United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

April 2, 2019

VIA ELECTRONIC TRANSMISSION

Sir Andrew Witty
Chief Executive Officer
Optum

Dear Mr. Witty,

Just last year, the Federal government spent $334 billion on prescription drugs, which represents a significant portion of overall health care costs in the United States.[1] The cost of prescription drugs impacts hundreds of millions of patients who take prescription medications and the taxpayers who support our government health care programs. We want to ensure that patients are able to acquire prescription drugs necessary for them to enjoy a happy and healthy life, and to ensure that those drugs are affordable.

The Centers for Disease Control and Prevention has estimated that more than 30 million Americans have diabetes, equaling roughly 10 percent of the population, and the American Diabetes Association has estimated that 1.5 million people will receive new diagnoses each year.[2] For many with diabetes, particularly those with Type 1, leading a normal life requires daily insulin injections or an insulin pump to manage blood sugar levels. Even though insulin has been used to treat diabetes for almost 100 years, its price has continued to increase, putting stress on patients and taxpayers alike. For example, a recent study found that one in four diabetic patients reported underusing insulin due to its cost,[3] a worrying data point given the disastrous health consequences of undertreating diabetes.

Pharmaceutical manufacturers are the starting point for drug prices. To that end, on February 22, 2019, we sent letters to the three largest insulin manufacturers serving the U.S.

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[1] Ctrs. for Medicare & Medicaid Services, National Health Expenditures 2017 Highlights (last visited Mar. 29, 2019), *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf.

[2] Press Release, Ctrs. for Disease Control and Prevention, *New CDC report: More than 100 million Americans have diabetes or prediabetes,* (Jul. 18, 2017), *available at* https://www.cdc.gov/media/releases/2017/p0718-diabetes-report.html. *See also Statistics About Diabetes,* American Diabetes Association (Mar. 22, 2018), *available at http://www.diabetes.org/diabetes-basics/statistics/.*

[3] Darby Herkert, et al., *Cost-Related Insulin Underuse Among Patients With Diabetes*, 179 JAMA INTERNAL MED, 112-114 (Jan. 2019), *available at* https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2717499.

market—Eli Lilly, Novo Nordisk, and Sanofi—inquiring about how these companies price their insulin products. However, while manufacturers set the list price for insulin, pharmacy benefit managers (PBM) play a critical role in the pricing of insulin on which people living with diabetes depend.

As the primary negotiators for government payers, commercial insurers and individual employers, PBMs are in a unique position to leverage their size to lower drug prices. On the front end of the supply chain, PBMs can accept or reject rebates offered by drug companies, which directly affects total spending on prescription drugs. They also determine a given drug's placement on a formulary—a list developed by PBMs that dictates what therapies an insurance plan covers—and the amount of cost-sharing. Exclusion from a formulary can have an immediate impact on patient access and the ability to pay for a therapy, and has enormous financial implications for pharmaceutical manufacturers. On the back end, PBMs set reimbursement fees for pharmacies, determine which pharmacies are included in a plan's network, and, in many cases, operate their own mail order and specialty pharmacies. In addition to other ancillary services offered to various actors in the pharmaceutical supply chain, PBMs exercise incredible power over the price and availability of prescription drugs for consumers.

As consumers face rising bills at the pharmacy counter, it is unclear whether PBMs are appropriately leveraging their power for the benefit of taxpayers and patients, especially patients who take multiple or high-cost medications. One recent analysis of Part D formularies found that PBMs may be producing formularies that encourage the use of more expensive branded drugs by assigning them fewer utilization controls compared to generic equivalents.[4] Other reports of troubling industry practices include improperly using therapeutic substitutions on formularies to increase rebates,[5] and using spread pricing to maximize profits without discernable benefits for consumers.[6] The Health and Human Services Inspector General (HHS OIG) has also raised concerns that PBMs have employed accounting tricks to hide revenue that should be used to lower costs for Federal health programs and their beneficiaries.[7] PBMs continue to face significant legal scrutiny, and have a history of paying millions of dollars in connection to damages, settlements, and fines connected to kickback schemes, fraud allegations, and false claims.[8] And while the HHS OIG found that "[t]he lack of transparency raises concerns

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[4] Mariana P. Socal, Ge Bai & Gerard F. Anderson, *Favorable Formulary Placement of Branded Drugs in Medicare Prescription Drug Plans When Generics Are Available*, Research Letter, JAMA INTERNAL MED. (Mar. 18, 2019), *available at* https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2728446.

[5] Milt Freudenheim, "Medco to Pay $29.3 Million to Settle Complaints of Drug Switching," N.Y. TIMES (Apr. 27, 2004), *available at* https://www.nytimes.com/2004/04/27/business/medco-to-pay-29.3-million-to-settle-complaints-of-drug-switching.html.

[6] Robert Langreth, David Ingold, & Jackie Gu, "The Secret Drug Pricing System Middlemen Use to Rake in Millions," BLOOMBERG (Sept. 11, 2018), *available at* https://www.bloomberg.com/graphics/2018-drug-spread-pricing/.

[7] U.S. DEPT. OF HEALTH AND HUMAN SERV., OFFICE OF INSPECTOR GEN., OEI-02-08-00050, CONCERNS WITH REBATES IN THE MEDICARE PART D PROGRAM, at 19 (2011) (stating that "Because sponsors may not always be able to verify whether these fees should be considered rebates or bona fide service fees, they may be inaccurately reporting this information to CMS."), *available at* https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf.

[8] Nate Raymond, "Ohio accuses UnitedHealth's OptumRx of drug overcharges in lawsuit" REUTERS (Mar. 18, 2019, 11:29 AM) (emphasizing the significance of current legal scrutiny), *available at* https://www.reuters.com/article/us-ohio-drugprices-lawsuit/ohio-accuses-unitedhealths-optumrx-of-drug-overcharges-in-lawsuit-idUSKCN1QZ1UH; *see also* CVS Health Corp., *2017 Annual Report* (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

that sponsors may not always have enough information to oversee the services and information provided by PBMs,"[9] the industry continues to fight efforts to bring visibility to its operations.[10]

Given this concerning history, the essential question is whether the practices employed by PBMs actually reduce the cost of insulin for patients and achieve the lowest possible federal spending. As the committee with jurisdiction over Medicare and Medicaid, this question has serious ramifications for how these programs function and the prices beneficiaries pay. Accordingly, please provide the below requested documents and information no later than April 16, 2019:[11]

1. Regarding your business relationships with insulin manufacturers:

    a. Please provide a list of all insulin manufacturers with which your company has had contracts, agreements or business relationships at any time since January 1, 2013. Please explain the nature and scope of your company's business relationships with each manufacturer, including but not limited to, the size of the insulin business and any ancillary, consulting or other services, such as patient on-boarding, that your company provided these manufacturers. In addition to rebates, please list all other discounts and price concessions your company receives from insulin manufacturers—with respect to their insulin products—and fees collected that were based upon each price concession. Please also describe all other benefits that were agreed to as part of the price concession negotiation including, but not limited to, elimination of prior authorization, step therapies, and other utilization management methods.

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would be shared with California, Florida, Minnesota, New Mexico, and the District of Columbia.), *available at* https://s2.q4cdn.com/447711729/files/doc_financials/annual/annual-report-2017.pdf; *Cf.* U.S. SECURITIES & EXCHANGE COMM'N, Form 10-K, at 32 (Feb. 27, 2018) (noting that the company, Express Scripts "... 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."), *available at* https://www.sec.gov/Archives/edgar/data/1532063/000153206318000004/esrx-12312017x10k.htm. Additionally, in regard to past damages, settlements and fines, *see Hearing on the State of Competition in the Pharmacy Benefits Manager and Pharmacy Marketplaces Before the House Judiciary Subcommittee on Regulator Reform, Commercial and Antitrust Law* (Nov. 17, 2015) (statement of David A. Balto), *available at* https://docs.house.gov/meetings/JU/JU05/20151117/104193/HHRG-114-JU05-Wstate-BaltoD-20151117.pdf citing Press Release, U.S. Dep't of Justice, "Medco to Pay $7.9 Million to Resolve Kickback Allegations" (May 20, 2015), *available at* 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), *available at* https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-60-million-civil-fraud-settlement-accredo-health-group; Press Release, Washington State Office of the Attorney General, "Attorney General McKenna Announces Caremark To Pay $41 Million To Resolve Multistate Consumer Protection Claims" (Feb. 14, 2008), *available at* 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), *available at* 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), *available at* https://www.justice.gov/archive/opa/pr/2005/November/05_civ_595.html.

[9] *See* CONCERNS WITH REBATES IN THE MEDICARE PART D PROGRAM, *supra* note 7, at ii.

[10] *See* Langreth, *supra* note 6.

[11] The scope of this request should be understood to include all predecessor entities over which your company maintains or previously maintained control.

b. Please provide all contracts between your company and each of these insulin manufacturers that are or have been in effect at any time since January 1, 2013. Examples of the types of contracts include, but are not limited to, supply agreements, pricing agreements, rebate agreements, other types of pricing concession agreements, and all agreements involving the performance of services or the providing of data.

c. What cost inflation or growth rate limits does your company require from insulin manufacturers, specifically, and other manufacturers, generally? Are such limits based on list price, net price or both? What penalties, fees, rebates or other payments, if any, must manufacturers make if they exceed such commitments? How does your company account for such penalties, fees, rebates or payments from manufacturers? That is, are they kept separate from other rebate revenue, or accounted for together?

d. Please provide a list of all instances in which a contract was terminated before its expiration date. In each instance, please provide the reason for such termination, and identify the party responsible for such termination.

2. Regarding your business relationship with health plans and programs:

a. Please provide a list of all payers for which your company has been responsible for negotiating insulin products at any time since January 1, 2013. This list should include Part D plans, Medicare Advantage, Medicaid programs or Medicaid managed care plans, Qualified Health Plans under the Affordable Care Act, and commercial group, self-insured employers and individual health plans. Please also provide a list all "classes," i.e., groups of plans for which rebates are negotiated *en bloc*.

b. For each plan and class, please provide the number of covered lives, the number of covered lives believed to have diabetes, the number of covered lives who made claims for insulin, and the number of insulin claims on an annual basis. In providing these data, please include lives who were covered for only a portion of the calendar year. To the extent this information is reportable on a class level, please provide a list of the plans that are included in each respective class. In all cases, please delineate whether the plan is a Medicare or Medicaid plan.

c. What assurances, if any, does your company make to health plans or programs regarding cost inflation, growth rate limits and trend agreements for insulin specifically, and prescription drug prices, generally? What, if any, penalties, fees or payments is your company required to pay if these limits are exceeded? How are these penalties accounted for?

3. Please explain your process for making pricing and rebate determinations. Please provide the names of the departments, divisions and key employees involved in rebate and pricing

decisions. Please provide the names and positions of all members of your company's manufacturer contracting group, and all policies, procedures and guidelines to which that group adheres. Please explain how the manufacturer contracting group interacts with the PBM's Pharmacy and Therapeutics (P&T) Committee. Who has final approval of pricing and rebate decisions, and how are these decisions communicated to plans, manufacturers and other entities within the insulin supply chain? Has your company ever had discussions with insulin manufacturers about the list prices they set for insulin products? If so, what were the nature of those discussions?

4. Please explain your process for making PBM-based formulary placement decisions for insulin products, including specifically answering the following questions:

    a. Please provide the names of the departments, divisions and key employees involved in formulary placement decisions. Who has final approval of formulary decisions, and how are these decisions communicated to plans, manufacturers and other entities within the insulin supply chain?

    b. What is the role of the PBM's P&T Committee? What is the process that the P&T Committee uses to determine pricing and rebate decisions? Does the P&T Committee have discretion to make decisions and recommendations independently? Please provide any policies, guidelines or other documents that set out the process for the P&T Committee generally and in relation to insulin products specifically. Please provide all names, positions and professional qualifications of P&T Committee members since January 1, 2013. If the company contracted, employed or otherwise consulted with any specialists or experts in regards to insulin placements, please provide their names as well as a description of the work they did and contributions they made in regard to such decisions. Please provide the minutes for any P&T Committee meeting since January 1, 2013 that included a discussion of any insulin products. Please also provide all recommendations, memoranda, reports or other communications the P&T Committee produced regarding insulin, whether for internal consideration or for clients.

    c. What, if any, analysis is conducted to gauge the impact of formulary placement decisions on patients, including, but not limited to, cost and clinical effects? Please provide all analyses, memoranda, presentations, data and other information that has been used in relation to patient or clinical impacts of insulin formulary placements since January 1, 2013. Please also provide any written communications that discuss patient or clinical impacts of insulin formulary placement decisions since January 1, 2013.

    d. What, if any, analysis is conducted to gauge the impact of formulary placement decisions on your company's business, including, but not limited to revenue, gross profit per claim, rebate amounts, plan costs, and other financial metrics? Please

provide all analyses, memoranda, presentations, data and other information that has been used in relation to the business impacts of insulin formulary placement since January 1, 2013. Please also provide any written communications that discuss the business impacts of insulin formulary placement decisions since January 1, 2013.

e. Please provide a list and describe any instances in which an insulin product was provided preferred formulary treatment when a therapeutic substitute was available for a lower net price. What was the reason for this decision? What was the difference in the rebate, discount or price concession between the two drugs?

5. For all FDA-approved insulin products since January 1, 2013, please provide a list of each PBM-based formulary placement positions, and the time periods when the formulary positions were in effect. If any FDA-approved insulin product was excluded at any time since January 1, 2013, please indicate the period when such exclusions were in effect. In addition, please provide:

   a. The number of claims for each FDA-approved product, by year, since January 1, 2013. To the extent that your company excluded an FDA-approved insulin product from its formulary, please provide for each product the number of claims that were made for the product in the calendar year before the exclusion was instituted;

   b. On a unit basis, the size of all rebates, discounts and other price concessions for each FDA-approved product, by year, since January 1, 2013, including any intra-year changes of such rebates or concessions. Please also provide the aggregate amount of rebates, discounts, other price concessions and fees collected for each year since January 1, 2013, annually;

   c. For each year since January 1, 2013, a breakdown of the total number of claims that fell into different formulary tiers, including but not limited to preferred, and non-preferred tiers;

   d. The average gross profit per claim for each FDA-approved insulin product, by year, since January 1, 2013;

   e. A description of the financial considerations, including but not limited to list price, rebates, other price concessions, price inflation agreements, and profit margins affected each FDA-approved product's formulary placement; and

   f. A description of how clinical efficacy and patient outcomes affected the FDA-approved product's formulary placement.

6. Regarding negotiations with pharmaceutical companies:

    a. Please list all types of financial transactions, contracts, terms of service and other agreements that are contingent in any way upon the size of a rebate or other price concessions paid by insulin manufacturers. In regard to insulin transactions, how do the size of rebates and other price concessions from pharmaceutical manufacturers affect the financial compensation your company receives? How does the size of a rebate and other price concessions affect your company's revenue and gross profit per claim? How would it affect the cost to the plans on behalf of which you are negotiating? Are there situations in which a larger rebate or price concession would incentivize your company to select a higher-priced insulin over a lower-priced therapeutic equivalent? Why or why not?

    b. Please provide a list of all revenue types that your company receives from manufacturers, including but not limited to rebates, other price concessions, fees for services, and any other payments. Please describe each type of revenue and the purpose for which your company receives it. How does your company account for each of these payments for reporting to the Securities and Exchange Commission? How does your company account for these payments for reporting to Part D plans and the Centers for Medicare and Medicaid Services? Is revenue derived from rebates or pharmacy reimbursements ever accounted for as fees? If so, does accounting for such payments as fees allow your company to not report and pass on these fees to Part D plan sponsors?

    c. Please list and describe all instances since January 1, 2013 in which your company negotiated a rebate for an insulin product that was bundled with a rebate for another product produced by the manufacturer.

    d. Please list and describe all instances since January 1, 2013 in which your company declined an insulin manufacturer's offer of a lower list price in the renegotiation of an existing contract or development of a new one.

7. Regarding your insulin business:

    a. Please provide the average per member per month (PMPM) insulin costs for members who have made claims for insulin at any time since January 1, 2013. Please provide this information for each month of the year—i.e., there should be 12 values for each year—rather than an annual average.

b. Please provide the average per member per year (PMPY) insulin costs for members who have made claims for insulin at any time since January 1, 2013. Please provide this data for each of the last six calendar years.

c. Please provide your annual gross profit per claim for each year since January 1, 2013.

d. Please provide the average out-of-pocket expense per claim for each year since January 1, 2013. In providing these data, please show how much of the expense is attributable to direct-to-patient costs—i.e. cash, credit card, check, etc.—versus coupons or patient assistance programs. If you are unable to provide such a breakdown, please explain why.

e. When your company sets co-pays for insulin products, is the co-pay linked to the list price or the rebated price?

8. Please explain the health information your company—or any parent company, subsidiary or affiliates, including affiliated pharmacies—collects regarding patients who are pre-diabetic, have been diagnosed with diabetes and/or make claims for insulin. For example, does your company collect health information or maintain records for levels of blood sugar, HbA1c, or albumin in the urine? What information regarding diagnostic and procedure codes does your company maintain? What information is collected regarding patients' prescription adherence? Please detail any other types of diabetes-related health information that is tracked or collected. In each instance, please specify whether this information is collected on a patient level and how the information is collected. Please also answer the following questions:

   a. For what purposes is this information collected and used?

   b. How is this information used in relationship to your company's analysis of plan costs?

   c. How is this information used to track the health status of individual patients?

   d. Does your company, or any parent company, subsidiary, or affiliates, including affiliated pharmacies, make decisions regarding an individual patient's coverage, treatment, or any other matter based on his or her collected information? If so, please provide detailed explanations of the types of decisions that would be based on collected information, and how the information influences the outcomes.

   e. How does your company store the information it collects? What does your company define as authorized and unauthorized uses? What specific measures are taken to protect against an unauthorized breach or use of the information? For example, has your company implemented the National Institution of Standards and Technology

Cybersecurity Framework or other safeguards? If not, why not? Has your company ever suffered a breach of this information? If so, please detail the time and scope of such a breach.

f. Does your company sell, profit from, or otherwise share any of the collected information with any third parties, including but not limited to, pharmaceutical manufacturers and consultants? Does your company sell, profit from, or otherwise share any of the collected information with any affiliated entities, including but not limited to, a parent company, subsidiary, or any other affiliate, including affiliated pharmacies? If so, please provide your privacy policy and any contractual restrictions your company impose on these parties' use or further sharing of such information. Please identify each entity to which such information is shared or has been shared since January 1, 2013. Please also explain the specific purposes behind any sharing of such information.

g. How is this information used to inform the work of diabetes management programs that your company runs?

h. Which of these data are collected by your company's diabetes management programs?

9. Regarding business relationships with pharmacies:

a. How does your company determine the reimbursement rate for pharmacies that dispense medications? In your answer, please explain whether and how your company considers overhead costs, profit margins, costs to obtain the prescription drugs from the manufacturers and/or wholesalers, and out-of-pocket costs to the patient when determining the reimbursement rate.

b. Does your company use a Maximum Allowable Cost (MAC) list? If so, please provide copies of that list relating to any insulin products on formularies your company created.

c. Does your company employ spread pricing contracts? If yes, please provide the following:

i. The number of contracts that operate under this structure, and the percent of volume across your book of business these contracts represent.

ii. The gross profit per claim your company made on pass-through contracts on an annual basis for each year since January 1, 2013.

d. Does your company employ pass-through contracts? If yes, please provide the following:

   i. The number of contracts that operate under this structure, and the percent of volume across your book of business these contracts represent.

   ii. The gross profit per claim your company made on pass-through contracts on an annual basis for each year since January 1, 2013.

10. Does your company operate a mail order pharmacy service? If so, please provide the following:

    a. The formula you use to price insulin purchased through this service, including whether you use a MAC or Average Wholesale Price and what discounts are applied in the calculation.

    b. The difference between the prices charged to plans for insulin products at preferred retail pharmacies versus through mail order.

    c. The difference in the gross profit per claim your company made on insulin product claims filled through your mail order pharmacy and insulin product claims filled through preferred retail pharmacies on an annual basis for each year since January 1, 2013.

Should you or your staff have any questions, please contact Joshua Flynn-Brown of Chairman Grassley's Committee staff and Peter Gartrell of Ranking Member Wyden's Committee staff at 202-224-4515.

Sincerely,

Charles E. Grassley
Chairman
Senate Finance Committee

Ron Wyden
Ranking Member
Senate Finance Committee