

Congress of the United States
Washington, DC 20515

May 16, 2022

VIA ELECTRONIC TRANSMISSION

The Honorable Lina M. Khan
Chair
Federal Trade Commission
Washington, D.C. 20580

Re: FTC-2022-0015-0001
Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and their Impact on Independent Pharmacies and Consumers

Dear Chair Khan:

We write to you today regarding the Federal Trade Commission's (FTC) Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and their Impact on Independent Pharmacies and Consumers, document identification FTC-2022-0015-0001. Please submit this letter on the public record as a formal comment submitted by Senators Charles Grassley, Ron Wyden, and Mike Braun.

I. Background

On January 14, 2021, Senator Grassley and Senator Wyden released an 88-page bipartisan staff report titled, "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug."¹ Our report provides a comprehensive overview of the Senate Finance Committee's nearly two-year investigation into how the three largest insulin manufacturers—Sanofi, Novo Nordisk, and Eli Lilly—and the three largest pharmacy benefit managers (PBM)—OptumRx, Express Scripts, and CVS Caremark—price insulin medication. We reviewed more than 100,000 pages of internal company documents and exposed the behind the scenes negotiations that take place between insulin manufacturers and PBMs. Information and documents collected during this investigation suggest that a combination of factors contribute to patients facing higher costs for insulin.² Most notably, however, the practice of offering rebates, discounts, and other fees to PBMs

¹ STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

² STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

to secure preferred formulary placement seems to be connected to increasing wholesale acquisition price (WAC), known colloquially as “list price.” The materials we reviewed showed that such list price increases benefitted both PBMs and manufacturers, to the detriment of consumers.

We initiated this investigation for several reasons. At the time, it was widely reported that Americans living with diabetes were rationing their insulin medication, or forgoing it entirely, because of the drug’s high list price—practices that can lead to blindness, kidney failure, diabetic ketoacidosis, or even death.³ For example, during the Committee’s hearing titled *Drug Pricing in America: A Prescription for Change, Part I*, we heard testimony from Kathy Sego, a resident of Indiana and mother whose son has Type 1 diabetes.⁴ According to Ms. Sego, unbeknownst to her, her son began rationing his insulin in order for his family to afford the \$1,700 monthly price tag.⁵ Unfortunately, Ms. Sego’s family is not alone in this struggle.

As of 2019, more than 37 million Americans live with diabetes.⁶ Of this figure, more than 7 million use insulin on a daily basis.⁷ Diabetes disproportionally affects communities of color and those who live in rural communities. According to the CDC, the prevalence of diagnosed diabetes is highest among American Indians, Hispanics, and Black Americans.⁸ Recent research also suggests a surge in diabetes among American’s youth as well.⁹ The science is clear—this disease will play a role in the health of Americans for years and decades to come.

With these health disparities at the forefront of public discourse, we became concerned that the market power and opaque business practices of PBMs were affecting insulins’ list prices. As you know, PBMs manage the prescription drug benefit on behalf of health insurers and other payers, including employer-sponsored health plans and the Federal government.¹⁰ Through mergers and acquisitions, just three PBMs—OptumRx, Express Scripts, and CVS Caremark—

³ Tiffany Stanley, *Life, Death, and Insulin, As the cost of the lifesaving medication skyrockets, some desperate diabetics are rationing – and risking their lives. Was Alex Raeshawn Smith one of them?* THE 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>; Alexa Lardieri, *Study: Almost half of diabetics skip care because of high cost*, U.S. NEWS (June 18, 2018), <https://www.usnews.com/news/health-care-news/articles/2018-06-18/study-almost-half-of-diabetics-skip-care-because-of-high-cost/>.

⁴ *Drug Pricing in America: A Prescription for Change Part I, Hearing Before the S. Fin. Comm., 106th Cong.* (2019) (statement of Kathy Sego), <https://www.finance.senate.gov/download/segotestimony>.

⁵ *Drug Pricing in America: A Prescription for Change Part I, Hearing Before the S. Fin. Comm., 106th Cong.* (2019) (statement of Kathy Sego), <https://www.finance.senate.gov/download/segotestimony>.

⁶ *The Facts, Stats, and Impacts of Diabetes*, CDC <https://www.cdc.gov/diabetes/library/spotlights/diabetes-facts-stats.html#:~:text=Key%20findings%20include%3A,t%20know%20they%20have%20it> (last reviewed Jan. 24, 2022).

⁷ *Drug Pricing in America: A Prescription for Change Part I, Hearing Before the S. Fin. Comm., 106th Cong.* (2019) (statement of Kathy Sego), <https://www.finance.senate.gov/download/segotestimony>.

⁸ *Prevalence of diagnosed diabetes*, CDC, <https://www.cdc.gov/diabetes/data/statistics-report/diagnosed-diabetes.html> (last reviewed Dec. 29, 2021).

⁹ *New Research Uncovers Concerning Increases in Youth Living with Diabetes in the U.S.*, CDC (Aug. 24, 2021), <https://www.cdc.gov/media/releases/2021/p0824-youth-diabetes.html>.

¹⁰ STAFF OF S. FIN. COMM, 116TH CONGRESS, *INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG* (COMM. PRINT 2021), at 24, <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

control more than 80% of drug benefits administered to more than 180 million Americans.¹¹ PBMs are also vertically integrated with health insurers and operate their own pharmacies.¹² Despite, or perhaps because of, this level of consolidation, PBMs operate with little transparency, making it difficult, if not impossible to understand how PBMs influence prescription drug pricing. This opacity led to the beginning of the Committee’s bipartisan investigation in 2019, and it is why Senator Grassley called on the FTC earlier this year to move forward on a revised 6(b) study to examine competitive concerns within the PBM industry.¹³

This letter will provide a brief overview of the Committee’s investigative findings, explain how the business practices of PBMs influence list price especially in the insulin therapeutic class, and describe how these practices affect patients, payers, and the Federal government. We are also attaching a copy of the Committee’s 88-page bipartisan report to this letter. We strongly encourage your staff to read its contents as you formulate your 6(b) study.

II. High List Prices Appear to Be Related to Certain PBM Contracting Practices

During the Committee’s nearly two-year bipartisan investigation, PBMs argued that they work to obtain the lowest net price for their clients (or, the price realized by the health plan after deducting rebates, discounts, and other fees) and that manufacturers are, “solely responsible for the high cost of prescription drugs.”¹⁴ Manufacturers on the other hand argued PBMs “favor products with high list prices and deep rebates” to attract and retain clients and that rebates do not directly benefit patients.¹⁵ During the Committee’s investigation, we found that certain contracting practices create incentives for PBMs to favor drugs with high list prices and high rebates, which discourages manufacturers from competing to lower list prices.¹⁶ We also found that insulin is

¹¹ STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 24-29, <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

¹² STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 24-25, <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

¹³ Press Release, Grassley, Wyden Release Insulin Investigation, Uncovering Business Practices Between Drug Companies and PBMs that Keep Prices High (Jan. 14, 2021), <https://www.finance.senate.gov/chairmans-news/grassley-wyden-release-insulin-investigation-uncovering-business-practices-between-drug-companies-and-pbms-that-keep-prices-high>; Press Release, Grassley Presses FTC to Investigate Pharmacy Benefit Managers’ Role in Consumer Drug Prices (Mar. 10, 2022), <https://www.grassley.senate.gov/news/news-releases/grassley-presses-ftc-to-investigate-pharmacy-benefit-managers-role-in-consumer-drug-prices>.

¹⁴ *Drug Pricing in America: A Prescription for Change Part III, Hearing Before the S. Fin. Comm., 106th Cong.* (2019) (statement of John M. Prince, Chief Executive Officer, OptumRx), <https://www.finance.senate.gov/imo/media/doc/435631.pdf>.

¹⁵ *Drug Pricing in America: A Prescription for Change Part II, Hearing Before the S. Fin. Comm., 106th Cong.* (2019) (in response to questions submitted for the record by Sen. Menendez), <https://www.finance.senate.gov/imo/media/doc/37143.pdf>; *Drug Pricing in America: A Prescription for Change Part II, Hearing Before the S. Fin. Comm., 106th Cong.* (2019) (statement of Albert Bourla, Ph.D., Chief Executive Officer, Pfizer), <https://www.finance.senate.gov/imo/media/doc/37143.pdf>.

¹⁶ STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 63, <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

unaffordable for many Americans, especially those with high-deductible health plans, those who are underinsured, or those who have no insurance.¹⁷

a. PBM Contracting Practices: Rebates, Formulary Exclusion Lists, Administrative Fees, and Price Protection Clauses

Rebates have increased in lock step with list price since at least 2013. For example, internal company documents collected for the Committee’s investigation show that, in 2013, average rebates for long-acting insulin products hovered around 2% and 4% for preferred formulary placement.¹⁸ However, approximately six years later, rebates for the same product were as high as 79.75%.¹⁹ [It’s important to note that rebates vary by product, payer, and placement on a plan’s formulary. However, in the insulin therapeutic class, we found that PBMs with a large volume of clients are able to extract higher rebates from manufacturers when compared to smaller payers, who often lack leverage and resources.²⁰] WAC data collected for the Committee’s investigation also suggest list prices for long-acting and short-acting insulins have increased rapidly during this same period. 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
- 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

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As list price and rebates have increased in the insulin therapeutic class, the cost to patients and the Federal government has ballooned. Based on data provided by the Centers for Medicare and Medicaid Services (CMS), annual spending on insulin has increased by billions of dollars over the past decade. Between 2010 and 2018, Medicare Part D spent \$78.4 billion prior to rebates.²²

¹⁷ STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 10-12,

<https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

¹⁸ STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 60,

<https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

¹⁹ STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 60,

<https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

²⁰ STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 62,

<https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

²¹ STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 37,

<https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

²² STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 40,

<https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

Patients' costs for insulin have also soared. Based on Medicare Part D gross drug cost data, in 2018, more than a quarter of patients enrolled in Medicare Part D spent upwards of \$5,000 a year on their insulin medications.²³ This is why the Federal government must continue to take steps to lessen the financial burden of Americans living with diabetes, including investigating ways in which certain business practices impact list price.²⁴

We found that a manufacturer's decision to increase insulin's list price was influenced, in part, by certain PBM contracting practices. For example, beginning in 2012, payers and PBMs increased their use of formulary exclusion lists to control drug costs.²⁵ When a drug is excluded from a formulary, it means the drug will not be covered by insurance unless an exception is granted for the patient.²⁶ Exclusion can have significant consequences for patients and manufacturers. For patients, if a drug is excluded from coverage, they are forced to either switch to another product or pay significantly more to stay on their preferred medication.²⁷ For manufacturers, exclusion can result in significant financial loss and reduced market share.²⁸ Indeed, the Committee's investigation found several instances where manufacturers increased their rebate offers to PBMs significantly following the threat of exclusion, which appears to have contributed to higher list prices.

Other PBM contracting practices also appear to embolden high list prices. For example, PBMs earn an administrative fee for each unit of a manufacturer's drug dispensed at the pharmacy counter.²⁹ These fees, which are calculated as a percentage off WAC, are negotiated between the PBM and manufacturer to cover costs related to the rebate program like monitoring their client's compliance with rebate eligibility requirements and preparing reports on product utilization.³⁰ The amount of administrative fees paid industry-wide is not well known because this information is contained in confidential rebate agreements and not disclosed by PBMs. However, information

²³ STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 42,

<https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

²⁴ Senator Grassley's Prescription Drug Price Reduction Act (PDPRA) of 2019 is one such example where Congress can take meaningful action to lower drug costs for seniors. PDPRA modernizes Medicare Part D, limits patients' out-of-pocket costs, and penalizes manufacturers who raise list price higher than inflation. This bill was discharged by the Senate Finance Committee in a bipartisan vote (19-9) in July 2019.

²⁵ STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 63,

<https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

²⁶ STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 66,

<https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

²⁷ STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 66,

<https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

²⁸ STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 66,

<https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

²⁹ STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 72,

<https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

³⁰ STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 73,

<https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

collected for this investigation suggests that, in the insulin therapeutic class, administrative fees are between 3% and 5% of WAC.³¹ Administrative fees appear problematic because manufacturers are willing to increase list price in order to offer PBMs these additional concessions to secure preferred formulary placement. As one law review article explained it, when discussing administrative fees in the context of PBMs:

“[T]hese payments reduce the drug company’s net income from sales of the drug and increase the PBM revenue related to a specific drug. Even when a drug company pays for services from a PBM, if the value of the service is substantially less than the payment made, the transaction is simply an indirect price concession. Once again, raising list price can leave room for the drug company to offer these goodies . . . [and, as a result], many people be will be forced to pay higher list prices.”³²

In addition to rebates and administrative fees, PBMs also negotiate price protection clauses. Price protection clauses are meant to limit a drug manufacturer from increasing list price beyond an agreed upon percentage.³³ If the manufacturer increases the list price beyond the agreed upon percentage, the PBM and health plan receive an additional rebate depending on the terms of the contract.³⁴ Based on the Committee’s investigation, price protection clauses do not deter annual inflation of a manufacturer’s list price.³⁵ Instead, PBMs accept list price increases as long as they continue to secure more and more price concessions for themselves and their clients.

III. Conclusion

We found that PBM contracting practices do little to discourage high list prices, especially in the insulin therapeutic class. In fact, this perverse system exacerbates the problem by discouraging manufacturers from competing to lower list price and prevents competitors with lower priced alternatives from gaining a foothold. This prevents meaningful competition, harming taxpayers and the Federal government in the process. This is why it is important that the FTC conduct a 6(b) study and review the ways in which PBMs serve as the gate keepers for prescription

³¹ STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 74, <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

³² Robin Feldman, *Perverse Incentives: Why Everyone Prefers High Drug Prices—Except for Those Who Pay the Bills*, 57 HARV. J. ON LEGIS. 303, 328 (2020).

³³ STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 75-76, <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

³⁴ STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 76, <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

³⁵ STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 75-80, <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

drugs for millions of Americans and how other business practices may harm patients, payers, and the Federal government.³⁶



Charles E. Grassley
Ranking Member
Senate Judiciary Committee



Ron Wyden
Chairman
Senate Committee on Finance



Mike Braun
Senator

³⁶ As the FTC formulates its 6(b) study, it may want to pay special attention to spread pricing, direct and indirect remuneration (DIR), white bagging, and the impact of vertical integration on patients, payers, and the Federal government. There is a dearth of information about these practices, which calls for sunshine-like transparency.