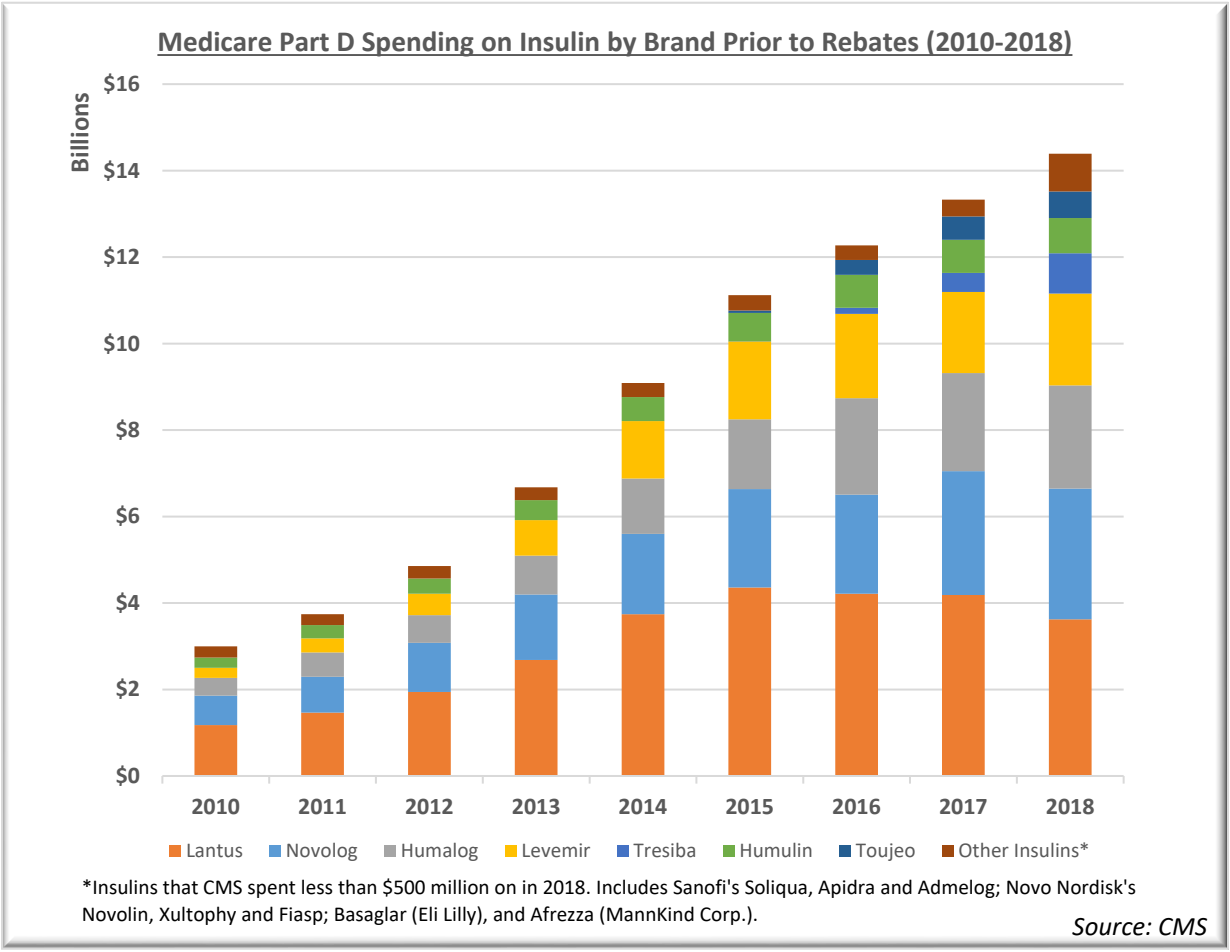
b. Medicare Part D's Pre-Rebate Spending on Insulin has Risen Steadily Since 2010

CMS provided the Finance Committee with data that show the growing amount of money that Medicare Part D plans have paid for insulin, prior to rebates and other discounts, since 2010. Rebates negotiated by Part D plans are treated as confidential information by Federal law,

[221] LLY-SFCOM-UR-00003170.
[222] LLY-SFCOM-UR-00003170.
[223] LLY-SFCOM-UR-00003170.

therefore, this analysis examines spending before rebates.[224] Spending before rebates is an important data point to consider, as patients' out-of-pocket costs are affected in part by a drug's WAC price before rebates, discounts, and other fees are included.

Based on data provided by CMS, annual spending on insulin has increased by billions of dollars over the last decade. Between 2010 and 2018, Medicare Part D spent $78.4 billion on insulin prior to rebates, the majority of which was spent on Lantus ($27.4 billion), Novolog ($16.5 billion), Humalog ($12.3 billion), and Levemir ($11 billion).[225]



The growth of CMS's pre-rebate spending on insulin also significantly outstripped the growth rate of beneficiaries utilizing insulin from 2010 to 2018. For instance, the number of Part

[224] According to Medicare actuaries, the average rebate negotiated by Medicare Part D plan sponsors for all drugs has increased substantially in recent years. 2020 ANNUAL REPORT OF THE BOARDS OF TRUSTEES OF THE FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUNDS (2020), https://www.cms.gov/files/document/2020-medicare-trustees-report.pdf.

[225] During this investigation, the Committee received data from CMS on insulin spending on Medicare Part B and D. Spending for Medicare Part B drugs also increased between 2010 and 2018. For example, in 2010, the Federal government spent $14 million prior to rebates on insulin drugs administered by a physician and covered by Medicare Part B. By 2018, the Federal government reported spending over $96 million prior to rebates on Medicare Part B insulin payments—representing an increase of approximately 585% in less than 8 years.

D beneficiaries using insulin increased 51%, from over 2.1 million in 2010 to approximately 3.2 million in 2017, whereas spending on insulin prior to rebates increased more than 470%, from over $3 billion in 2010 to roughly $14.3 billion in 2018. To put this into perspective, the $11 billion increase in pre-rebate annual spending on insulin over those eight years is roughly equal to the total proposed budget of the Federal Transit Administration for Fiscal Year 2021.[226]

c. Patient Out-of-Pocket Spending in Medicare Part D

As noted above, rising WAC prices can increase a patient's out-of-pocket costs. However, out-of-pocket costs vary widely due to multiple factors, including WAC price, dosage quantity, days' supply, formulary and utilization management decisions made by the health plan, and the relevant coverage phase of the Part D benefit.[227] A recent study published in *The New England Journal of Medicine* breaks down the considerable costs faced by Part D beneficiaries using insulin:

> When examining strategies for making insulin more affordable for older adults, it is important to consider how Part D plans currently cover insulin. Of the 3649 outpatient prescription-drug plans that were available to Medicare beneficiaries (Part D plans) in 2019, we found that nearly 90% offered long-acting insulin products (the most commonly used insulin in Part D) with copayments ranging from $45 to $47 per fill in the initial coverage phase (up to $4,020 in total drug spending in 2020) of the Part D benefit. We expect benefit designs to be similar for 2020 plans. Thus, for beneficiaries with less than $4,020 in total drug spending in 2020, copayments would be used for every insulin fill. For beneficiaries with more than $4,020 in total drug spending (average monthly drug costs of more than $335), nearly all plans required 25% coinsurance in the Part D coverage gap, with median out-of-pocket costs ranging from $72 to $236 per fill in this benefit phase. Considering average list prices, patients with typical Part D plans who use long-acting insulin and have no other drug expenditures would spend $1,140.68 out of pocket on 12 fills of insulin ($46.00 per fill for about 6.5 fills in the initial coverage phase and $153.75 per fill for the remaining fills in the coverage gap).[228]

However, a patient's out-of-pocket costs are likely higher, as a majority of diabetics also utilize short-acting, rapid-acting, and/or intermediate-acting insulins, buy test-strips and other medical devices, and take medications for other comorbidities (e.g., hypertension or renal disease).[229] Indeed, based on Part D gross drug cost data collected from CMS, in 2018, more than a quarter of patients enrolled in Medicare Part D spent upwards of $5,000 a year on their

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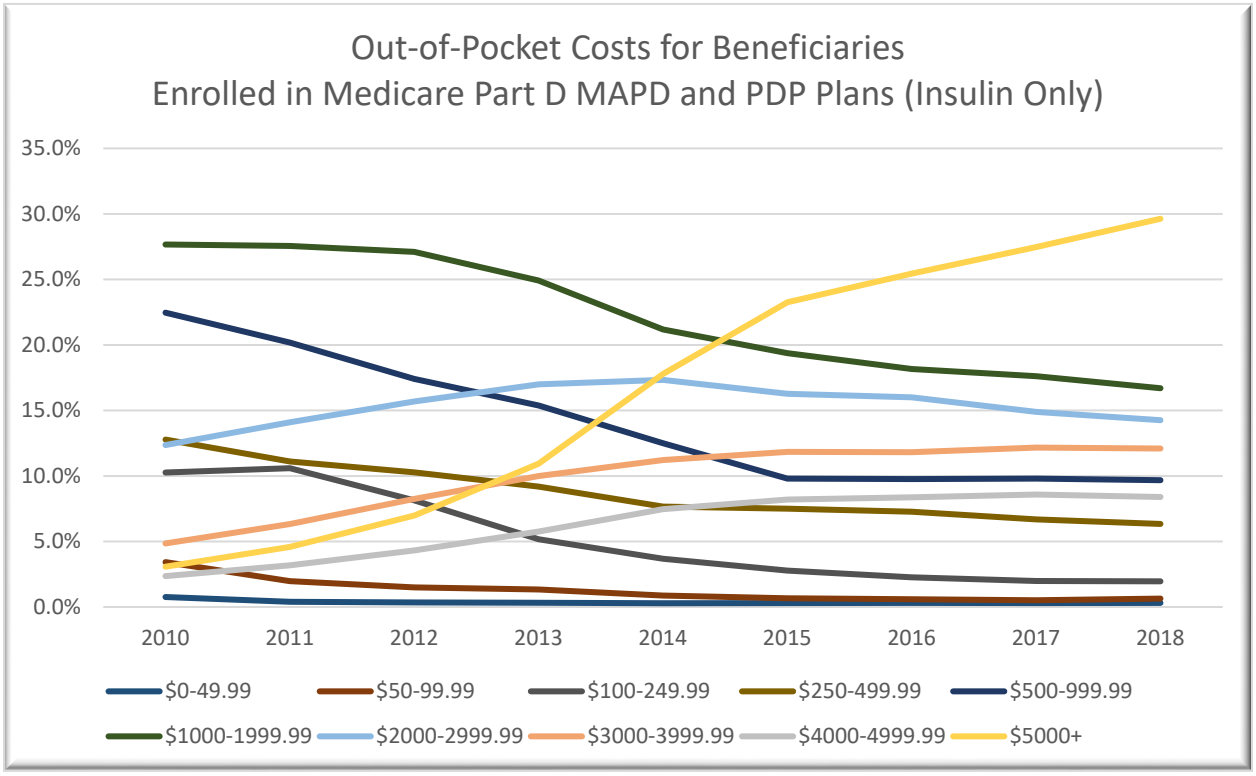
[226] *See* PRESIDENT DONALD J. TRUMP'S FY 2021 BUDGET TITLED: A BUDGET FOR AMERICA'S FUTURE, https://www.whitehouse.gov/wp-content/uploads/2020/02/budget_fy21.pdf.
[227] Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Apr. 20, 2019).
[228] Stacie B. Dusetzina et al., *Medicare Part D and Insulin Affordability—The Devil is in the Details*, N. ENG. J. MED. 1878, 1878 (Apr. 1, 2020).
[229] *Type 1 diabetes*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/type-1-diabetes/diagnosis-treatment/drc-20353017(last viewed Jan. 4, 2021); *Type 2 diabetes*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/type-2-diabetes/diagnosis-treatment/drc-20351199 (last viewed Jan. 1, 2021).

insulin medications.[230] This represents a dramatic increase in out-of-pocket spending compared to 2010 where a majority of Medicare Part D patients spent $2,000 or less.



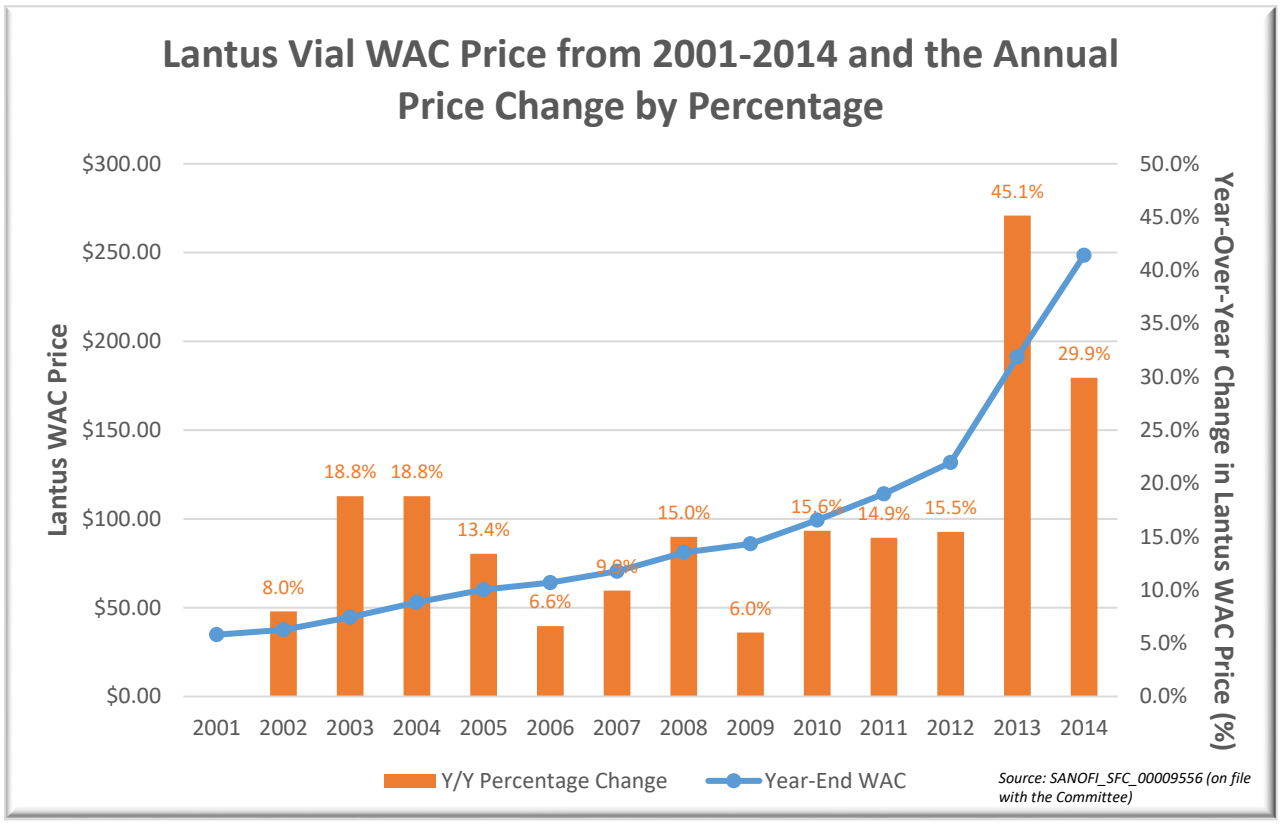
Documents produced to the Committee show that rebates, administrative fees and other price concessions are significant factors affecting how manufacturers determine WAC prices. In the insulin therapeutic class, PBMs consider insulins to be interchangeable in their safety, efficacy, and kinetics.[231] It has also become increasingly common for PBMs and health insurers to offer only one line of insulin products on their formularies while excluding the rest.[232]

d. A Case Study: Examining Sanofi and Novo Nordisk's Decision to Implement Aggressive List Price Increases and the Impact on the Long-acting Insulin Market

Sanofi's decision to significantly increase Lantus's list price between 2001 and 2014 contributed to the dramatically increasing cost of long-acting insulins over the past decade. Sanofi manufactures two long-acting insulins under the trade names Lantus and Toujeo,[233] in

[230] During this investigation, we collected data from CMS on insulin spending on Medicare Part C and D gross drug costs by coverage type. Medicare Part D prescription drug events contain prescription drug costs and payment data that enable CMS to make payments to plans. Using this data, CMS was able to calculate gross drug costs for insulin drugs from 2012 through 2018.
[231] *See* Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Apr. 16, 2019).
[232] Letter from Joseph B. Kelly, Vice President, Global Government Affairs, Eli Lilly, to Senator Grassley and Senator Wyden (Mar. 8, 2019).
[233] Sanofi manufactures insulin glargine, a type of long-acting insulin that mimics the flat profile of insulin released from a healthy pancreas. *See* Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, to Senator Grassley and Senator Wyden (Mar. 8, 2019).

addition to rapid-acting insulins Apidra and Admelog (a biosimilar of the mealtime insulin Humalog).[234] According to internal documents and correspondence acquired by the Committee, Sanofi's intent behind Lantus's price increase centered on its objective to maximize profits, ensure the overall long-term success of its diabetes franchise, and respond to aggressive rebate and discount activity from Novo Nordisk and PBMs.[235]



According to internal data, Lantus's WAC price was $34.81 in 2001.[236] See graph above. From 2005 to 2011, internal memoranda show Sanofi increased Lantus's list price as much as 18% annually.[237] However, between 2012 and 2014, Sanofi increased Lantus's list price at a rate significantly higher than it had done previously. For example, Sanofi increased Lantus's list price three times in 2013 alone—on April 26, 2013, August 2, 2013, and December 13, 2013—resulting in a total increase of approximately 39.7% for Lantus vials and 29.7% for Lantus pens.[238] Data provided to the Committee by Sanofi show the company increased Lantus's price two more times in 2014 and, by December 1, 2014, Lantus cost $248.51 per vial, and Lantus pens cost $372.76 per package.[239] However, Sanofi's decision to increase Lantus's list price was

[234] *See* Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, to Senator Grassley and Senator Wyden (Mar. 8, 2019).
[235] SANOFI_SFC_00009132, at SANOFI_SFC_00009135.
[236] SANOFI_SFC_00009556.
[237] This figure represents Lantus's average WAC increase between 2005 and 2011 on a percentage basis. *See* SANOFI_SFC_0011407, at SANOFI_SFC_00011416.
[238] SANOFI_SFC_00014580, at SANOFI_SFC_00014582; NNI-FINANCE-001699, at NNI-FINANCE-001701.
[239] *See* Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, to Senator Grassley and Senator Wyden (Mar. 8, 2019) (attachment 1(a) and (b)).

not without consequences. In the run-up to rebate negotiations with Express Scripts in 2015, Sanofi noted that "Lantus price increases over the past two years have positioned Sanofi as a cost driver that has triggered significant attention from [Express Scripts]."[240]

According to an internal memo created by Sanofi in 2013/2014, the company took aggressive pricing actions for several reasons. First, Sanofi sought to retain as many diabetes patients as possible in advance of future pipeline expansion and product competition and, in 2013, decided to close the price differential between Lantus vials and Lantus pens on a per unit basis.[241] By setting a single price point for Lantus, and by launching Toujeo—its next-generation concentration of insulin glargine—at WAC parity to Lantus, Sanofi believed that it would remove cost as a barrier for switching patients to Toujeo to become the preferred basal insulin.[242] The diabetes franchise was—and remains—extremely important to the company, with Sanofi describing Lantus as a "flagship product" of its diabetes division, accounting for revenue of €4.9 billion in 2013, equal to 14.2% of the company's revenue that year.[243] According to Sanofi, if Lantus were to encounter product challenges, such as pressure from existing competitive products or a reduction in sales, the adverse impact to Sanofi's business "could be significant."[244]

Second, Sanofi raised Lantus's list price to respond to rebate and discount competition from Novo Nordisk. Novo Nordisk manufactures two long-acting insulins under the trade names Levemir and Tresiba as well as two rapid-acting insulins NovoLog and Fiasp.[245] In the long-acting insulin category, Lantus and Levemir often compete to win the same accounts. According to internal memoranda, in 2013, Sanofi believed that Novo Nordisk was attempting to minimize the clinical difference between Lantus and Levemir and was offering "increased rebates and/or portfolio offers for the sole purpose of removing Lantus from favorable formulary access."[246] According to an internal Sanofi memo, "the strategy to close the price differential between the Lantus vial and pen before the LOE [loss of exclusivity] period was believed to be critical to the overall long-term success of the franchise."[247]

Third, Sanofi also faced increased pressure from its payer and PBM clients to offer more generous rebates and price protection terms or face exclusion from formularies, developments that were described as "high risk for our business" that had "quickly become a reality."[248] These insurance market changes were partly driven by the implementation of the ACA, which put pressure on plan margins, and a willingness by plans to exclude drugs from their formularies as a negotiating tool.[249] This market environment created an enormous challenge for Lantus and, in order to protect its flagship diabetes franchise, Sanofi appears to have increased Lantus's list

[240] SANOFI_SFC_00014648, at SANOFI_SFC_00014653.
[241] SANOFI_SFC_00009132, at SANOFI_SFC_00009135.
[242] SANOFI_SFC_00009377, at SANOFI_SFC_00009378, SANOFI_SFC_00009388-89.
[243] Sanofi 20-F, page 8 (2013). Sanofi reported revenue to the Securities and Exchange Commission in Euros. €4.9 billion is approximately $5.96 billion in today's dollars.
[244] Sanofi 20-F, page 8 (2019); Sanofi 20-F, page 8 (2013).
[245] *See* Letter from Raphael Prober, Counsel, Akin Gump, on Behalf of Novo Nordisk, to Senator Grassley and Senator Wyden (June 28, 2019).
[246] *See* SANOFI_SFC_00009211, at SANOFI_SFC_00009217. Sanofi believed that Novo Nordisk was offering rebates as high as 53% on Levemir during this time. SANOFI_SFC_00009132, at SANOFI_SFC_00009140.
[247] SANOFI_SFC_00009132, at SANOFI_SFC_00009135.
[248] SANOFI_SFC_00009132, at SANOFI_SFC_00009135.
[249] SANOFI_SFC_00009132, at SANOFI_SFC_00009132-33.

price so that it could improve its rebate and discount offering to payers while maintaining net sales.

Sanofi understood the risk of its decision and "went into 2013 with eyes wide open that the significant price increases planned would inflame [its] customers," and that its aggressive pricing actions would cause an immediate reaction from Novo Nordisk.[250] However, it was seeking to make up for "shortfalls with Lantus demand generation and global profit shortfalls" which it said "put pressure on the US to continue with the price increases to cover gaps."[251] The company conceded that it was "difficult to determine whether we would face these risks anyway if we hadn't taken the price increases."[252]

Internal documents and correspondence show that immediately following Sanofi's 2013 pricing actions, Novo Nordisk increased Levemir's list price in lockstep with Lantus in its continued effort to offer increased rebates and discounts to payers and displace Lantus from preferred formulary placement.

i. In 2014, Novo Nordisk Engaged in Shadow Pricing to Respond to Sanofi's 2013 Pricing Actions

The cornerstone of Novo Nordisk's pricing strategy was to follow Sanofi's actions—a practice that has been referred to as "shadow pricing."[253] Industry observers have described shadow pricing as a phenomenon of "price increases on related brands of aging products from competing companies that often seem to move in synchronized fashion," that "are not tied to the health care inflation rate or cost of goods, but seemingly to the ability of insurance payers and consumers to pay."[254] The practical effect eliminates any meaningful or sustained price variation between Sanofi and Novo Nordisk's basal insulins, which at the time were the only basal insulins available to patients.

Internal documents show that Novo Nordisk's U.S. Pricing Committee (USPC), which makes pricing recommendations for insulin and other drugs, repeatedly suggested matching competitors' pricing for insulin and other products. For example, on May 19, 2014, Novo Nordisk's USPC discussed how to price Levemir in response to Sanofi's 2013 pricing actions.[255] Based on an internal presentation created for this meeting, Novo Nordisk's USPC discussed

[250] SANOFI_SFC_00009132, at SANOFI_SFC_00009135.
[251] SANOFI_SFC_00009132, at SANOFI_SFC_00009135.
[252] SANOFI_SFC_00009132, at SANOFI_SFC_00009135.
[253] An internal presentation revealed that Novo Nordisk amended its pricing strategy on October 21, 2013, to follow Sanofi's marketing, access and profits movements" to "Maximize Brand Value." NNI-FINANCE-001699, at NNI-FINANCE-001701.
[254] Anurag Rathore & Faheem Shereef, *Shadow pricing and the art of profiteering from outdated therapies*, NATURE BIOTECHNOLOGY (2019), https://www.nature.com/articles/s41587-019-0049-7. *See* also Lydia Ramsey Pflanzer, *There's something off about the way insulin prices change*, BUSINESS INSIDER (Sept. 17, 2016), https://www.businessinsider.com/rising-insulin-prices-track-competitors-closely-2016-9.
[255] NNI-FINANCE-0001699. Pricing decisions for drugs marketed and sold by Novo Nordisk in the U.S. are made by its USPC. Between 2014 and 2019, Novo Nordisk's USPC was comprised of 17 members with 4 voting members responsible for insulin pricing. The four voting members responsible for insulin pricing are: Doug Langa, Executive Vice President, North America Operations, and President of Novo Nordisk; Steve Albers, Corporate Vice President, Market Access and Public Affairs; David Moore, Senior Vice President, Commercial; and, Ulrich Ottee, Senior Vice President, Finance and Operations. *See* Letter from Raphael Prober, Counsel, Akin Gump, on Behalf of Novo Nordisk, to Senator Chuck Grassley and Senator Wyden (Mar. 8, 2019); Letter from Raphael Prober, Counsel, Akin Gump, on Behalf of Novo Nordisk, to Senator Chuck Grassley and Senator Wyden (June 28, 2019).

whether it should be a follower in the market, in relation to Sanofi, and considered external factors like press coverage, payer reactions, profits, and performance.[256] In each case, the company's strategic recommendation was to follow Sanofi's pricing moves, rather than lead.[257] Of note, the presentation shows that the USPC considered Levemir's performance, which was ahead of 2014's annual budgeting by $89 million, but that "overall company performance [is] behind."[258] The presentation appears to recommend following Sanofi's pricing actions if the brand's performance is the priority, and to lead if the company's performance is the priority.[259] An excerpt of Novo Nordisk's presentation is shown below.[260]

Changing and challenging 2014 environment

Today's Environment	Considerations	NNI Strategic Recommendation
1 **SANOFI** • Lilly biosimilar 18-month stay • Improving financial performance	Sanofi doesn't need to be as aggressive	**FOLLOW**
2 **PRESS COVERAGE** • New York Times 4/5 *"Even Small Medical Advances Can Mean Big Jumps in Bills"* • Bloomberg 4/30 *"Drug Prices Defy Gravity, Doubling for Dozens of Products"* • 60 Minutes story late May/June?	Sanofi feeling reputational pressure?	**FOLLOW**
3 **PAYER PRESSURES** • Basal class reviews – big growth in spend • Rebate pressure and price protection	Two key basal negotiations in progress: CVS July, ESI August	**FOLLOW/WAIT**
4 **PROFITS AND PERFORMANCE** • Levemir® ARP ahead of AB14 +$89M • But overall company performance behind	Brand versus Company?	Brand focus → **FOLLOW** Company focus → **LEAD?**

In alignment with this strategy, Novo Nordisk's USPC debated potential pricing scenarios based on Sanofi's actions, which they projected with a great deal of specificity. The presentation provided options regarding whether the company should follow Sanofi—and increase list price in July—or lead with a 9.9% increase in August which it considered "optically less aggressive."[261] Based on internal memoranda, it appears that Novo Nordisk's USPC decided to revisit the issue with specific recommendations once Sanofi took action.[262]

Less than two weeks later, on May 30, 2014, Farruq Jafery, Vice President of Pricing, Contract Operations and Reimbursement, emailed Novo Nordisk's USPC to inform them that

[256] NNI-FINANCE-001699, at NNI-FINANCE-001702.
[257] NNI-FINANCE-001699, at NNI-FINANCE-001702.
[258] NNI-FINANCE-001699, at NNI-FINANCE-001702.
[259] NNI-FINANCE-001699, at NNI-FINANCE-001702.
[260] NNI-FINANCE-001699, at NNI-FINANCE-001702.
[261] NNI-FINANCE-001699, at NNI-FINANCE-001703.
[262] NNI-FINANCE-001699, at NNI-FINANCE-001703.

"Sanofi took a price increase on Lantus effective today: 16.1% vial and 9.9% pen."[263] He further wrote that the USPC had "agreed that the best strategy for Levemir is to observe the market and maintain list price parity to competitors."[264] Mr. Jafery then requested that Novo Nordisk's USPC vote "ASAP" to raise the list price of Levemir effective May 31, 2014 (the next day) from $191.28 to $222.08 for vials and from $303.12 to $333.12 for pens.[265] Only a few hours after Sanofi took its list price increase, members of the USPC approved Mr. Jafery's request and Novo Nordisk moved forward with a 16.1% increase on Levemir vial, and a 9.9% increase on Levemir FlexPen and FlexTouch.[266] An excerpt of Mr. Jafery's email is shown below.[267]

Dear Pricing Committee:

Sanofi took a price increase on Lantus effective today: 16.1% vial and 9.9% pen.

Based on our PC discussion on 5/19/2014, we agreed that the best strategy for Levemir® is to observe the market and maintain list price parity to competitors**.

As such, we will be moving forward with a 16.1% increase on Levemir® vial and a 9.9% increase on Levemir® FlexPen® and FlexTouch® effective tomorrow 5/31/2014. This is the approach which minimizes Price Protection impact in 2015 (avoids $13M in incremental PP rebates vs. taking after 6/1/14).

As we need to move immediately to ensure the increase is operationalized in time, please reply back ASAP. We have discussed the impact with Brand and Trade on FlexTouch launch and with Market Access on impact on ongoing negotiations. Although this will generate some pushback from customers, it is believed that this can be managed to mitigate negative impact.

Note that the RE2 forecast assumed 14.9% vial and 9.9% pen, so the ARP upside from this increase is +$32.3M vs RE2 and +$125.9M vs AB14.

List prices resulting from the proposed increase are shown in the table below:

NDC#	Product Name	Current WAC/pkg	Pct Change	WAC/pkg	Effective Date*
00169-3687-12	Levemir®	$191.28	**16.1%**	**$222.08**	5/31/2014
00169-6438-10	Levemir® FlexTouch®	$303.12	**9.9%**	**$333.12**	5/31/2014
00169-6439-10	Levemir® FlexPen®	$303.12	**9.9%**	**$333.12**	5/31/2014

** or as soon as operationally feasible upon approval.*

*** Prior to taking any price increase, Novo Nordisk undertakes a review of all factors relevant to the price increase to ensure that the increase remains consistent with brand pricing strategy.*

Kind regards,
Farruq

By following Sanofi's actions, Novo Nordisk stood to make an additional $125 million in revenue above its baseline estimates for the year.[268] Mr. Jafery noted that the company's second quarter forecast assumed only a 14.9% price increase for vials. Therefore, by following Sanofi's 16.1% increase, the "ARP [annual revenue projection] upside … is +$32.3M in RE2 and

[263] NNI-FINANCE-001713, at NNI-FINANCE-001714. Based on internal memoranda, Sanofi increased Lantus's list price because Lantus was at WAC parity with Levemir. Sanofi believed that the increase would provide a financial upside and bring vial and pen to WAC parity. SANOFI_SFC_00014580.
[264] NNI-FINANCE-001713, at NNI-FINANCE-001714.
[265] NNI-FINANCE-001713, at NNI-FINANCE-001714.
[266] NNI-FINANCE-001713, at NNI-FINANCE-001714.
[267] NNI-FINANCE-001713, at NNI-FINANCE-001714.
[268] NNI-FINANCE-001713, at NNI-FINANCE-001714.

+$125.9M vs AB14."[269] In the same email chain, one USPC member asks whether Novo Nordisk would "pass on" the price increase to CVS's commercial book of business.[270] Mr. Jafery again signaled that the company would follow Sanofi's lead:

> Since we have heard that Sanofi is not passing this through to CVS Commercial, the recommendation is to follow course and not pass on to their commercial book so as not to disadvantage us in the current negotiations. For their Part D business, we have not heard anything yet to indicate that Sanofi is not passing on. In the event of major pushback on the Part D side, we would need to assess implications and decide whether to pass on or not. By taking this by 6/1, this at least provides us this option.[271]

The back-and-forth between Novo Nordisk officials underscores how closely it was monitoring Sanofi's actions, and appears to mirror the approach laid out in a January 27, 2014 presentation regarding the company's bidding strategy that hinged on CVS's Part D business.[272] Novo Nordisk described its bids for the Part D business as "pivotal," and laid out a game of cat-and-mouse across different accounts in which company officials sought to have Levemir be the only therapeutic option on different PBM formularies.[273] Novo Nordisk recognized that offering "attractive exclusive rebates to large, receptive customers" [274] would "encourage a stronger response from Sanofi."[275] However, Novo Nordisk was willing to take this risk because it would result in "immediate volume and value" for the company and could lead to an exclusive deal for CVS's commercial formulary.[276]

Another series of emails show that Novo Nordisk again shadowed Sanofi's price increase in November 2014, increasing Levemir's list price immediately after Sanofi increased Lantus vials and pens by 11.9%. [277] On the morning of November 7, 2014, Novo Nordisk's USPC learned that Sanofi increased Lantus's list price overnight.[278] (An excerpt of this email is shown below.)[279] And, by the afternoon they were asked to approve the same exact price increase for Levemir, which was approved hours later.[280]

[269] NNI-FINANCE-001713, at NNI-FINANCE-001714.
[270] NNI-FINANCE-001713.
[271] NNI-FINANCE-001713. Emphasis included in the original.
[272] NNI-FINANCE-001939.
[273] NNI-FINANCE-001939.
[274] NNI-FINANCE-001939, at NNI-FINANCE-001941.
[275] NNI-FINANCE-001939, at NNI-FINANCE-001945.
[276] NNI-FINANCE-001939, at NNI-FINANCE-001945.
[277] NNI-FINANCE-001719-20.
[278] NNI-FINANCE-001719-20.
[279] NNI-FINANCE-001719-20.
[280] NNI-FINANCE-001719-20.

From: RDZI (Rich DeNunzio)
Sent: Friday, November 07, 2014 4:03 PM
To: LAG (Lars Green); JESH (Jesper Hoiland); CLEE (Camille Lee); ANAJ (Andy Ajello); CUOT (Curt Oltmans); PFO (Phil Fornecker)
Cc: SEAP (Sean Phillips); DUGL (Doug Langa); FAJA (Farruq Jafery); KAYE (Karen Yee); BKNO (Bill Knott); BBRT (Bill Breitenbach)
Subject: Approval Requested: Levemir Price increase

Dear Pricing Committee,

As stated earlier this morning, we found out, via Trade, that Lantus has taken an 11.9% increase on both their vial and device and we would follow up with a vote post analysis on the optimal time of the increase.

After analyzing the additional cost of rebates and price protection, based on specific contracting terms, it was determined that it makes better financial sense **(~+$10M benefit)** to wait until after the 45th day of the quarter (11/18 is the first feasible date for the increase) vs increasing price today (effective 11/8). **Therefore, we are asking for your approval to follow their 11.9%** on November 18th** (first feasible increase date post the 15th). Approving this request will have a **benefit to 2014 of ~$25M.**

Please respond with your approval prior to November 13th. Please reach out if you have any questions.

Have a nice weekend,
Rich

*** Prior to taking any price increase, Novo Nordisk undertakes a review of all factors relevant to the price increase to ensure that the increase remains consistent with brand pricing strategy.*

NDC#	Product Name	Current WAC/pkg	Pct Change	WAC/pkg	Effective Date
00169-3687-12	Levemir® 10mL vial	$222.08	11.9%	$248.56	11/18/2014*
00169-6438-10	Levemir® FlexTouch® - 5x3mL	$333.12	11.9%	$372.76	11/18/2014*

** or when operationally feasible upon approval.*

The speed with which Novo Nordisk reacted to Sanofi's price changes is notable. Within 25 minutes after learning of Sanofi's price increase, Rich DeNunzio, Senior Director of Novo Nordisk's Strategic Pricing, emailed Novo Nordisk's USPC to alert them of the change and promise a recommendation the same afternoon after reviewing the financial impact of any move.[281] By late afternoon, Mr. DeNunzio had requested Novo Nordisk's USPC "follow [Sanofi's] 11.9% [list price increase] on November 18th" and vote to increase Levemir's list price, which was promptly approved by Novo Nordisk's chief financial officer for U.S. operations, Lars Green. [282]

ii. In 2015, Novo Nordisk Ended its Shadow Pricing Strategy to Set Up a New Basal Insulin Therapy, Tresiba

After more than a year and a half shadowing Sanofi's insulin pricing, Novo Nordisk adopted a new pricing strategy. According to a series of emails sent in 2015, Novo Nordisk's leadership changed their basal insulin strategy in anticipation of launching Tresiba—Novo Nordisk's second generation basal insulin that was a follow-on product to Levemir. The company wanted to ensure that they set a high basal insulin price floor from which to launch

[281] NNI-FINANCE-001719-20.
[282] NNI-FINANCE-001719. Emphasis included in the original.

Tresiba's initial list price.[283] In order to do so, Novo Nordisk broke with its shadow pricing strategy and increased the price of Levemir, independent of a Lantus increase.

In June 2015, Novo Nordisk officials debated increasing Levemir's price increase in July, to set up Tresiba during negotiations with Express Scripts and CVS Caremark for the 2016 contract year.[284] Doing so would be a departure from following Sanofi. Bill Breitenbach, Vice President of Basal Portfolio Marketing, wrote:[285]

> Good morning,
>
> I spoke with Doug last night about the CVS and ESI 2016 negotiations and it appears they should be completed by the end of June. With that in mind, I recommend we pull forward the Levemir price increase to July 1st. Taking an increase in July 1st will be 7 months since our last and given the timing we can take a leadership position. The sooner we take the increase the better positioned we'll be in the market place and for the potential launch of Tresiba. I see more downsides by waiting until September vs moving now.
>
> Thoughts?
>
> BR,
>
> Bill

Mr. DeNunzio, pushed back, arguing there was little upside "outside of the few months of added revenue."[286] He further added that, by allowing Lantus to lead, Novo Nordisk would be better positioned as they launched Tresiba with "payers still on our side in basal and not fighting Tresiba."[287] An excerpt of this exchange is shown below.[288]

> On Jun 2, 2015, at 8:20 PM, RDZI (Rich DeNunzio) <rdzi@novonordisk.com> wrote:
>
> Thanks Bill.
>
> I'm sure I'm swimming upstream on this one, as it sounds like JESH okay moving, but I would hold until September. Assuming we gain tresiba approval, I think we'll launch at the same price if we take increase in July vs September, so because of that and this isn't aligned to strategy (follow lantus and no sooner than 9 months), i don't see the upside outside of the few months of added revenue. I feel we could be better positioned allowing lantus to lead, let them be the bad guys again, and as we launch tresiba we do so into what could be good situation - open environment and payers still on our side in basal and not fighting tresiba. So potentially short term upside of a few months could hinder longer term opportunity and I think fast access/uptake with tresiba could outweigh '15 gain.

In August 2015, as contract negotiations with CVS Caremark came to a close, the question of leading or following on insulin prices came up again. On August 6, 2015, Mr. DeNunzio—who earlier in the year had advocated for Novo Nordisk getting out ahead of Sanofi on insulin pricing—sent an email to Novo Nordisk's USPC asking if there was any appetite to delay Levemir's next scheduled price increase on August 18, 2015.[289] He further noted that

[283] *See* NNI-FINANCE-001732.
[284] NNI-FINANCE-001771.
[285] NNI-FINANCE-001771.
[286] NNI-FINANCE-001771.
[287] NNI-FINANCE-001771.
[288] NNI-FINANCE-001771.
[289] NNI-FINANCE-001792, at NNI-FINANCE-001793-94.

"LRS said he would recommend waiting due to [the public relations] risk of leading."[290] ("LRS" appears to stand for Lars Rebien Sorensen, Novo Nordisk's former CEO). Mr. Sorensen's view deviated from other senior executives, including "LAG" (Lars Green, SVP and CFO of Novo Nordisk U.S.) and "JESH" (Jesper Hoiland, President and Executive Vice President U.S.), who were "aligned to take [the price increase] now." [291]

In response to Mr. DeNunzio's email, some Novo Nordisk officials raised concerns that CVS, a major account, would push back on the pricing increase.[292] After several back-and-forth emails—and apparently additional behind-the-scenes discussion—the company struck a compromise on the timing of the price increase that would ultimately move Novo Nordisk to get ahead of Sanofi on insulin pricing. Mr. DeNunzio elaborated:[293]

> Lars informed me today that him and Jesper were having a conversation on Levemir and that they have to "manage their stakeholders", which I'm interpreting as ExecMan. ExecMan agreed to take a Levemir a price increase to set up Tresiba, however they have concerns this far ahead of launch/approval (and they want us to be confident of approval before moving/leading with Levemir).
>
> With this said, Jesper and Lars suggested we take an increase with an 8 in front of it, to appease our internal stakeholders (justification is us showing the market we're not going to take double digit increases here anymore), but still moving on the 18th to hit what's in RE2 and 3. I then informed Lars of CVS issue and PrePC thoughts (minus Doug's).

One senior vice president went along with the decision, but expressed his reservations about moving away from the shadow pricing strategy:[294]

> In the end as I have stated all along, I don't believe that we should be leading with price increases. Again, I understand the rationale (certainly as it impacts next generation products) but I think that it hurts the message that we have been sending to the market and a bit of our credibility with payers.

However, any question about the motivation of moving away from shadow pricing are erased in the final approval request to the USPC. On August 14, 2015—just a few days after requesting their input—Mr. Jafery sent an email to the USPC requesting their final approval to execute an 8.2% price increase on Levemir, effective August 25, 2016. According to Mr. Jafery, "the proposed timing and magnitude is slightly later and lower than what we had previously agreed too, but it balances the concerns of ExecMan while also meeting our strategic objectives which are outlined below."[295] ("ExecMan" refers to Novo Nordisk's "Executive Management" team, which is made up of the company's CEO and his direct reports, which are typically executive vice presidents.) An excerpt of this email is shown below.[296] The USPC agreed to Mr. Jafery's proposal that same day.[297]

[290] NNI-FINANCE-001792, at NNI-FINANCE-001793-94.
[291] NNI-FINANCE-001792, at NNI-FINANCE-001793-94.
[292] *See* NNI-FINANCE-001792-94.
[293] NNI-FINANCE-001792.
[294] NNI-FINANCE-001792.
[295] NNI-FINANCE-001801-02.
[296] NNI-FINANCE-001801-02.
[297] NNI-FINANCE-001801-02.

Rationale:

Timing is important for executing our Tresiba® premium strategy. With FDA approval anticipated late September (or early October) and "soft launch" in mid-November, we want to ensure a Levemir® price increase sooner rather than later to allow enough time for competition to assess and potentially respond in advance of Tresiba® launch.

- HQ asked us to consider delaying the price increase to as close as possible to Tresiba® launch, however, they ultimately agreed that we should use our best judgment to set up Tresiba® for success.
- From a Levemir® access perspective, we have confirmation that Levemir® will remain on formulary in 2016 at CVS and ESI.
- The price increase is still timed to minimize rebate and price protection impact (many of our contracts have language whereby the rebate and price protection are based on our WAC as of mid-point of the quarter). Note that CVS has pushed back on the timing of our list price increases and demanded changes in contract language which will take effect 1/1/16 to address this. We're finalizing the amendment language which is expected to be signed before 8/25.

Magnitude is within industry norms and is lower than recent history in the basal market.

- It sends a signal to stakeholders that we're cognizant of the public discourse around manufacturer price increases.
- The financial impact to 2015 is negligible given that we have CPP of 8%; downside impact to 2016 is ~$11M (vs. RE2 assumption).

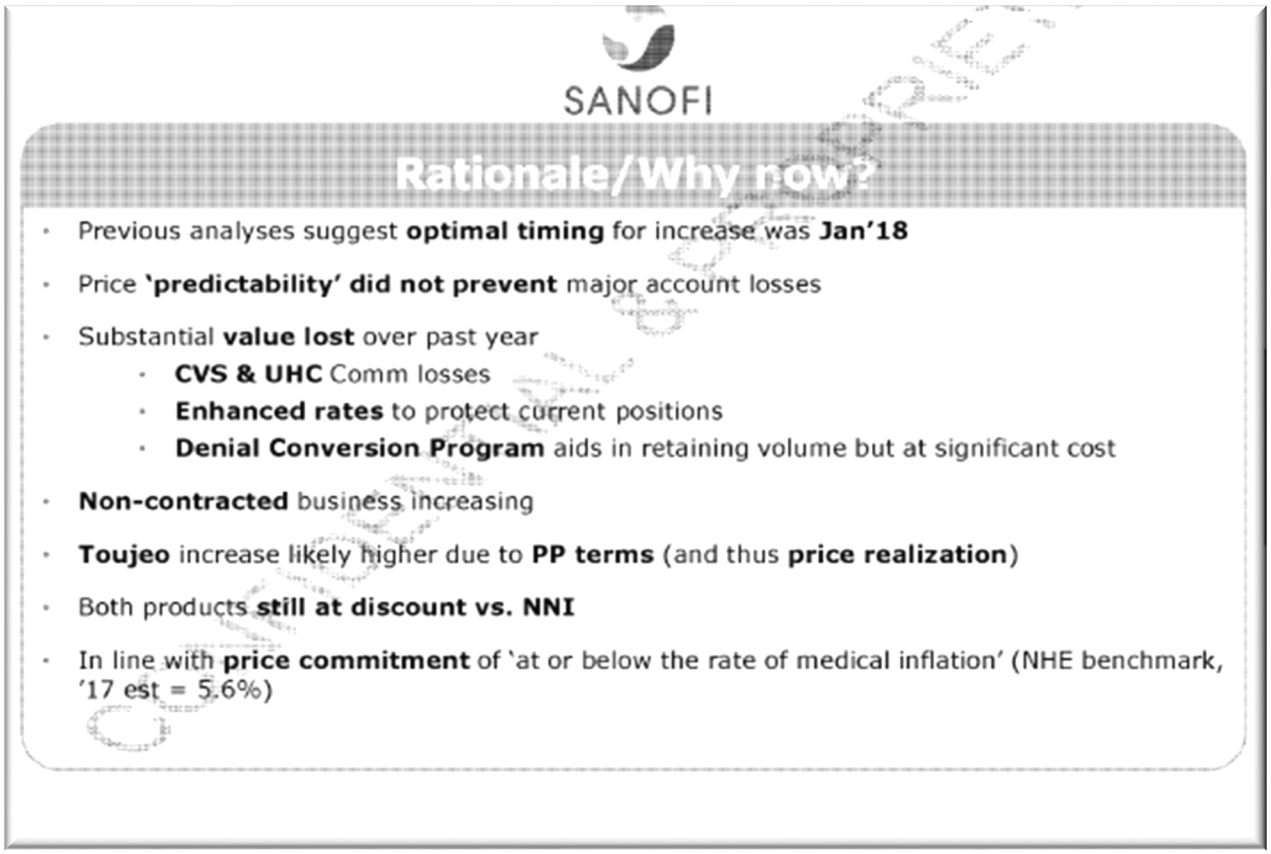
Internal correspondence and memoranda show that Novo Nordisk did not increase Levemir's list price for at least two years following its August 2015 pricing actions and remained the basal pricing leader over Sanofi until 2017. However, Novo Nordisk resumed its strategy of following, rather than leading, Sanofi's pricing actions in 2017 when Sanofi began to increase the price of Lantus.[298]

iii. In 2017 and 2018, Novo Nordisk Resumed Shadow Pricing to Respond to Sanofi's Pricing Actions

Based on data collected for this investigation, Novo Nordisk continued to increase list prices in response to Sanofi's pricing actions. On October 1, 2017, Sanofi increased Lantus's list price by 3% to $256 for vials and $384 for pens, respectively, and Toujeo's list price by 5.4% to $354.[299] Roughly three weeks later, on October 26, 2017, Novo Nordisk's USPC called a "special" USPC meeting to discuss Sanofi's pricing action.[300] During this meeting, Novo Nordisk's USPC debated why Sanofi took a list price increase in October when their "previous analysis suggest optimal timing for increase was Jan'18 [sic]."[301] (An excerpt of the presentation used during this meeting is shown below.)[302] Novo Nordisk believed that Sanofi was forced to pay enhanced rebates and price protection terms to its payer and PBM clients over the past year to protect its current formulary position.[303] In alignment with the list price approach endorsed by its USPC, Novo Nordisk recommended that the company follow Sanofi and take a 4% list price

[298] Internal WAC data shows that Sanofi did not take another list price increase on its long-acting insulins until October 1, 2017. *See* Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, to Senator Grassley and Senator Wyden (Mar. 8, 2019) (attachment 1(a) and (b)).
[299] NNI-FINANCE-003621; NNI-FINANCE-003624, at NNI-FINANCE-003626. *See* Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, to Senator Grassley and Senator Wyden (Mar. 8, 2019) (attachment 1(a) and (b)).
[300] NNI-FINANCE-003621.
[301] NNI-FINANCE-003621; NNI-FINANCE-003624, at NNI-FINANCE-003626.
[302] NNI-FINANCE-003624, at NNI-FINANCE-003626.
[303] NNI-FINANCE-003624.

increase to $279.76 for vials and $419.64 for pens, respectively, in January 2018, which was "approved as recommended on November 3, 2017."[304]

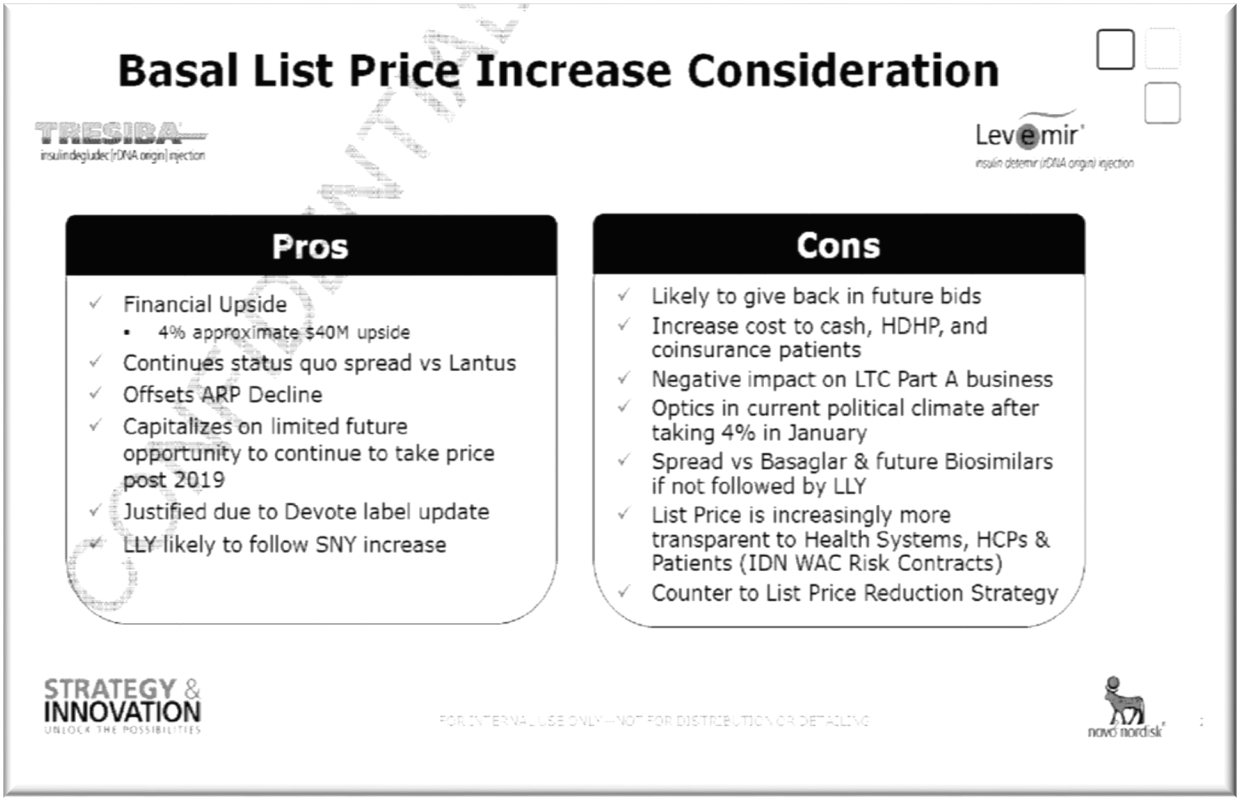


On April 13, 2018, Sanofi again increased the list price of its long-acting insulins by 5.3%, effective May 1, 2018.[305] At this point, the list price of Lantus vials was $269.54 and the price of Lantus pens was $404.29.[306] Based on internal memoranda, it is clear that Novo Nordisk's USPC believed that Sanofi's latest price increase put Levemir at a disadvantage in negotiations with health insurers and their PBMs. On April 19, 2018, Novo Nordisk's USPC recommended another "4% increase on both Levemir and Tresiba."[307]

According to internal memoranda prepared in advance of an April 20, 2018 executive management meeting, Novo Nordisk rationalized its decision with a pro-con list, noting that a 4% increase would result in $40 million gain in revenue and capitalize on "limited opportunities to take price [increases]" with multiple insulin glargine biosimilars on the horizon.[308] The price increase would also stay within Novo Nordisk's commitment to not raise list prices more than 9.9%.[309] This commitment was only taken after the company had spent years dramatically

[304] NNI-FINANCE-000002-03; NNI-FINANCE-003621; NNI-FINANCE-002950.
[305] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, to Senator Grassley and Senator Wyden (Mar. 8, 2019) (attachment 1(a) and (b)). *See also* NNI-FINANCE-003191, at NNI-FINANCE-003192.
[306] *See* Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, to Senator Grassley and Senator Wyden (Mar. 8, 2019) (attachment 1(a) and (b)).
[307] NNI-FINANCE-003190; NNI-FINANCE-003191-92.
[308] NNI-FINANCE-003190; NNI-FINANCE-003191-92.
[309] NNI-FINANCE-003190; NNI-FINANCE-003191-92.

raising insulin's WAC on which its percentage increases were based. However, the company also noted "cons" which included the increased "cost to cash, [high deductible health plan], and coinsurance patients," a "negative impact on [long-term care] Part A business," and "optics in the current political climate after taking a 4% increase in January."[310] An excerpt of Novo Nordisk's pro-con list is shown below.[311]

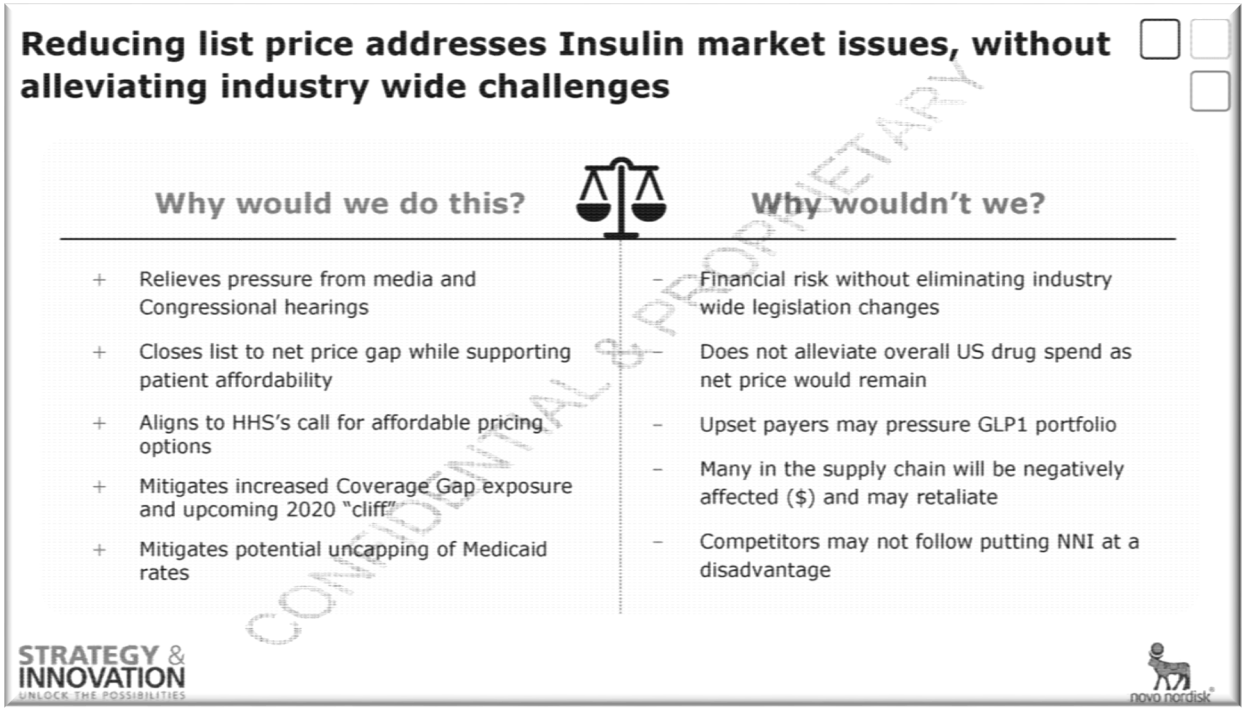


iv. In 2018, Novo Nordisk Discussed List Price Decreases after Feeling Outside Pressure

Following its April 2018 list price increase, Novo Nordisk began to face pressure from payers, the media, and Congress to reduce the price of its insulin drugs.[312] On May 29, 2018, Novo Nordisk's USPC debated whether it should reduce the list price of its insulin drugs by 50% after a string of news reports detailed how patients were struggling to afford their medications.[313] Novo Nordisk believed that a 50% cut would be a meaningful reduction to patients, significantly close the list to net gap, head off negative press attention, and reduce "pressure" from Congressional hearings.[314] However, Novo Nordisk was concerned that a list price reduction

[310] NNI-FINANCE-003190; NNI-FINANCE-003191-92.
[311] NNI-FINANCE-003191.
[312] *See* INSULIN ACCESS AND AFFORDABILITY: THE RISING COST OF TREATMENT, SENATE SPECIAL COMMITTEE ON AGING, 115TH CONG. (2018); Aimee Picchi, *The rising cost of insulin: "Horror stories every day"*, CBS News (May 9, 2018), https://www.cbsnews.com/news/the-rising-cost-of-insulin-horror-stories-every-day/; Irl Hirsh, *Paying the price for insulin*, STAT (May 17, 2018), https://www.statnews.com/2018/05/17/insulin-paying-the-price/.
[313] NNI-FINANCE-002025.
[314] NNI-FINANCE-002025, at NNI-FINANCE-002026-27.

posed significant financial risk to the company.[315] It is noteworthy that the company's primary concerns were retributive action from other entities in the pharmaceutical supply chain, many of which derive payments that are based on a percentage of a drug's WAC price.[316] An excerpt from a memo created for this meeting is show below.[317]



Despite these concerns, internal memoranda suggest that Novo Nordisk was prepared to lower its list price by 2019 or 2020 if its "must haves" were met, which included an agreement from its payer and PBM clients that they would not retaliate against them by changing their formulary placement and would accept lower rebate percentages.[318] It is unclear if Novo Nordisk eventually received an agreement from its payer and PBM clients. However, according to internal memoranda created for Novo Nordisk's USPC, its board of directors voted against this strategy in June 2018 and recommended that the company continue its reactive posture.[319] The rationale for this decision was the "$33 million downside identified (NovoLog only)," "risk of payer backlash or demand for current rebate on new NDC," and "high likelihood of immediate pressure to take similar action on other products."[320] Following the decision by its board of directors, on August 30, 2018, Novo Nordisk decided to continue its strategy to "monitor the market . . . to determine if other major pharma companies are taking list price [increases]."[321] An excerpt from this email is shown below.[322]

[315] *See* NNI-FINANCE-003737.
[316] NNI-FINANCE-002025, at NNI-FINANCE-002026.
[317] NNI-FINANCE-002025, at NNI-FINANCE-002026.
[318] NNI-FINANCE-002025, at NNI-FINANCE-002029.
[319] NNI-FINANCE-003906; NNI-FINANCE-003907-08.
[320] NNI-FINANCE-003906; NNI-FINANCE-003907-08.
[321] NNI-FINANCE-002969.
[322] NNI-FINANCE-002969.

From:	FAJA (Farruq Jafery)
To:	DUGL (Doug Langa); UCO (Ulrich Christian Otte); SALR (Steve Albers); DDME (David Moore); MPDU (Pia D'Urbano)
CC:	CBLE (Craig Bleifer); BKNO (Bill Knott); RDZI (Rich DeNunzio); FCC (Franco Cognata); EDCI (Ed Cinca); ELIV (Elena Livshina); BLMI (Blandine Lacroix); JTCX (Jack Cox)
Sent:	11/21/2018 5:56:47 PM
Subject:	PC Vote - CA Notification of Planned Price Increase for Victoza & Execution of 2019 Planned Price Increases
Attachments:	2019 List Price Alignment.pptx

Dear Pricing Committee,

Please recall that on Aug 30 PC discussion around 2019 list price, PC concluded on the following:

- Monitor the market in 4Q18 and Jan. 2019 to determine if other major pharma companies are taking list price. If the market supports it, we would continue to take a list price increase in 2019 across our portfolio (with the exception of NovoLog, NovoLog Mix and Novolin)
- Continue to stick to our pricing pledge and do not anchor to another benchmark such as NHE (Nat'l Healthcare Estimate)
- Limit any price increases to once per year per brand

In November 2018, Novo Nordisk learned that Pfizer intended to increase the list price for 41 of its products (or 10% of its portfolio) effective January 15, 2019.[323] Novo Nordisk also discovered that Bristol Myers Squibb and Allergan would do the same in January 2019.[324] After learning of these list price increases, Mr. Jafery immediately emailed Novo Nordisk's USPC and requested a vote to move forward with all "other 2019 planned increases effective February 1 instead of June 2019."[325] Novo Nordisk would ultimately proceed with its 2019 planned list price increases and vote to increase Levemir's and Tresiba's list prices by 4.9%.[326] On January 8, 2019, Levemir cost $308.14 per vial and $462.21 for pens.[327]

e. Beyond Long-Acting Insulin: Companies Used Shadow Pricing Across Multiple Product Lines

Novo Nordisk was not the only company that mimicked its competitor's price increases, nor was the practice limited to long-acting insulins. Documents produced by Eli Lilly and Sanofi show that these companies, at a minimum, closely tracked and responded to price increases. For example, on May 30 2014, company officials at Eli Lilly proposed increasing the list prices of Humalog and Humulin by 9.9%.[328] At the time, the list prices for these drugs were $184.30 per

[323] NNI-FINANCE-002969.
[324] NNI-FINANCE-002969; NNI-FINANCE-002971.
[325] NNI-FINANCE-002969; NNI-FINANCE-002971.
[326] NNI-FINANCE-003988; NNI-FINANCE-002063. The investigation sought information from insulin manufacturers between 2013 and 2019. Therefore, the Committee cannot determine whether Novo Nordisk continued to follow Sanofi's list price increases in 2020.
[327] NNI-FINANCE-000002-03.
[328] LLY-SFCOM-UR-00003044, at LLY-SFCOM-UR-00003045.

vial for Humalog and $99.80 per vial for Humulin.[329] In asking for a price increase, a company official noted:[330]

From: Michael B Mason
Sent: Friday, May 30, 2014 5:36 PM
To: Enrique A Conterno
Cc: Martin Bott
Subject: Fwd: Humalog and Humulin - list price

Enrique:

As you know we have been discussing a price increase in June. Attached is our proposed price increase.

Let me know if you have any questions.

Mike

P.S. We learned from public sources on Thursday that Novo took a 9.9% price increase across their Insulin portfolio.

Sent from my iPad

Six months later, on November 19, 2014, when Novo Nordisk increased prices again, Eli Lilly's CEO, John Lechleiter, was notified by Enrique Conterno, the head of the company's diabetes unit, who wrote, "[t]oday Novo took a price increase of 9.9% for Novolog and 11.9% for Levemir. As you are aware, we have assumed as part of our business plan a price increase of 9.9% for Humalog before the end of the year."[331] Mr. Conterno, discussing the move with his colleagues over email a few days later, noted, "[g]iven Novo's price increase, let's compensate by taking the price increase earlier,"[332] adding later that day, "I think we should push for [a list price increase] asap given that Novo has taken a price increase already and thus, distributors will start to inventory."[333] Ultimately the company decided to move up their planned pricing increase in response to Novo Nordisk's unexpected price increase, and reiterated that their distributors would expect a price increase from Lilly.[334]

This investigation also showed that Sanofi had a shadow pricing strategy for their short-acting insulin, Apidra, which it called a "fast follower" approach. In November 2014, Sanofi's USPC recommended Sanofi approve a WAC increase of 9.9% because "Apidra has employed a fast follower strategy to Novolog/Humalog prices increases – Novolog just implemented their increase effective November 18th."[335] Along with the pricing recommendation, the USPC

[329] LLY-SFCOM-UR-00003044, at LLY-SFCOM-UR-00003045.
[330] LLY-SFCOM-UR-00003044.
[331] LLY-SFCOM-UR-00003198.
[332] LLY-SFCOM-UR-00003200.
[333] LLY-SFCOM-UR-00003202.
[334] LLY-SFCOM-UR-00003206.
[335] SANOFI_SFC_00014206. This request would result in the WAC price of Apidra vials increasing from $184.85 to $203.15 and Apidra Solostar (pens) from $357.10 to $392.45. *Id.*

included a two-line risk assessment stating matter-of-factly that "[a]ll price increases have the potential to subject the organization to public scrutiny from payers, physicians and patients."[336]

This investigation specifically examined manufacturers' business decisions related to insulin and their contracting practices with PBMs and other plans. While not discussed in this report, the Committee's investigation found that shadow pricing is not limited to the insulin product portfolio.[337]

Shadow pricing practices among pharmaceutical manufacturers are simple: leaders lead and the competitors follow. For a time, Sanofi had the higher price in the basal insulin market with Lantus, so Novo Nordisk followed its competitor's pricing signals with Levemir, deviating slightly from the prices Sanofi settled on. Similarly Novo Nordisk had the highest price in the rapid-acting market, with NovoLog, so they led while Sanofi followed with Apidra and Eli Lilly followed with Humalog.

IV. Rebates, Administrative Fees and Other Common Contract Provisions Related to Insulin WAC and Other Therapies

PBMs have been subject to a great deal of scrutiny for their role in rising drug prices.[338] Although they are the centerpiece of drug pricing negotiations, their practices and business relationships remain largely opaque. As discussed above, the lack of transparency is due in large part to the confidentiality of contractual relationships PBMs have with both health insurers and drug manufacturers, as well as Federal laws barring disclosure of some information related to these negotiations.[339] While the HHS OIG found that this "lack of transparency raises concerns that sponsors may not always have enough information to oversee the services and information provided by PBMs,"[340] the industry continues to fight efforts to bring visibility to its operations.[341] Likewise, PBMs were not fully responsive to the Finance Committee's requests during this investigation, variously failing to timely produce documents, produce all of the requested documents, or produce documents that were fully un-redacted.[342]

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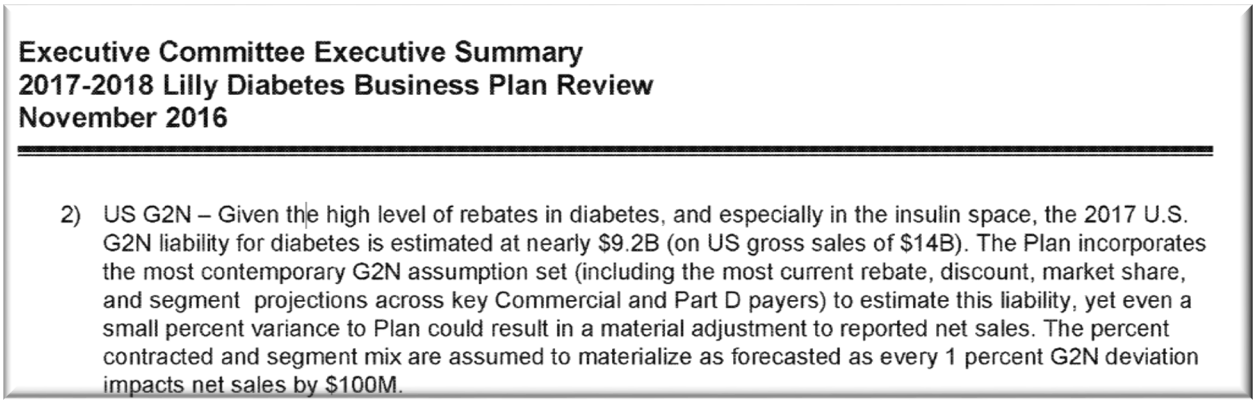
[336] SANOFI_SFC_00014206.
[337] For example, *see* SANOFI_SFC_00014352, at SANOFI-SFC_00014358-59.
[338] Duane Schulthess, *Insulin prices and pharmacy benefit manager rebates: pin the tail on the patient*, STAT (Mar. 19, 2020), https://www.statnews.com/2020/03/19/insulin-prices-pbm-rebates/; Oliver McPherson-Smith and Steve Pociask, *Rx middlemen cost American consumers billions each year*, THE HILL (Jan 27, 2020), https://thehill.com/blogs/congress-blog/health care/480155-rx-middlemen-cost-american-consumers-billions-each-year; Laura Entis, *Why Does Medicine Cost So Much? Here's How Drug Prices Are Set*, TIME (Apr. 19, 2019), https://time.com/5564547/drug-prices-medicine/.
[339] *See, e.g.,* 42 U.S.C. 1396r-8(b)(3)(D)(cross-referenced at 42 U.S.C. 1395w-102(d)(2) and 42 U.S.C. 1396r-8(b)(3)(D)).
[340] DEP'T HEALTH AND HUMAN SERVS., OFF. OF INSPEC. GEN., CONCERNS WITH REBATES IN THE MEDICARE PART D PROGRAM (Mar. 11, 2011), https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf.
[341] Robert Langreth et al., *The Secret System Middlemen Use to Rake in Millions*, BLOOMBERG (Sept. 11, 2018), https://www.bloomberg.com/graphics/2018-drug-spread-pricing/.
[342] On February 25, 2020, the Committee sent OptumRx and Cigna Corporation letters detailing their failure to produce information and records pertaining to their formulary management committees, and other related information. Press Release, Grassley, Wyden Warn PBM: Cooperate with Insulin Investigation or Face Subpoena (Feb. 26, 2020), https://www.grassley.senate.gov/news/news-releases/grassley-wyden-warn-pbm-cooperate-insulin-investigation-or-face-subpoena. Although CVS Caremark didn't receive a public letter, the Committee did not view the company's production to be fully responsive to the senators' requests for information.

At the same time, industry representatives from both sides have attempted to shift blame for increasing drug prices. In response to the Committee's April 2nd letter, CVS Caremark, Express Scripts, and OptumRx blamed drug manufacturers for increasing insulin prices, arguing that they unilaterally set list prices.[343] Sanofi, Novo Nordisk, and Eli Lilly, on the other hand, blamed PBMs for their demand for ever-higher rebates which has caused them to raise list prices to maintain profitability and patient access.[344] Indeed, PBMs have been accused of "play[ing] drug companies off one another"; "want[ing] juicy rebates"; and "profiting on all sides."[345] What is clear is that the money that flows through PBMs is nothing short of enormous. As discussed throughout this report, rebates have grown at a rapid pace in the insulin market in recent years, which is not true in all therapeutic markets. A 2016 memo to Eli Lilly's executive committee underscored the evolving market:[346]



Executive Committee Executive Summary
2017-2018 Lilly Diabetes Business Plan Review
November 2016

2) US G2N – Given the high level of rebates in diabetes, and especially in the insulin space, the 2017 U.S. G2N liability for diabetes is estimated at nearly $9.2B (on US gross sales of $14B). The Plan incorporates the most contemporary G2N assumption set (including the most current rebate, discount, market share, and segment projections across key Commercial and Part D payers) to estimate this liability, yet even a small percent variance to Plan could result in a material adjustment to reported net sales. The percent contracted and segment mix are assumed to materialize as forecasted as every 1 percent G2N deviation impacts net sales by $100M.

As Congress considers policy solutions to address prescription drug costs, it is important to understand how rebates and other PBM contracting practices contribute to list price increases, especially in the insulin therapeutic class. The following section provides insight into the PBMs' business practices and their role in the insulin market.

a. Rebates for Insulins Have Increased Exponentially Since 2013

[343] Letter from Enu Mainigi, Counsel, Williams & Connolly, on Behalf of CVS Health Corp., to Senator Grassley and Senator Wyden (Apr. 26, 2019); Letter from Enu Mainigi, Counsel, Williams & Connolly, on Behalf of CVS Health Corp., to Senator Grassley and Senator Wyden (May 24, 2019); Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, Corporation, to Senator Grassley and Senator Wyden (Apr. 16, 2019); ORX_Sen_Fin_00001935.

[344] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019); Letter from Raphael Prober, Counsel, Akin Gump, on Behalf of Novo Nordisk, to Senator Grassley and Senator Wyden (Mar. 8, 2019); Letter from Joseph Kelly, Vice President, Global Affairs, Eli Lilly, to Senator Grassley and Senator Wyden (Mar. 8, 2019).

[345] Duane Schulthess, *Insulin prices and pharmacy benefit manager rebates: pin the tail on the patient*, STAT (Mar. 19, 2020), https://www.statnews.com/2020/03/19/insulin-prices-pbm-rebates/; Oliver McPherson-Smith and Steve Pociask, *Rx middlemen costs American consumers billions each year*, THE HILL (Jan 27, 2020), https://thehill.com/blogs/congress-blog/health care/480155-rx-middlemen-cost-american-consumers-billions-each-year; Laura Entis, *Why Does Medicine Cost So Much? Here's How Drug Prices Are Set*, TIME (Apr. 19, 2019), https://time.com/5564547/drug-prices-medicine/.

[346] LLY-SFCOM-UR-00006921.

Based on internal memoranda and correspondence collected for this investigation, the practice of offering rebates in the insulin therapeutic class appears to be contributing to both increasing insulin WAC prices and limited uptake of lower-priced products. Drug manufacturers—typically on an annual, but sometimes more frequent, basis—submit bids to PBMs which reflect a variety of different rebate offers that manufacturers are willing to pay depending on where the drug is placed on a health plan's formulary.[347] However, it's important to note that the final agreement does not guarantee a product's placement. Instead, health insurers make the final decision with regard to formulary placement and the patient's cost-sharing responsibility for the product.

This investigation found that manufacturers offer substantial rebates to PBMs and their clients for the purposes of securing preferred formulary placement for their products, and to ensure strong market access by securing formulary positions that minimize cost-sharing for patients.[348] Low cost-sharing is an important consideration for manufacturers when developing their rebate offers because patients often gravitate towards the cheapest drug to save on their out-of-pocket expenses. A patient's cost-sharing responsibility can affect a manufacturer's market share and profitability.

As noted above, rebates for insulins have increased steadily as manufacturers attempted to secure preferred placement. Rebate offers made by Sanofi and Novo Nordisk to CVS Caremark have increased exponentially between 2013 and 2019. For example, in July 2013, Sanofi offered rebates between 2% and 4% for preferred placement on CVS Caremark's client's commercial formulary.[349] Five years later, in 2018, Sanofi rebates were as high as 56% for preferred formulary placement.[350] Similarly, rebates to Express Scripts and OptumRx increased dramatically between 2013 and 2019 for long-acting insulins. For example, in 2019, Sanofi offered OptumRx rebates up to 79.75%[351] for Lantus for preferred formulary placement on their client's commercial formulary, compared to just 42%[352] in 2015. Similarly, in 2017, Novo Nordisk offered Express Scripts rebates up to 47%[353] for Levemir for preferred formulary placement on their client's commercial formulary, compared to 25%[354] in 2014.

This investigation also found that rebate offers for Medicare Part D, and other high-control formularies, appear to be just as high (if not higher) than those offered for placement on PBMs' commercial formularies. For example, in 2019, Novo Nordisk offered rebates as high as 71% for preferred formulary placement on CVS Caremark's Medicare Part D formulary.[355]

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[347] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019); Letter from Eni Mainigi, Counsel, CVS Caremark, to Senator Grassley and Senator Wyden (Apr. 26, 2019). Rebates are often calculated on a per unit basis and are billed to the drug manufacturer monthly after the drug is dispensed at the pharmacy. *See* Cigna-SFC-00009847. PBMs also reserve the right to solicit new bids or new offers based on changes in the marketplace, and often do so each year. *Id.*

[348] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (May 24, 2019).

[349] CVSCM_SFC_0003979, at CVSCM_SFC_0004000.

[350] CVSCM_SFC_0004331, at CVSCM_SFC_0004334.

[351] ORX_Sen_Fin_0009384, at ORX_Sen_Fin_0009413.

[352] ORX_Sen_Fin_0009066, at ORX_Sen_Fin_0009078.

[353] Cigna-SFC-00009578, at Cigna-SFC-00009582.

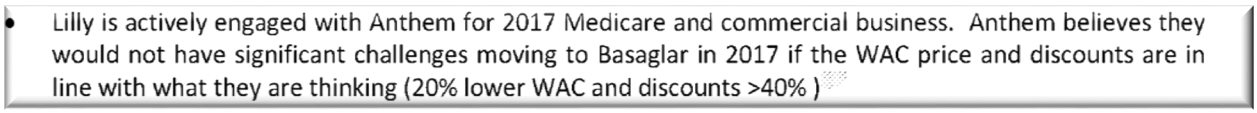
[354] Cigna-SFC-00009535, at Cigna-SFC-00009544.

[355] CVSCM_SFC_0004991, at CVSCM_SFC_0004993-94.

Similarly, in 2019, Eli Lilly also offered rebates as high as 74%[356] for preferred formulary placement.

Rebates have increased for several reasons. Just three PBMs (CVS Caremark, Express Scripts, and OptumRx) now manage 80% of drug benefits for more than 220 million Americans, resulting in manufacturers facing high stakes when negotiating for formulary placement.[357] Pharmaceutical companies are sensitive to the sheer size of PBMs and the resulting product volumes they can affect, which allows the middlemen to extract higher rebates from manufacturers through the use of formulary exclusion tactics. Internal memoranda and correspondence collected for this investigation suggest that manufacturers seek to avoid triggering Medicaid "best price" when developing their bids for commercial plans.[358] As discussed in more detail in this report's background section, under Medicaid "best price," drug manufacturers must give Medicaid the lowest price they offer private plans, wholesalers, providers, and other purchasers, with rebates taken into account.[359] However, rebates offered to Part D plans are excluded from the Medicaid best price calculation, allowing manufacturers to offer higher rebates under Medicare Part D without triggering best price.

Manufacturers have increased their rebates in order to win preferred formulary placement and block competitors. In 2016, Sanofi and Novo Nordisk enhanced their rebate offers around the same time Eli Lilly introduced Basaglar, a follow-on biologic to Lantus. Basaglar is a long-acting insulin and is "[c]linically . . . very similar" to Lantus.[360] Because of its near clinical equivalence, Basaglar introduced additional competition in the long-acting insulin market. Payers used the competition to threaten to switch to Basaglar because it was priced lower and they expected Eli Lilly to offer larger discounts. (This investigation confirmed Eli Lilly offered rebates between 60% and 70% off WAC).[361] A 2016 Sanofi memo describes the market dynamic:[362]



[356] CVSCM_SFC_0004838, at CVSCM_SFC_0004843.
[357] Letter from Raphael Prober, Counsel, Akin Gump, on Behalf of Novo Nordisk, to Senator Grassley and Senator Wyden (June 28, 2019).
[358] *See* SANOFI_SFC_00014281, at SANOFI_SFC_00014285. In developing its OptumRx Medicare Part D bid for Lantus, Sanofi discusses how its pricing strategy for Toujeo could set a high "best price" and thus a high Medicaid rebate "from day one and for the lifecycle of Toujeo." *Id.*
[359] 42 U.S.C. 1396r-8(c)(1)(C)(i).

> The term 'best price' means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal, Food, Drug, and Cosmetic Act), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity . . . *excluding* . . . any prices charged . . . [to] part D."

Id.
[360] SANOFI_SFC_00011791.
[361] CVSCM_SFC_0004784, at CVSCM_SFC0004805.
[362] SANOFI_SFC_00012618, at SANOFI_SFC_00012619.

In an attempt to avoid payers switching to Basaglar, Sanofi and Novo Nordisk increased their rebate bids to respond to Eli Lilly. For example, according to internal memoranda collected from Sanofi, sometime around April 2016, Express Scripts requested bids for its 2017 national commercial formulary and indicated its desire to only add one insulin glargine product to its basal insulin category.[363] Express Scripts communicated to Sanofi that "with the right competitive price, [it] would not have significant challenges moving [from Lantus and Toujeo] to Basaglar"[364] and that Sanofi must enhance its current rebate rate of 42% to maintain current access for their basal insulins.[365] An internal Sanofi memo describes this dynamic:[366]

Likely Competitive Approach and Response:

- Lilly is actively engaged with ESI for 2017 commercial business. Pricing has not been confirmed however ESI has informed that the following assumptions pose a threat to Sanofi's glargine franchise:
  - Discounts for Basaglar in the mid 60's have been communicated by ESI to Sanofi. This is likely a starter for ESI to consider excluding Lantus and Toujeo. Modeling assumed 70%.
  - Basaglar WAC will be 15% to 25% less than the WAC price of Lantus. Sanofi modeling assumed 15%.
- ESI has signaled, with the right competitive price, they would not have significant challenges moving to Basaglar in 2017 despite a follow-on biologic (Basaglar) approval.
- In addition ESI has indicated that Novo must also enhance its current rate to maintain current access for their basal insulin(s). Novo is likely to enhance its current rebates given recent Tresiba addition to part D formulary.

Rebate contracts confirm that Sanofi increased its offer up to almost 55%[367] off its WAC of $248.51 for Lantus vials and $372.76 for Lantus pens.[368]

i. Rebates Vary Widely by Payer

Rebates also vary greatly across payers. For example, payers with more bargaining power (i.e., more members) enjoy higher rebates than payers with less bargaining power (i.e., fewer members). Although the investigation did not seek out agreements between PBMs and health insurers, manufacturer rebate agreements do support the assertion that smaller health insurers do not always enjoy the same level of rebate offers as their larger peers. For example, in 2014, Novo Nordisk offered WellPoint, the largest for-profit managed health care company with over 40 million members, a larger rebate (40.625%) for Novolin vials for preferred formulary placement as 1 of 2 manufacturers on their client's commercial formulary compared to North Carolina State Employees (27.625%).[369] Similarly, Eli Lilly proposed a widely divergent rebate bid within a

[363] SANOFI_SFC_00012279.
[364] SANOFI_SFC_00012279, at SANOFI_SFC_00012280.
[365] SANOFI_SFC_00012279, at SANOFI_SFC_00012281.
[366] SANOFI_SFC_00012279, at SANOFI_SFC_00012280.
[367] Cigna-SFC-00009781, at Cigna-SFC-00009786.
[368] Letter from Jeffrey Handwerker, Counsel, Arnold & Porter, on Behalf of Sanofi, to Senator Grassley and Senator Wyden (Mar. 8, 2019) (attachment 1(a) and (b)).
[369] Cigna-SFC-00009550, at Cigna-SFC-00009552.

few months of each other for Humulin and Humalog to a commercial health plan in Puerto Rico called SIS (25%),[370] Cigna (45%-55% depending on formulary placement),[371] a PBM called Abarca Health (up to 54%),[372] and Optum's Part D business (68%).[373] A Sanofi presentation for its long-acting insulin products further underscores how rebates can vary not only between companies, but between books of business within those companies, with larger accounts tending to receive larger rebate offers:[374]

Glargine 2018 Tracker

Glargine 2018 Bids

		Lives (M)	Latest Offer Date	Latest Offer Blended Rate	Offer Details	Status	Expected Date of Notification	Term	Offer Gross Sales	Offer Net Sales	Approved Rates Blend	Approved Rates LAN	Approved Rates TOU	2018 LRP Gross Sales	2018 LRP Rate	2018 LRP Net Sales	2018 LRP Access Start Date	2018 LRP Form Position	Δ vs LRP
Commercial	ESI	50.2	06/16/17	69%	1-1 70/70%, 1-2 68/68%, 1-3 63/63% [L/T]	In progress	9/30/2017	1/1/18-12/31/19	1,162	359	63%	65%	60%	1,147	69%	351	1/1/2018	Pref 1of3	8
	CVS*	41.7	06/16/17	63%	Lantus 1-1 70%, 1-2 68%, 1-3 64%. Toujeo 1-1 68%, 1-2 65%, 1-3 61%.	Loss	8/3/2017	1/1/18-12/31/18	101	38	70%	70%	70%	101	66%	34	1/1/2018	NC	3
	UHC Optum Rx	15.9 10.5	07/15/16	51%	No Opportunity (UHG) Tier 2 = 51% (OPT)	No update from 2017		1/1/17-12/30/20	224	110	65%	65%	65%	224	65%	78	1/1/2018	Pref 1of2	31
	Humana	2.5	03/20/17	52%	1-1 63% L, 61% T 1-2 53% L, 51% T	In progress	9/30/2017	1/1/18-12/31/19	35	17	55%	55%	53%	35	55%	16	1/1/2018	Pref 1of2	1
	Aetna	9.6	5/15/17 P 5/16/17 V	54%	Prem 1-2 55% L, 52% T Value 1-2 58% ('18), 62% ('19)	Prem ACCEPTED Value Loss	8/10/2017	1/1/18-12/31/19	81	37	59%	60%	58%	81	58%	34	1/1/2018	Pref 1of2 Val NC	3
	CIGNA	6.4	05/23/17	0%	1-1 55%, 1-2 51%, 1-3 38%, 55% (T), 6% pp	Loss	6/19/2017	1/1/18-12/31/19	25	25	51%	55%	55%	123	55%	55	1/1/2018	Pref 1of2	(31)
	Prime	12.5	10/06/16	50%	1-2 50%	No update from 2017	N/A	1/1/17-12/31/18	224	112	54%	57%	52%	224	60%	90	1/1/2018	Pref 1of2	22
Medicare	ESI	4.5	06/01/17	56%	1-1 ESI PDP 63%, 1-1 56%, 1-2 54%, 1-3 53%, 6% PP	In progress	10/1/2017	1/1/18-12/31/19	619	276	55%	56%	54%	619	54%	287	1/1/2018	Pref 1of2	(11)
	CVS	8.9	08/03/17	78%	Plus/Custom (1-2) LAN 80% LIS/74% STD TOU 75% LIS/69% STD Choice/Template (1-3) LAN 80% LIS/72% STD TOU 75% LIS/67% STD 0% PP LAN, 3% PP TOU	In progress	10/1/2017	1/1/18-12/31/19	1,071	239	64%	65%	60%	1,157	69%	356	1/1/2018	Pref 1of2	(117)
	Optum Rx	7.8	11/06/16	60%	1-1 66%, 1-2 60%	In progress	8/23/2017 (UHC) 10/1/2017 (Optum)	1/1/18-12/31/19	1,087	430	65%	65%	65%	1,087	64%	391	1/1/2018	Pref 1of2	39
	Humana	7.5	03/20/17	52%	1-1 63% L, 61% T 1-2 53% L, 51% T	In progress	9/1/2017	1/1/18-12/31/19	720	346	55%	55%	53%	720	52%	346	1/1/2018	Pref 1of2	-
	Aetna	2.7	12/12/16	69%	Currently NC, 1-2 70% L, 65% T	In progress	10/1/2017	1/1/18-12/31/19	12	4	55%	55%	53%	12	52%	6	1/1/2018	NC	(2)
	CIGNA	1.4	12/16/16	36%	1-2 36%	In progress	10/1/2017	1/1/18-12/31/19	180	116	39%	39%	39%	180	40%	108	1/1/2018	Pref 1of2	7
	Prime	1.1	02/14/17	54%	1-1 56%, 1-2 53%	In progress	10/1/2017	1/1/18-12/31/19	125	58	52%	53%	51%	125	54%	58	1/1/2018	Pref 1of2	(0)
	Kaiser	8.1	08/12/16	66%	LAN = 65% TOU NP = 15%, Fixed Price	Status Quo	8/12/2016	1/1/17-12/31/20	139	47	66%			139	66%	48	1/1/2018	Pref 1of1	(0)

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USMarket Access

b. PBM Contracting Practices May Contribute to High Rebates and High List Prices in the Insulin Therapeutic Class

In response to the Committee's April 2nd letter, CVS Caremark, Express Scripts, and OptumRx stated that they work to obtain the lowest net cost (the drug price realized by plan sponsors after receiving rebates, discounts, and other fees from manufacturers) by soliciting

[370] LLY-SFCOM-UR-00003596, at LLY-SFCOM-UR-00003597.
[371] LLY-SFCOM-UR-00003325, at LLY-SFCOM-UR-00003326.
[372] LLY-SFCOM-UR-00003532. *See Smarter PBM Platform Selected by PerformRx*, PR Newswire (Oct. 22, 2018), https://www.prnewswire.com/news-releases/abarcas-smarter-pbm-platform-selected-by-performrx-300734745.html. (Abarca is a PBM with a significant customer base in Puerto Rico. It serves more than 2.5 million lives, but is relatively small when compared to CVS Caremark, Express Scripts, and OptumRx.)
[373] LLY-SFCOM-UR-00003449.
[374] SANOFI_SFC_00010668.

manufacturers to submit competing rebate offers.[375] While net cost is an important data point to consider, it does not address WAC, which can affect the price patients pay at the counter. Information collected for this investigation suggests that certain contracting and business practices may create incentives for PBMs to favor drugs with high rebates and, in turn, discourage manufacturers from competing to lower WAC prices.

i. Use of Exclusion Lists

Prior to 2012, most health insurers offered patients open formularies, giving them the ability to access "non-formulary" drugs with higher copays.[376] This changed in 2012 when CVS Caremark began excluding drugs from its formulary and expanded the practice in the following years.[377] Other PBMs and insurers would follow suit,[378] although internal documents show that health plan clients expressed concern about patients being able to access insulin and other prescription medications.[379] Today, the practice is widely used by PBMs, as demonstrated by the roughly 400 medications Express Scripts excludes from its 2021 formularies—an almost eight-fold increase since 2014.[380]

An internal Sanofi memo detailed the company's view on how the ACA changed market dynamics between manufacturers and health plans. The memo also laid out some of the ACA provisions that provided the government additional regulatory power over the private health care market that likely resulted in increased costs to health plans and more restrictive formularies. Portions of the memo and Sanofi's view on how the ACA altered the market dynamics between pharmaceutical companies and payers are listed verbatim below:

- ***Guaranteed Issue/Elimination of Pre-Existing Condition Denials****. Beginning in 2014, health plans are no longer allowed to deny enrollment or policy enrollment based [on] their costly pre-existing conditions. This increases health plans' costs.*

- ***Elimination of lifetime and annual covered benefit spending.*** *Before the health care law, many health plans set an annual or lifetime limit – a dollar limit on their yearly spending for each enrollee's covered benefits. Enrollee's [sic] would need*

[375] Letter from Enu Mainigi, Counsel, Williams & Connolly, on Behalf of CVS Health Corp., to Senator Grassley and Senator Wyden (Apr. 26, 2019); Letter from Kristin Julason Damato, Vice President Government Affairs, Cigna Corporation, to Senator Grassley and Senator Wyden (Dec. 7, 2020); ORX_Sen_Fin_00001935.
[376] SANOFI_SFC_00009132. *See also* Joshua Cohen et al., *Rising Drug Costs Drives the Growth of Pharmacy Benefit Managers Exclusion Lists: Are Exclusion Decisions Value-Based?*, HEALTH SERV. RES. (Aug. 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6056588/.
[377] SANOFI_SFC_00009132, at SANOFI_SFC_00009134.
[378] SANOFI_SFC_00009132, at SANOFI_SFC_00009134.
[379] A series of internal memos outlined health plans' concerns about Express Scripts' decision to begin excluding drugs from their national formulary. Some clients threatened to terminate their relationship with the PBM. Cigna-SFC-00015251. Another client's insurance board ruled it could not "adopt this strategy … due to their union contract obligations and their diabetes education funded by Novolog." Cigna-SFC-00015246. Other clients raised concerns related to disruption to their beneficiaries, such as "increased costs due to additional office visits and additional member hassle." Cigna-SFC-00015242. And, "major member disruption." Cigna-SFC-00015244. *See* Cigna-SFC-00015236-60.
[380] In 2014, Express Scripts excluded approximately 57 drugs from its formulary. In 2021, that figure jumped to over 400. *See 2021 National Perferred Formulary Exclusion Lists*, EXPRESS SCRIPTS (2021), https://www.express-scripts.com/art/open_enrollment/DrugListExclusionsAndAlternatives.pdf.

to pay for the medical expenses beyond those limits. ACA no longer allows plans to do this. This increases health plan's [sic] costs.

- ***Medical loss ratio.*** *Health plans must meet certain thresholds when it comes to revenue and expenses. The intent of the MLR is to eliminate excess profits and encourage administrative efficiencies. Plans must demonstrate that at least 80% of their revenues (85% in the large group market) must be accounted for with enrollee medical expenses. If they do not, consumers must receive rebate checks to bring the accounting into line with the threshold. The US government has publicized that in 2012, consumers received $500 million in MLR rebate checks and avoided $3.4 billion in upfront premium increases that would have occurred had this and other polices not been in place. This is money that has been taken out of the health care plan sector.*

- ***Government premium rate reviews.*** *Health plans must submit to the government justification for any premium rate increases of 10% or greater. The US government has publicized that in 2012, consumers saved $1.2 billion as a result of this policy. This is money that has been taken out of the health plan sector.*

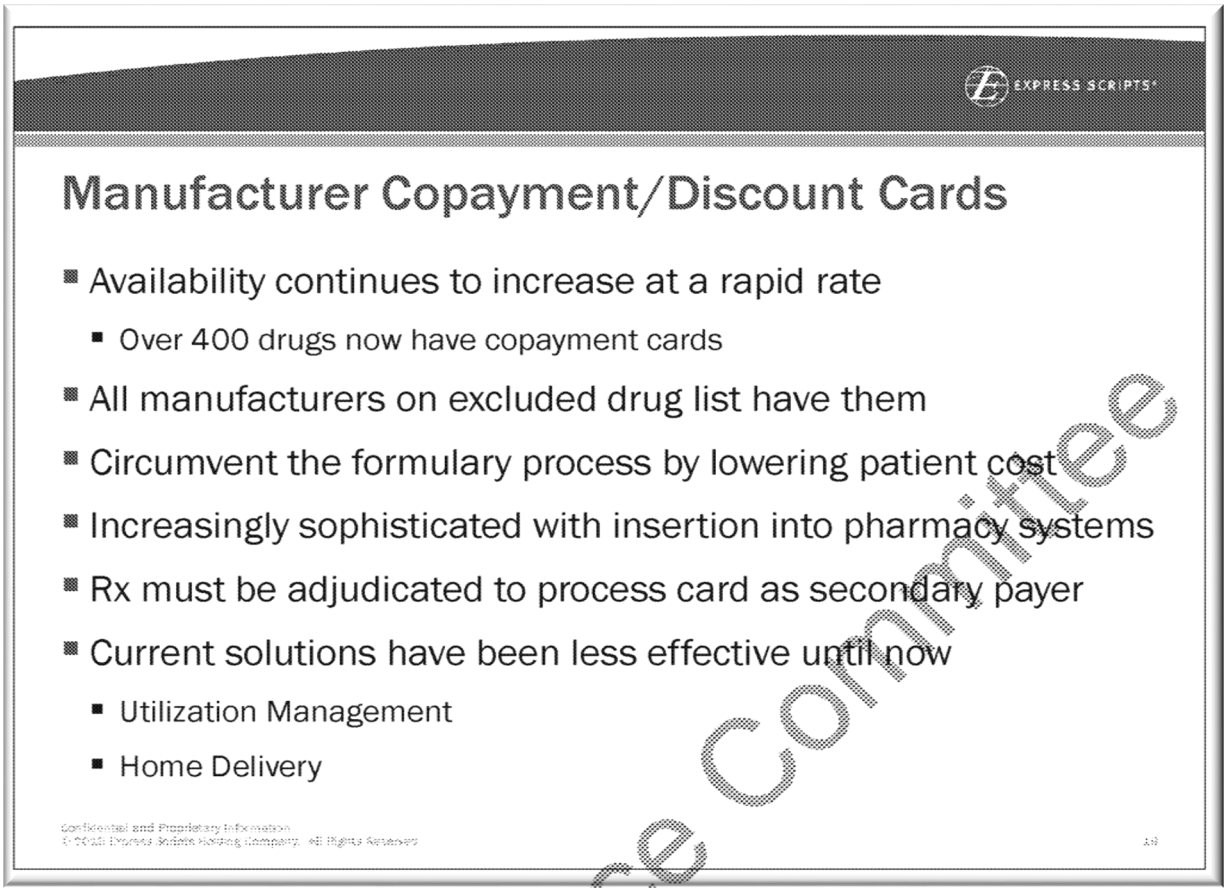
- ***Fees to support the exchanges****. In order to manage some of the risk of high cost enrollee's [sic] in the exchanges, health fees have been imposed on plans outside of the exchanges. Additionally, for health plans that participate in the exchanges, fees are imposed for participation. This increases plan's [sic] costs. The 10 essential health benefits. The ACA requires plans to cover 10 essential health benefits: 1) ambulatory patient services; 2) emergency services; 3) hospitalization; 4) maternity and newborn care; 5) mental health and substance use disorder services, including behavioral health treatment; 6) prescription drugs; 7) rehabilitative services and devices; 8) laboratory services; 9) preventive and wellness services and chronic disease management; and 10) pediatric services, including oral and vision care. For those plans that did not offer such robust benefits previously, their costs increased with ACA . . .*

- ***Uncertainty on enrollment and patient mix.*** *Exchange plans are expected to cover the medical expenses of a currently uninsured population. No historical data exists as to whether or not the consumer penalties associated with not buying insurance (the individual mandate) is significant enough to encourage enrollment of healthy individuals. In the event health plans end up covering only the sick, and those expenses exceed the revenue generated from premiums, plans will incur losses. While there are risk protections in place to help compensate for some of these risks and losses, much uncertainly [sic] still exists.*

- ***[Formulary coverage policy.]*** *Finally, the ACA set a precedent with is formulary coverage policy. While this policy does not place pressure on plan's [sic] margins, it does provide an excuse for health plans to assert more exclusivity on drug formularies. ACA regulation allows plans to cover one drug per USP category. (Medicare requires at least two drugs per category). Plans may choose to exploit*

this precedent setting government policy as they operate in the non-exchange market in order to leverage more rebates and reduce costs.[381]

Increased use of manufacturer co-payment and discount cards also made it difficult to control drug spending. An internal Express Scripts presentation underscores the PBM industry's view that co-pay coupons circumvent the formulary process by lowering patient costs and incentivizing patients to use drugs with higher list prices.[382] An excerpt concerning manufacturer copay coupons taken from an Express Scripts internal memo is shown below.[383]



When a drug is excluded from a formulary it means that it will not be covered by the insurer unless an exception is granted for the patient.[384] In the insulin therapeutic class, PBMs consider certain insulins interchangeable, meaning that their P&T committees have determined the competing brands are similar in their safety, efficacy, and kinetics.[385] The P&T's determination allows PBMs to solicit competing bids from manufacturers in an effort to obtain

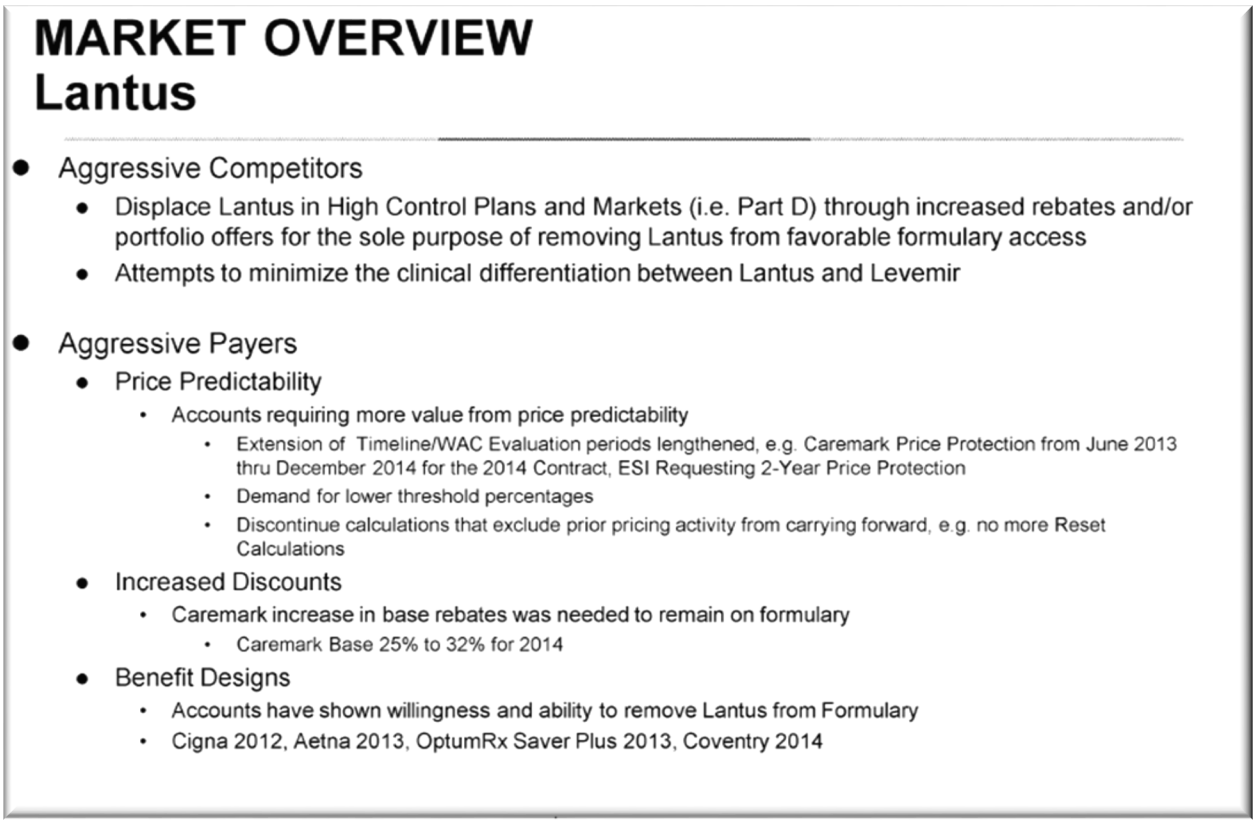
[381] SANOFI_SFC_00009132, at SANOFI_SFC_00009132-33.
[382] Cigna-SFC-00018522, at Cigna-SFC-00018540-41.
[383] Cigna-SFC-00018522, at Cigna-SFC-00018540.
[384] Letter from Michael Bopp, Counsel, Gibson Dunn, on Behalf of Cigna Corporation, to Senator Grassley and Senator Wyden (Apr. 16, 2019).
[385] *Id. See also* ORX_Sen_Fin_0004777 (OptumRx's P&T had designated Basaglar, Lantus, Levemir, and Toujeo as part of an "essential class"); ORX_Sen_Fin_0005377, at ORX_Sen_Fin_0005383 (Drugs designated as an "essential class" are similar in their safety and efficacy when used to treat the same or similar medical condition).

the lowest net cost for their clients. While formulary exclusions are intended help control drug costs, they can affect a patient's ability to access medication, and revenue generated by drug manufacturers from their products.[386] For the patient, if a drug is excluded, they can be forced to either switch to another product, which could affect adherence and health outcomes, or pay significantly more to stay on their preferred medication. For manufacturers, the investigation found that the mere threat of exclusion typically forces them to offer substantially greater discounts to maintain formulary position, reducing net price. When exclusions are actually imposed, manufacturers often face a significant loss of market share, leading to lower revenue. On the other hand, being the exclusive therapy on a formulary can be advantageous for a brand's market share and revenue, which incentivizes companies to offer large discounts to maintain such status.[387] The use of exclusions has led to a market dynamic in which manufacturers offer ever-higher rebates to avoid exclusion, which appears to have contributed to higher list prices.

The investigation found several instances where manufacturers increased their rebate bids following the threat of formulary exclusion.

Prior to 2013, Sanofi offered an average rebate of 5% on Lantus.[388] However, in 2013, Sanofi began to increase its rebate and discount offerings to health plans for two reasons. First, Sanofi increased its rebate and discount offerings to respond to Novo Nordisk's aggressive rebate strategy.[389] Beginning in 2013, competitors sought to "[d]isplace Lantus in High Control Plans and Markets (i.e., Part D) through increased rebates" for the purposes of capturing market share.[390] Secondly, Sanofi increased its rebate and discount offerings because payers began to demand increased discounts from drug manufacturers to remain on their formulary.[391] A Sanofi memo, shown below, further explains this dynamic:[392]

[386] Letter from Raphael Prober, Counsel, Akin Gump, on Behalf of Novo Nordisk, to Senator Grassley and Senator Wyden (June 28, 2019).
[387] *See* LLY-SFCOM-UR-00003699. This June 2015 email exchange amongst Eli Lilly employees shows how manufacturers seek to maintain exclusive status for their drugs and will offer increased rebates to maintain preferred status.
[388] SANOFI_SFC_00008916-17.
[389] SANOFI_SFC_00014532, at SANOFI_SFC_00014533.
[390] SANOFI_SFC_00009211, at SANOFI_SFC_0009217.
[391] SANOFI_SFC_00009211, at SANOFI_SFC_0009217.
[392] SANOFI_SFC_00009211, at SANOFI_SFC_0009217.



While PBMs may have initially utilized formulary exclusions in the insulin therapeutic class as a way to drive cost down for their clients, internal correspondence and memoranda suggest that increased use of formulary exclusions have had unintended consequences: WAC prices have continued to increase, leading to higher prices for some at the pharmacy counter.

For example, in 2013, Express Scripts threatened to move patients to other diabetes drugs in order to "break even on [the] rebate line" unless Sanofi increased its Medicare Part D rebate offer for Lantus in 2014.[393] As a result, Sanofi considered increasing its rebate offer from 7.45% to 15% in order to prevent formulary exclusion.[394] Sanofi also faced similar pressure to increase rebates for Express Scripts' commercial contracts. Internal memoranda collected from Sanofi suggest that "Sanofi was notified by [Express Scripts] that Lantus was positioned to be removed from the formulary effective 2013 . . . [as a result] rebates were re-negotiated."[395] An excerpt from this memo, discussing the threat to Lantus, is shown below.[396]

[393] SANOFI_SFC_00009282, at SANOFI_SFC_00009287-88.
[394] SANOFI_SFC_00009282, at SANOFI_SFC_00009287.
[395] SANOFI_SFC_00008920, at SANOFI_SFC_00008923.
[396] SANOFI_SFC_00008920, at SANOFI_SFC_00008923.

Lantus Contracting History with ESI

Account Management and Contracting have worked closely together to maintain a 5% rebate for Commercial contracts through 2012. Sanofi was notified by ESI that Lantus was positioned to be removed from formulary effective 2013. Rebates were re-negotiated resulting in a 6% Lantus Vial & 9% Lantus SoloStar rebate (no price protection).

Lantus Overall Threat

The Commercial business is at additional threat due to competitive rebate pressures and changing formulary design as well as Lantus pricing actions.

- ESI has shared that Novo has been extremely aggressive the last few months and this has triggered the need to revise our offer.
    - For 2014 ESI made Humalog exclusive in the RAI category, moving Novolog to Not Covered and made Byetta & Bydureon the only options in the GLP1 category, moving Victoza to Not Covered.
- Comments during discussion with ESI confirmed that modeling has occurred and that the current contracted offer will result in a Not Covered position for 2015. This is based on competitive offers by Novo and client plans requesting exclusive offers for comparison.
- They have shared that the basal category is under consideration for exclusion list status for 2015. This interest in an exclusive offer is consistent with recent actions they have taken to reduce the number of branded options available to patients.
- Lantus price increases over the past two years have positioned Sanofi as a cost driver that has triggered significant attention from ESI.

Express Scripts is an important account to retain for Sanofi's diabetes drugs because of the large volume of its customer base. According to internal memoranda, in 2014, Express Scripts and its affiliated businesses managed the prescription drug claims of over 4.6 million people, representing 15% of the total business in the Medicare Part D channel.[397] Rebate agreements confirm Sanofi renegotiated rebates and entered into an agreement to provide up to 10.625% for Lantus, effective January 1, 2014.[398] Rebates were renegotiated again that same year, and Sanofi increased its rebate offer up to 14.625%, effective October 1, 2014.[399]

Around this same time, payers eventually learned that Sanofi had offered competitive rebates to Express Scripts which caused them to question their rebate status with Lantus.[400] As a result, payers began to demand higher rebates and threatened to exclude Lantus from their formulary to achieve this result. For example, in 2014, UnitedHealthcare (UHC) threatened to remove Lantus from its commercial formulary because of Lantus's price increases.[401] Sanofi offered an enhanced rebate for FY2015 in the 15% range, but UHC rejected Sanofi's offer and removed Lantus from its commercial formulary.[402] Sanofi responded with a last minute bid of 45% rebate for Tier 2 which UHC countered with 45% for Tier 3.[403] According to Sanofi, UHC's counteroffer was "ultimately accepted over access concerns to future products and the need to secure access to patient lives."[404] Rebate agreements confirm Sanofi renegotiated rebates

[397] SANOFI_SFC_00009282, at SANOFI_SFC_00009283.
[398] Cigna-SFC-00010029, at Cigna-SFC-00010040.
[399] Cigna-SFC-00010043, at Cigna-SFC-00010044.
[400] For example, in 2014, internal memoranda suggest that Sanofi was "at risk with [Prime Therapeutics] due to public comments around increases in Lantus rebates impacting the U.S. market for diabetes." According to Sanofi, at the time, "Prime is questioning their current rebate status with Lantus . . . [and] are requesting/requiring an increase in 2015." SANOFI_SFC_00014267.
[401] SANOFI_SFC_00008934.
[402] SANOFI_SFC_00008934.
[403] SANOFI_SFC_00008934.
[404] SANOFI_SFC_00008934. Emphasis included in the original.

and entered into an agreement to provide up to 45% for Lantus, effective December 15, 2015.[405] An excerpt of this email exchange is shown below.[406]

From: Ingram, Garrett PH/US
Sent: Tuesday, August 19, 2014 4:12 PM
To: Guenter, Peter PH/FR; Purcell, Andrew PH/US; Bartner, Natalie PH/US; Whitaker, Anne PH/US; Kaseta, Michael PH/US
Cc: Du, Wei Wei PH/FR; Bray, Scott PH/US; Borneman, James PH/US; Loreaux, Sandy PH/US; McClellan, Mike PH/US
Subject: RE: Lantus Weekly Report - Week Ending August 1, 2014

Andrew, Peter & all,

Per Andrew's response the contract is performing to the expectations/forecasts we set when we signed the deal. We will continue to monitor and focus on accelerating pull through. Below is our initial assessment. Additionally, attached are the whitepapers & financials for the OptumRx Commercial & Part D deals. Due to the sequence of events we have completed a post action review that we will be sharing with you in September. Our response to customer feedback resulted in incremental impact. Look forward to reviewing learnings with you. Please let me know if you have any questions or feedback. Best,

Garrett

UHC Commercial and Part D Response

Overview: Driven by increasing costs in the basal category, including sanofi price increases on Lantus, UHC approached sanofi with a request for incremental commercial rebate targets. Following a series of sanofi offers in the 15% range, UHC removed Lantus from commercial formulary. Sanofi responded with a last minute bid of 45% for Tier 2 which was rejected by UHC who counteroffered with a 45% rebate for Tier 3 + 7% cumulative PP. Although this offer was deemed to be negative financially vs. a no-contract scenario, the offer was ultimately accepted over access concerns to future products and the need to secure access to patient lives.

In Part D, UHC similarly moved to remove Lantus from formulary in 2015, particularly unhappy about the December 2013 pricing action and suggesting that agreed terms of 35% +7% PP were insufficient. Final terms of 55% + 6% PP were agreed to which also included access to the Saver Plus formulary, a segment of lives of which Lantus had previously been excluded. Lantus Vial added - 7/1/14 and SoloSTAR -10/1/14.

Similarly, in 2016, Express Scripts threatened to remove Lantus and Toujeo from its Medicare Part D formulary and requested that Sanofi submit its "best and final offer" or else face formulary exclusion.[407] According to internal memoranda, during negotiations, Express Scripts told Sanofi that it was justified in removing Lantus and Toujeo from its Medicare Part D formulary because it had allowed "quite a few years of price increases" and that Novo Nordisk's rebate offer was more competitive.[408] In response to Express Scripts' threat, Sanofi discussed revising its rebate offer up to 40% with 4% price protection for Lantus and Toujeo.[409]

[405] ORX_Sen_Fin_0009099, at ORX_Sen_Fin_0009126.
[406] SANOFI_SFC_00008934.
[407] SANOFI_SFC_00012556, at SANOFI_SFC_00012558.
[408] SANOFI_SFC_00012556, at SANOFI_SFC_00012558.
[409] SANOFI_SFC_00012556.

Although contracts with PBMs included larger and larger rebates, manufacturers still expected to remain profitable—up to a point. For example, on July 28, 2017, one Sanofi official wrote to colleagues after considering their offer to CVS Caremark for placement on the Part D formulary: "After inclusion of additional fees, we are still profitable up to an 89% rebate."[410] The official included an analysis that assumed "CVS would need to shift 68.9% of [its] glargine volume to Novo to break even (at an assumed 81% rebate offer)."[411] In its analysis, Sanofi compared various negotiation scenarios including a "no contract" scenario, which it determined would be more profitable to the company even with the resulting reduction in sales volume and revenue.[412] It appears that one of the deciding factors was optics, as one colleague put bluntly: "How would it look to be removed from the largest Medicare plan?"[413]

As PBMs expanded the practice of using exclusions to extract greater rebates, Sanofi's counterstrategy was to bundle unrelated products that had been excluded—Lantus and an epinephrine injection called Auvi-Q—to win formulary inclusion for both. (Bundling is a practice where manufacturers offer rebates and discounts for multiple products, but only if certain conditions are met.) Both drugs had been excluded from various accounts, such as some of Aetna's Part D plans, resulting in rapid erosion of market share:[414]

Background:

- As of 3Q14, Aetna has approximately 2.3 Million Medicare Part D lives (~6% of MMA channel) in the U.S.
- Aetna acquired Coventry in May 2013 and enhanced Medicare footprint by adding > 1.0 Million Part D members with largest enrollment in Texas, Michigan, California and Pennsylvania.
- Lantus is in a Not Covered position for 60% of the business and Non-Preferred for 40% of the business.
- Lantus Family market share share fell from 66.3% (1/13) to 47.3% (1/14) and is currently 33.7% (9/14). Lantus was moved to Not Covered on Aetna's MMA formulary on 1/1/13.
- Auvi-Q is in a Not Covered position for 100% of the business and market share is 0.6% (9/14).

Sanofi faced significant financial pressure across all accounts, and sought to include bundling agreements in several of its contracts. While negotiating contracts for the 2015/2016 plan year, Express Scripts advised Sanofi that they needed to be far more aggressive with rebate offers to gain access to the PBM's commercial book of business than in past years.[415] Internally, Sanofi officials warned in a memo that "Novo, specifically Levemir, has changed the game with regard to rebates," and that Sanofi would "need to rebate aggressively."[416] The memo noted that Lantus and Auvi-Q were initially bundled together—an offer that had since been withdrawn from consideration.[417] A separate presentation describes "[c]ontracts that increase Lantus rebates if Auvi-Q is added to [the] formulary thus creating a bundled arrangement," and notes that the company had even considered a "triple product bundle" with Toujeo, despite concerns about the

[410] SANOFI_SFC_00010874.
[411] *Id. See also* SANOFI_SFC_00010880, at SANOFI_SFC_00010884.
[412] SANOFI_SFC_00010874, at SANOFI_SFC_00010877-79; SANOFI_SFC_00010880, at SANOFI_SFC_00010883.
[413] SANOFI_SFC_00010874.
[414] SANOFI_SFC_00013990.
[415] SANOFI_SFC_00014648.
[416] SANOFI_SFC_00014648.
[417] SANOFI_SFC_00014648, at SANOFI_SFC_00014653.

arrangements triggering Medicaid best price.[418] It's important to note that this counterstrategy was not limited to Sanofi. Another internal memo shows that Sanofi's competitors were using the same strategy: "Lantus is losing accounts and share within the institutional channel because of aggressive discounting and bundled contract offerings from Novo Nordisk and Lilly."[419]

Sanofi was not the only company that sought to use bundling to its advantage. For example, Novo Nordisk secured contract terms from CVS's Part D business in 2013 that tied its "exclusive" rebates for insulin to formulary access for a Type 2 diabetes drug called 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.[420] In order to qualify for the exclusive rebate, the plans would also need to list Victoza, a GLP-1 agonist,[421] on their formulary, exclude all competing insulin products, and ensure "existing patients using a [c]ompeting [p]roduct may not be grandfathered."[422] CVS also appears to have been prohibited from rebidding for products within the therapeutic class for placement on the national formulary until January 1, 2015, absent safety issues with one of the drugs.[423]

Following years of rebate and list price increases, manufacturers faced increased pressure from patients, payers, and the Federal government to decrease insulin's WAC price.[424] However, internal memoranda and correspondence collected for this investigation suggest that the downstream impact of lowering the WAC prices presented hurdles for pharmaceutical companies. A June 23, 2018 email memorializes a portion of a conversation Eli Lilly's President of the Diabetes Unit, Enrique Conterno, had with the CEO of OptumRx who allegedly "re-stated that [OptumRx] would be fully supportive of Lilly pursuing a lower list price option", but indicated that OptumRx would encounter challenges, namely, "the difficulty of persuading many of their customers to update contracts without offering a lower net cost to them."[425] In response, one executive noted, "we wouldn't be able to lower our list price without impacting our net price," and counseled waiting until early 2020 to reduce prices.[426] Two weeks prior to this email, Eli Lilly executives raised the possibility that PBMs would object to a list price reset because it would result in (1) a reduction in administrative fees for PBMs, (2) a reduction in rebates, which would impact PBMs' ability to satisfy rebate guarantees with some clients, and (3) impair their clients' ability to lower premiums for patients, thereby impacting their market competitiveness.[427] An excerpt of this email is shown below.[428]

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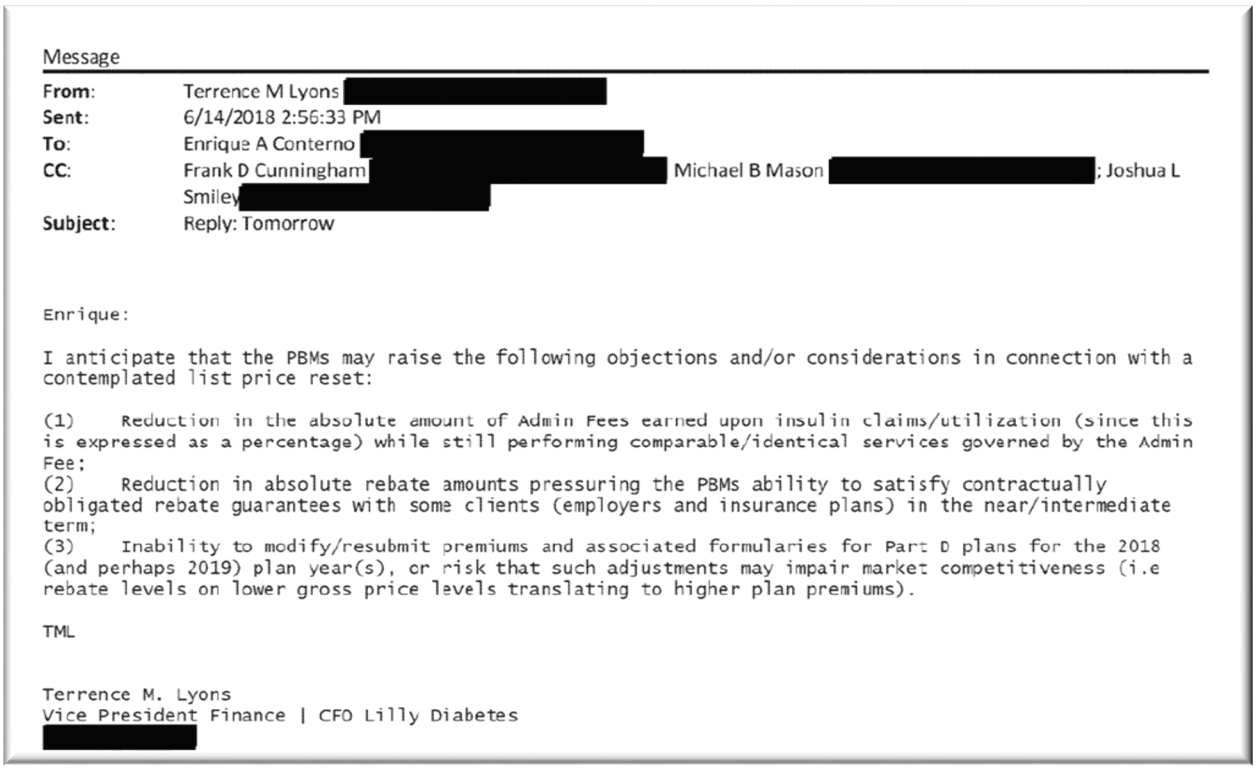
[418] SANOFI_SFC_00013800, at SANOFI_SFC_00013801.
[419] SANOFI_SFC_00009001, at SANOFI_SFC_00009002.
[420] NNI-FINANCE-000039, at NNI-FINANCE-000051.
[421] *GLP-1 agonists: Diabetes drugs and weight loss*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/type-2-diabetes/expert-answers/byetta/faq-20057955 (last viewed Jan 1, 2020).
[422] NNI-FINANCE-000039, at NNI-FINANCE-000052.
[423] NNI-FINANCE-000039, at NNI-FINANCE-000052.
[424] *See* LLY-SFCOM-UR-00005526.
[425] LLY-SFCOM-UR-00006684.
[426] LLY-SFCOM-UR-00006684.
[427] LLY-SFCOM-UR-00006563.
[428] LLY-SFCOM-UR-00006563.



Message

From: Terrence M Lyons [redacted]
Sent: 6/14/2018 2:56:33 PM
To: Enrique A Conterno [redacted]
CC: Frank D Cunningham [redacted] Michael B Mason [redacted]; Joshua L Smiley [redacted]
Subject: Reply: Tomorrow

Enrique:

I anticipate that the PBMs may raise the following objections and/or considerations in connection with a contemplated list price reset:

(1) Reduction in the absolute amount of Admin Fees earned upon insulin claims/utilization (since this is expressed as a percentage) while still performing comparable/identical services governed by the Admin Fee;
(2) Reduction in absolute rebate amounts pressuring the PBMs ability to satisfy contractually obligated rebate guarantees with some clients (employers and insurance plans) in the near/intermediate term;
(3) Inability to modify/resubmit premiums and associated formularies for Part D plans for the 2018 (and perhaps 2019) plan year(s), or risk that such adjustments may impair market competitiveness (i.e rebate levels on lower gross price levels translating to higher plan premiums).

TML

Terrence M. Lyons
Vice President Finance | CFO Lilly Diabetes
[redacted]

The internal memoranda and correspondence collected for this investigation show that exclusion lists have contributed to higher rebates in the insulin therapeutic class. Manufacturers increase rebates to respond to formulary exclusion threats, and to preserve revenue and market share through patient access. It also appears that increases in rebates are associated with increased list prices. This supports the notion that PBM demands for rebates contribute to rising insulin prices.

ii. Administrative Fees

Eli Lilly's reluctance to lower the list price of drugs—due partly to its effect on PBM revenue from administrative fees—illustrates a dynamic that the HHS OIG has identified as an area of concern for potential violations of the Anti-Kickback Statute.[429] According to rebate agreements collected for this investigation, PBMs earn administrative fees for each unit of a manufacturer's drug.[430] These fees, which are negotiated between the manufacturer and PBM in

[429] *See* DEP'T HEALTH AND HUMAN SERVS., OFF. OF INSPEC. GEN., FRAUD AND ABUSE; REMOVAL OF SAFE HARBOR PROTECTION FOR REBATES INVOLVING PRESCRIPTION PHARMACEUTICALS AND CREATION OF NEW SAFE HARBOR FOR PROTECTION FOR CERTAIN POINT-OF-SALE REDUCTIONS IN PRICE ON PRESCRIPTION PHARMACEUTICALS AND CERTAIN PHARMACY BENEFIT MANGER SERVICE FEES (Feb. 6, 2019), https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals. According to the HHS OIG, if administrative fees are tied to the list price of a prescription pharmaceutical product, based on sales volume, or far exceed fair market value of the services performed, these fees could function as a kickback. *Id.* HHS OIG proposed creating a new safe harbor that would provide a pathway, specific to PBMs, to protect remuneration in the form of flat service fees. *Id.*

[430] *See* ORX_Sen_Fin_0009384, at ORX_Sen_Fin_0009389. It's important to note that administrative fees only meant to be applied to drugs utilized by commercial and Medicare Part D plans. These are not charged on products utilized by Medicaid or the Children's Health Insurance Program (CHIP). *Id.*

rebate contracts, are meant to cover services such as reporting and monitoring health insurers' compliance with the rebate eligibility requirements, examples of which are detailed in a rebate contract between CVS Caremark and Novo Nordisk:[431]

> (h) Administrative Services. In consideration of the Administrative Fees, PBM will: (i) negotiate and contract with Part D Plan Sponsors for participation in the Rebates provided under this Agreement; (ii) notify Part D Plan Sponsors of the applicable requirements for receiving Rebates on Products in accordance with PBM's standard business practices; (iii) monitor Part D Plan Sponsor compliance with the Rebate eligibility requirements; (iv) calculate the amounts of Rebates applicable to Products for each Part D Plan Sponsor and invoice Manufacturer for such Rebates; (v) prepare detailed reports on Product utilization and Rebate calculations as described herein; (vi) allocate and distribute Rebates to Part D Plan Sponsors under the terms of PBM's agreements with Part D Plan Sponsors and provide supporting reports to the Part D Plan Sponsors; (vii) utilize internal control measures to protect against payment of unearned Rebates; and (viii) provide such other services related to the administration of the Rebate program as agreed upon by the parties from time to time. Administrative Fees are separate and apart from the Rebates paid to Part D Plans.

Administrative fees paid by drug manufacturers are calculated as a percentage off WAC.[432] Some Part D contracts even require manufacturers to pay administrative fees during the coverage gap phase (the phase that occurs between the initial coverage limit and the catastrophic coverage phase) of Medicare Part D.[433]

Although Part D plans are required to report rebates to CMS, they are not required to report administrative fees collected and retained by PBMs "if the fees are for bona fide services and are at fair market value."[434] This basic lack of transparency in the Medicare program has been an area of concern to HHS OIG, as has the competing interests that PBMs and manufacturers find themselves in due to the administrative fees being based on the WAC price. According to HHS OIG:

> When PBMs contract to administer the pharmacy benefit for health plans, the PBMs are the health plans' agents. However, the contracting health plans may not always know the services their PBMs are providing to pharmaceutical manufacturers. Manufacturers often pay PBMs fees for certain services (e.g., utilization management, medical education, medication monitoring, data management, etc.), and these fees may be calculated as a percentage of the list price of a particular drug product. If service fees paid by manufacturers are tied to the list price of the prescription pharmaceutical product, based on sales volume, or far exceed the fair market value of the services performed, these fees could function as a disguised kickback.[435]

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[431] CVSCM_SFC_0005005, at CVSCM_SFC_0005009.
[432] CVSCM_SFC_0005005, at CVSCM_SFC_0005018. *See also* ORX_Sen_Fin_0009384, at ORX_Sen_Fin_0009389.
[433] *See* CVSCM_SFC_0005005, at CVSCM_SFC_0005010.
[434] DEP'T HEALTH AND HUMAN SERVS., OFF. OF INSPEC. GEN., CONCERNS WITH REBATES IN THE MEDICARE PART D PROGRAM, at 4 fn. 16 (Mar. 11, 2011), https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf.
[435] *See* DEP'T HEALTH AND HUMAN SERVS., OFF. OF INSPEC. GEN., FRAUD AND ABUSE; REMOVAL OF SAFE HARBOR PROTECTION FOR REBATES INVOLVING PRESCRIPTION PHARMACEUTICALS AND CREATION OF NEW SAFE HARBOR FOR PROTECTION FOR CERTAIN POINT-OF-SALE REDUCTIONS IN PRICE ON PRESCRIPTION PHARMACEUTICALS AND

The amount of administrative fees paid industry-wide is not known because they are contained in the confidential rebate contracts with manufacturers and are not disclosed by the PBMs. However, a recent study by the *Pew Charitable Trusts* estimated that, between 2012 and 2016, the amount of administrative and other fees nearly tripled, reaching more than $16 billion.[436] While such totals are far from inconsequential, they appear to make up a relatively small amount of the $370 billion spent on retail prescription drugs in the United States,[437] and make up a relatively small share of the cost of individual pharmaceutical products.[438]

Administrative fees vary by contract, but generally fall between 3% and 5% in the insulin therapeutic class. For example, in 2019, OptumRx's administrative fee for Lantus represented 4.75% of WAC.[439] However, documents collected during the investigation show that PBMs have been collecting substantially greater revenue from administrative fees as WAC prices increase and the fees grow:[440]

Rationale for Recommendation:

- The recommendation is in response to the customer's request to increase Admin Fees from 3.00% to 4.75%.
- Factors leading to the reassessment and increase include:
  - Alignment with market competitive rates
    - Prime Therapeutics → 3%, Caremark →4% ESI →4.875% *note that ESI rate increased in 2016 by .5points*
  - Request of manufacturers to provide increased transparency to client-level compliance with rebate eligibility from prior levels
  - Increased number of manufacturer requested audits
  - Increased complexity of manufacturer required conditions for rebate eligibility
- The incremental 1.75% is <u>not</u> negotiable. If we do not agree to the 1.75% it will be captured from product(s) base rebate.

While the Committee's investigation did not request documents related to the agreement between PBMs and health insurers, Express Scripts provided a *pro forma* contract between the State of Tennessee and Cigna Corporation which suggests PBMs also charge health insurers non-rebate, administrative fees for providing pharmacy benefit management service—essentially profiting from all sides of the transaction.[441] This contract provides that Express Scripts earns administrative fees and, depending on the agreement, clinical fees[442] from the State of

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CERTAIN PHARMACY BENEFIT MANGER SERVICE FEES (Feb. 6, 2019), https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals.

[436] *The Prescription Drug Landscape Explored*, Pew Charitable Trust, at 35 (Mar. 2019), https://www.pewtrusts.org/-/media/assets/2019/03/the_prescription_drug_landscape-explored.pdf.

[437] *National Health Expenditures 2018 Highlights*, CTRS. FOR MEDICARE AND MEDICAID SERV. (2018), https://www.cms.gov/files/document/highlights.pdf

[438] *See Prescription Economics in the U.S. Drug Channel System*, DRUG CHANNEL INSTITUTE (Aug. 2017), http://www.drugchannelsinstitute.com/files/Drug_Channel_Economics-Pembroke-August2017.pdf.

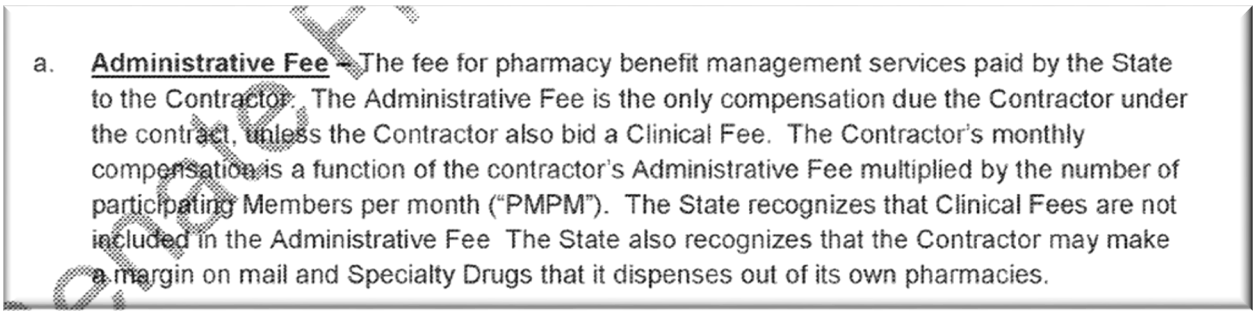
[439] ORX_Sen_Fin_0009384, at ORX_Sen_Fin_0009389.

[440] *See* SANOFI_SFC_00012321.

[441] Cigna-SFC-00017902, at Cigna-SFC-00017903.

[442] Clinical fees are defined as the amount paid to the PBM for their management of clinical programs such as safety and monitoring review, prior authorization, and step therapy edits and prior authorization and appeals. Cigna-SFC-00017902, at Cigna-SFC-00017904.

Tennessee, calculated as an agreed upon percentage multiplied by the number of participating members per month.[443] An excerpt from Express Scripts' pro forma contract is shown below.[444]



a. **Administrative Fee** – The fee for pharmacy benefit management services paid by the State to the Contractor. The Administrative Fee is the only compensation due the Contractor under the contract, unless the Contractor also bid a Clinical Fee. The Contractor's monthly compensation is a function of the contractor's Administrative Fee multiplied by the number of participating Members per month ("PMPM"). The State recognizes that Clinical Fees are not included in the Administrative Fee The State also recognizes that the Contractor may make a margin on mail and Specialty Drugs that it dispenses out of its own pharmacies.

The use of administrative fees between plans and PBMs is further supported by correspondence between Express Scripts and the Securities and Exchange Commission in 2017. The company explained that administrative fees and the percentage of rebates delivered to the plan are both negotiating levers PBMs use with their plan clients:

> The pricing for our PBM offering depends upon the benefit design selected by each individual client. The overall pricing in our client contracts depends on several components, including ingredient costs, administrative fees and rebates. We customize the economics of each client contract based on the client's assessment of how it can cost effectively deliver the pharmacy benefit package that provides appropriate care and value to its members. For example, one client may prefer to keep a greater percentage of rebates and compensate us for our services through greater administrative fees, while another client may prefer to keep a smaller percentage of rebates in exchange for reduced administrative fees. Furthermore, client pricing varies based on the mix of prescriptions dispensed — specifically the type of drug and the distribution method by which the drug is dispensed.[445]

Finally, 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 Swiss-based group purchasing organization (GPO), Ascent Health.[446] While there are several regulatory and legislative efforts underway to prohibit manufacturers from paying administrative fees to PBMs, there is no such effort to change the GPO safe harbor rules.[447] New arrangements used by PBMs to collect fees should be an area of continued investigative interest for Congress.

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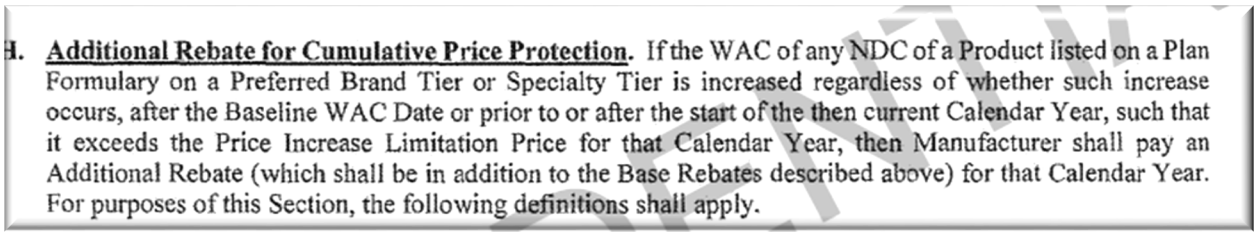
[443] Cigna-SFC-00017902, at Cigna-SFC-00017903.
[444] Cigna-SFC-00017902, at Cigna-SFC-00017903.
[445] *Express Scripts Response to Staff of the U.S. Securities Exchange Committee*, SEC (June 26, 2017), https://www.sec.gov/Archives/edgar/data/0001532063/000119312517213574/filename1.htm
[446] *See* Adam, Fein, *Express Scripts + Prime Therapeutics: Our Takeaways From This Market Changing Deal*, DRUG CHANNELS (Jan. 7, 2020), https://www.drugchannels.net/2020/01/express-scripts-prime-therapeutics-our.html.
[447] *Id.* It's important to note that GPOs are also compensated via manufacturer-paid administrative fees. *Id.*

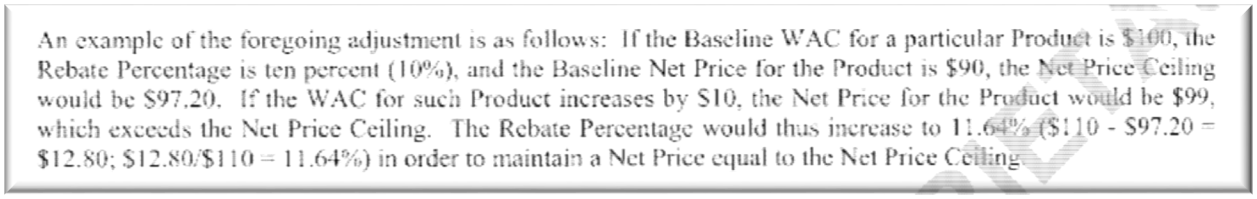
iii. Price Protection Clauses

In addition to rebates and administrative fees, PBMs also negotiate a price protection provision in their contract such that when a drug company increases the list price of its drug beyond a certain agreed upon percentage, the plan receives an additional rebate.[448] The caps in price protection terms vary widely. For example, one contract amendment between OptumRx and Sanofi had "price protection factors" that allowed the manufacturer to implement annual price increases from as little as 0% to as much as 12% depending on the therapy.[449]An example of a price protection clause in a rebate agreement between CVS Caremark and Sanofi is shown below:[450]



H. **Additional Rebate for Cumulative Price Protection.** If the WAC of any NDC of a Product listed on a Plan Formulary on a Preferred Brand Tier or Specialty Tier is increased regardless of whether such increase occurs, after the Baseline WAC Date or prior to or after the start of the then current Calendar Year, such that it exceeds the Price Increase Limitation Price for that Calendar Year, then Manufacturer shall pay an Additional Rebate (which shall be in addition to the Base Rebates described above) for that Calendar Year. For purposes of this Section, the following definitions shall apply.

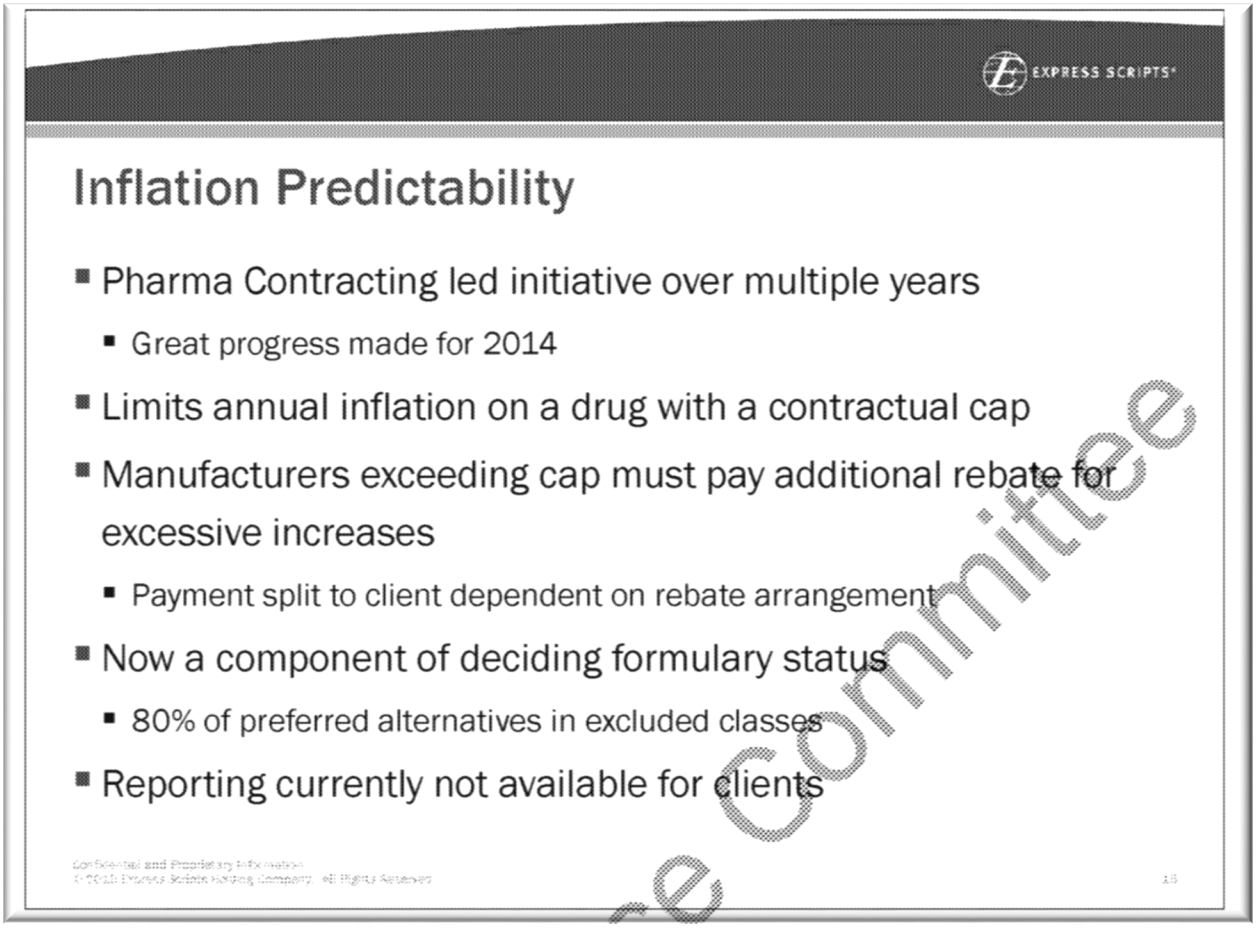
Another CVS contract with Novo Nordisk shows how price protection clauses can also be tied to a drug's net price (i.e. a manufacturer's revenue after rebates and discounts), as it was with Levemir, Novolog, and Novolog Mix 70/30:[451]



An example of the foregoing adjustment is as follows: If the Baseline WAC for a particular Product is $100, the Rebate Percentage is ten percent (10%), and the Baseline Net Price for the Product is $90, the Net Price Ceiling would be $97.20. If the WAC for such Product increases by $10, the Net Price for the Product would be $99, which exceeds the Net Price Ceiling. The Rebate Percentage would thus increase to 11.64% ($110 - $97.20 = $12.80; $12.80/$110 = 11.64%) in order to maintain a Net Price equal to the Net Price Ceiling.

Such payments are intended to limit annual inflation of a drug's price, and require manufacturers that exceed the cap to pay an additional rebate. An internal presentation from Express Scripts suggests that a portion of these payments may be retained by the PBM.[452] Shown below.[453]

[448] *See* CVSCM_SFC_0004331, at CVSCM_SFC_0004356.
[449] ORX_Sen_Fin_0009384. Please note that the Committee has redacted non-insulin therapies from this document.
[450] CVSCM_SFC_0004331, at CVSCM_SFC_0004356.
[451] NNI-FINANCE-000039, at NNI-FINANCE-000052-53
[452] Cigna-SFC-00018522, at Cigna-SFC-00018536.
[453] Cigna-SFC-00018522, at Cigna-SFC-00018536.



Although price protection clauses are intended to deter manufacturers from increasing prices too quickly, the investigation identified examples of manufacturers who found ways around them. For example, Novo Nordisk avoided price protection payments and rebate payments by timing drug price increases to occur just before or just after price protection penalties would have been triggered. In so doing, the company dodged millions of dollars in penalties for exceeding the contractual ceiling prices.

For example, in October 2014, company employees requested approval to increase the price of NovoLog and Novolin, noting that the "price increase is timed for mid-quarter to minimize price protection impact," and estimated that the moves would result in a $6 million upside for the brands that year.[454] A later email showed a similar strategy, as Novo Nordisk avoided $25 million in rebates and price protection penalties for Levemir by simply following Sanofi's price increase. Sanofi had taken a price increase of 11.9% on Lantus vials and pens the night before,[455] and Novo Nordisk employees saw an opportunity to avoid price protection by quickly following suit:

> Please note that many of our contracts look at the WAC price on the 45th day of the quarter (and monthly paid contracts at the 15th day), so … we will determine if it

[454] NNI-FINANCE-001715.
[455] NNI-FINANCE-001719-20.

makes better financial sense (due to rebate payments and price protection) to align the increase to the same date as NovoLog® (11/18).[456]

Following the analysis, the employee recommended that the company wait in order to capture a multi-million-dollar financial benefit:[457]

> After analyzing the additional cost of rebates and price protection, based on specific contracting terms, it was determined that it makes better financial sense **(~+$10M benefit)** to wait until after the 45th day of the quarter (11/18 is the first feasible date for the increase) vs increasing price today (effective 11/8). **Therefore, we are asking for your approval to follow their 11.9%** on November 18th** (first feasible increase date post the 15th). Approving this request will have a **benefit to 2014 of ~$25M.**

Novo Nordisk capitalized on this opportunity, making it an integral part of their pricing strategy. The company even built these avoided rebates and penalties into their revenue forecasts. In an email from May 2015, the Pricing Committee was asked to approve a planned price increase to specifically avoid price protection clauses for NovoLog and NovoLin:[458]

> We have secured Brand alignment on the timing and magnitude of the proposed increases. Please note that the price increase is timed for just after mid-quarter to minimize rebate and price protection impact. *(Many contracts base the rebate calculation on the WAC in effect at the 45th day of the quarter so taking on May 19 minimizes rebate impact in 2Q).*

Novo Nordisk repeatedly targeted CVS Caremark's Part D contract provisions to avoid paying price protection penalties. By increasing drug prices days before the price protection clauses took effect, Novo Nordisk avoided paying CVS Caremark millions of dollars in payments. In May 2014, the Pricing Committee was asked to approve the prices of NovoLog by the 27th of the month or "sooner to minimize the impact of price protection."[459] By increasing the list price by this date, Novo Nordisk estimated it would avoid paying roughly $12 million in price protection rebates.[460] Indeed, the contract between the two companies shows that the "Baseline Net Price," which the price protection caps are based on, is defined as the "Net Price in effect as of June 1st of the prior Contract Year and Baseline WAC means WAC in effect as of June 1st of the prior Contract Year."[461] This contract further defines the price protection provisions:

> The Net Price for each Product's Formulary Status shall be reviewed monthly by comparing the Net Price of the applicable calendar month to the Baseline Net Price. If the Product's Net Price has been increased by more than eight percent (8.00%) over Baseline Net Price ("Net Price Ceiling"), the Rebate percentage(s) for such product will be increased for such calendar month such that the Net Price will equal the Net Price Ceiling. The increased Rebate percentage(s) shall remain in effect during the remainder of the current Contract Year and shall return to their original percentage at the beginning of the next Contract Year.[462]

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[456] NNI-FINANCE-001719-18
[457] NNI-FINANCE-001719.
[458] NNI-FINANCE-001766.
[459] NNI-FINANCE-001709.
[460] NNI-FINANCE-001709.
[461] NNI-FINANCE-000082.
[462] NNI-FINANCE-000082, at NNI-FINANCE-000086.

The Pricing Committee approved the request and increased NovoLog and Novolin on May 28, 2014, three days before the 2015 CVS Caremark Part D pricing protection went into effect.[463] Two days later, Novo Nordisk took another price increase aimed at CVS Caremark Part D's 2015 price protection loophole, this time with its basal insulin, Levemir. Contract Operations Vice President Farruq Jafery informed the Pricing Committee that Sanofi had increased the price of Lantus—16.1% for the vial and 9.9% for the pen[464]—and that Novo Nordisk should follow their actions. He recommended Novo Nordisk follow Sanofi's lead and swiftly institute an identical pricing change (as discussed in further detail above) to avoid $13 million in incremental price protection rebates.[465]

However, by the time the 2016 contract bid cycle started in August 2015, CVS Caremark had caught on to Novo Nordisk's strategy and began to push back against Novo Nordisk's practices related to price protection:[466]

Background on CVS:

We know CVS has stated their disappointment with our price increase strategy (ie: taking just after the 45th day) and how it essentially results in a lower price protection, admin fee and rebate payment for that quarter/time after our increase. I don't think there's any disputing how we operationalize our price and that we do it this way to create the most value to NNI, but it has been costing CVS a good amount of money.

When CVS was here last week they reiterated their concern and Farruq/Brenda have committed to working on solution (WAC as of dispensed date), to be operationalized in 2016 with a resolution from a financial perspective to be effective 1/1/16 (ie: if implemented in 7/1/16 they will receive adjustment for the 1st half of 2016). CVS is requesting this to go back to 7/1/15.

To appease CVS, Novo Nordisk considered delaying a price increase on Levemir, but as the increase "capitalize[d] on all contracts" the company questioned the financial implications of such a move:

> We're scheduled to take a Levemir price increase next week (8/18) and Karen is about to finalize the formal email to [the] PC. The 18th is the first day after the 45th day we could operationalize the increase. We're doing it to capitalize on all contracts (rebate and PP payments). Specifically with CVS Maria is estimating that it will result in about $3.8M favorably to NNI (on the flipside cost CVS $3.8M then if they had WAC as of dispensed). Our price increase on **Levemir roughly garners us $2.5M per week and it costs CVS about $634k, so financially it makes sense to take the increase by about $2M per week. Question: Is there any appetite to delay the increase by a week or two so it's not apparent to CVS or are we okay recommending to PC as planned?**[467]

Despite their concerns with CVS, Novo Nordisk would approve the increase just after the 45th day of the quarter, even as the pricing committee agreed that CVS would "be upset regardless."[468] However, Novo Nordisk was not the only insulin manufacturer that repeatedly

[463] NNI-FINANCE-001965.
[464] NNI-FINANCE-001711, at NNI-FINANCE-001712.
[465] NNI-FINANCE-001711, at NNI-FINANCE-001712.
[466] NNI-FINANCE-001792, at NNI-FINANCE-001793.
[467] NNI-FINANCE-001792, at NNI-FINANCE-001793-94. Emphasis added.
[468] NNI-FINANCE-001792.

sought to avoid price protections. Eli Lilly internal communications also cited the elimination of price protection penalties as a reason for price increase timing.[469] These examples suggest that payers and PBMs accept list price increases as long as the increases do not affect their ability to collect higher rebates and discounts from manufacturers. However, this approach can lead to higher prices for the Federal government and individual consumer.

V. Conclusion

Diabetes is one of the most pervasive and deadly diseases in the United States. Millions of Americans live with this disease, and millions more are expected to be diagnosed this year alone. This disease also disproportionately impacts minority communities, rural communities, and those who are 65 and older. As insulin's list price has grown over time, so too have costs to consumers and the Federal government. As a result of these price increases, some diabetic patients have reportedly resorted to rationing their insulin medication, putting their lives at risk. Rising drug costs have also further strained the U.S. health care system.

The Committee conducted this investigation to better understand how the list price of insulin, a drug that's been available to patients for almost a century, has doubled (and, in some cases tripled) over the past decade. In pursuit of the facts, the Committee requested and reviewed over 100,000 pages of internal documents, memoranda, and rebate agreements produced by the three largest insulin manufacturers (Sanofi, Novo Nordisk, and Eli Lilly) and the three largest PBMs (CVS Caremark, Express Scripts, and OptumRx) in the United States. While the Committee feels that it received sufficient information to support the findings in this report, it notes that Novo Nordisk, CVS Caremark, Express Scripts, and OptumRx failed to fully respond to the Committee's document requests.

The investigation underscores how the opaque business practices of pharmaceutical manufacturers and PBMs have huge implications for patients, payers, and the Federal government, with respect to insulin and therapies for other diseases.

Insulin manufacturers compete fiercely, using rebates as bargaining chips to receive preferred formulary placement for their products and to block competition. The companies undertake these bidding wars to maximize revenue and capture—or maintain—market share. Furthermore, in some cases the investigation found that while insulin manufacturers closely monitor their competitors' pricing actions when determining their own list prices over time, there were multiple instances of companies increasing prices in lockstep with competitors. In part, insulin manufacturers make those decisions due to countervailing pressures in their relationships with PBMs. Higher list price increases the dollar value of rebates, discounts, and other fees that a manufacturer can offer to a PBM and health plans, which are based on a percentage of the list price. Internal documents showed that insulin manufacturers were sensitive not only to their own bottom lines, but the bottom line of PBMs and of health plans that set formularies, without which a manufacturer's product would likely lose significant market share.

PBMs appeared to be complicit in this behavior. There appeared to be little, if any, attempt by PBMs to discourage manufacturers from increasing the list price of their products. Instead, the Committee found that PBMs used their size and aggressive negotiating tactics, such as the threat of excluding drugs from formularies, to extract more generous rebates, discounts,

[469] LLY-SFCOM-UR-00003202, at LLY-SFCOM-UR-00003204-05.

and fees from insulin manufacturers. To be clear, PBMs have an incentive for manufacturers to keep list prices high, since the rebates, discounts, and fees PBMs negotiate are based on a percentage of a drug's list price—and PBMs retain at least a portion of what they negotiate. In fact, the investigation found instances in which insulin manufacturers were dissuaded from setting lower list prices for their products, which would have likely lowered out-of-pocket costs for patients, due to concerns that PBMs and health plans would react negatively.

Lastly, it is clear that the average net prices for insulin—that is, the revenue manufacturers receive after paying rebates—have declined in recent years due to the growth of rebate sizes. However, manufacturers are still retaining higher average net prices, and thus, generating more revenue per unit of insulin, than they were during the first decade of the 21st century. Large rebates have shrunk the percentage of gross revenue that manufacturers retain, but the exponential growth of WAC prices over the last 20 years has benefited insulin manufacturers by slowing margin declines, and PBMs by increasing revenue derived from rebates and fees.

In recent years, Senator Grassley and Senator Wyden have worked together to bring unparalleled transparency to pharmaceutical pricing and marketing. While this investigation was focused on insulin, it brings Congress and the public one step closer to better understanding the complex market dynamics of the U.S. drug pricing system. Undoubtedly, there is more work to be done. The Committee will continue to shed light on pharmaceutical pricing practices that cause financial harm and worse health outcomes for the American people.

Appendix

1. Documents Produced by Eli Lilly
2. Documents Produced by Sanofi
3. Documents Produced by Novo Nordisk
4. Documents Produced by CVS Health Corp. (CVS Caremark)
5. Documents Produced by OptumRx
6. Documents Produced by Cigna Corporation (Express Scripts)