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Healthcare Benchmarks Informational Hearing
Written Remarks of Amgen, Inc.

Amgen is driven by its mission to serve patients and committed to improving lives by discovering and developing treatments and cures for serious diseases. The need for innovative medicines has never been greater. The biopharmaceutical industry's ability to innovate and treat patients with medical breakthroughs is driven by remarkable advances in science and technology. These tremendous advances and improved understanding of biology will enable us to take on serious illness, such as cancer and cardiovascular disease, and help people live longer, healthier lives.

At Amgen, we recognize the importance of responsible pricing for our medications. Our pricing strategy is grounded in the value our products provide, while aiming to employ flexible pricing approaches to ensure patient access. However, Amgen understands that the cost of prescription drugs is a concern for many patients and has programs in place to ensure affordability, while avoiding access hurdles from pharmacy benefit managers (PBM) and others to the extent possible.

Much of the public discourse about the cost of medicines has been largely focused on list prices despite the fact that companies like Amgen pay billions of dollars in rebates to insurers and PBMs. Unfortunately, these rebates may not be reflected in what patients experience at the pharmacy counter. That's because patients' out-of-pocket costs are set by PBMs and plan sponsors, who often require patients to pay a percentage of a medicine's full, undiscounted list price. As a result, patients rarely benefit directly from the cost savings negotiated on their behalf.

Understanding who pays what for a prescription medicine involves a better understanding of the pharmaceutical distribution supply chain and the market dynamics at work. The US healthcare system involves a variety of stakeholders including wholesalers, distributors, PBMs, health plans, pharmacies and other entities in the supply chain and a myriad of rebates, discounts, fees and other payments. PBMs are situated between the biopharmaceutical companies that research and develop innovative medicines and the patients likely to benefit from those treatments. PBMs play a central role in controlling prescription medicine access and affordability for hundreds of millions of Americans. Price concessions to a PBM are often necessary to ensure a medicine's appropriate formulary placement and otherwise facilitate patient access without burdensome utilization management hurdles, such as requiring a patient to complete a course of therapy with a drug that may not be the best suited for his or her particular condition.

PBMs role in the distribution system has increased over the years. Through horizontal and vertical integration, PBMs' role in the prescription drug supply chain has grown, as has their influence over which medicines patients have access to and whether they are affordable for patients. According to the FTC's interim report released in 2024 the top six integrated health plans and PBMs controlled about 94% of all pharmacy prescriptions.[1] This high degree of consolidation among insurers, PBMs and other payers, including integrated healthcare delivery systems has increased the negotiating leverage such entities have which has resulted in greater price discounts, rebates and service fees realized by those payers from our business.

PBM business practices and financial incentives negatively impact patient out-of-pocket costs. Pharmaceutical companies set the Wholesale Acquisition Cost (known as "WAC"), which is often referred to as the "list price." The WAC for each Amgen product is established by considering its value involving a range of considerations including the benefit to patients, the economic and social value and the clinical and economic burden of disease. These considerations are frequently established against a competitive backdrop. The list price is the price Amgen charges to wholesalers and distributors who purchase medicines, but it does not reflect the true price of the medicine after the rebates and discounts are negotiated with PBMs, wholesalers, distributors, health plans, and other entities in the supply chain.

Due to the way PBMs structure relationships with pharmacies and patient enrollees, increases in list prices generally have a limited impact on net prices, while significantly increasing total rebates paid to the PBMs. Due to the PBM market power and this environment, Amgen has increased list prices over the years to remain available as a choice on PBM formularies. If Amgen had not done so, a likely outcome would have been the removal of Enbrel® from formularies in favor of a competitor which provided a higher rebate to the PBM. Since Enbrel® and its competitor products do not provide the same response in all patients, they are not simply therapeutically equivalent to other drugs in the class. If taken off formulary, many Enbrel® patients would not have access to the medicine that they and their doctor had determined worked best for them.

PBMs' influence and financial incentives has created a market for innovative products where the intermediaries not the patients benefit. In this environment another factor is that companies are forced to simultaneously compete both on lowest net price (i.e. the "all in" price to the PBM) and the highest total rebate. Enbrel is in a competitive class with many other medications that are competing for PBM formulary position to enable patient access. Therefore, in this market dynamic, increases in list prices are coupled with higher rebates. Amgen is often paying increasingly higher rebates to the PBMs to ensure products remain on the formulary, which is critical to ensure patient access to treatment. This dynamic results in rising list prices, while net prices to the PBMs decrease.

Furthermore, barriers to reducing list prices are created by the manner in which a PBM determines a drug's "net cost," which serves as an important figure for a PBM's current and potential payer-clients. PBMs calculate plan "net cost" by taking the net price of the drug (e.g., the list price reduced by all applicable rebates) then reducing it further by the patient's out-of-pocket cost. Thus, the more the patient pays out of pocket, the greater the reduction in the net price, meaning a more desirable "net cost" figure for the PBM's client. Because patient out-of-pocket cost is increasingly based on list price, higher list price drugs often result in higher patient out-of-pocket costs and, consequently, even lower "net cost" figures. This means a list price reduction that results in a corresponding reduction in the patient's copayment may be viewed negatively by a PBM as increasing plan "net cost." In other words, where net price to the healthcare system remains constant, a lower list price drug may be viewed by a PBM or payer as increasing plan "net cost" if the patient pays less out of pocket at the pharmacy counter.

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[1]U.S. Federal Trade Commission Office of Policy Planning; "Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies", July 2024
https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf

Contributing to this dynamic is the fact that payers including healthcare insurers, and PBMs continue to find ways to reduce their costs. This includes utilizing benefit designs that incorporate high deductibles and coinsurance which expose patients to high out-of-pocket costs based on undiscounted list prices, even though the net prices available to PBMs and health plans are often significantly lower. Today, nearly half (49 percent) of commercial total patient out-of-pocket spending for brand medicines is based on list price. Payers are also increasingly placing more significant limitations on patients' use of manufacturer commercial co-pay assistance programs.

Rebate guarantees collected by PBMs for their clients also drive list price increases. PBMs use rebate guarantees in contracts to provide predictability and assurance to plan sponsors on the level of expected rebates for the duration of the contract. PBMs collect these rebates from manufacturers. The goal for manufacturers with these rebates is to secure a favorable formulary placement, which may lower patients' out-of-pocket costs. However, rebate guarantees limit manufacturers' ability to reduce list prices since the guarantees dissolve when a manufacturer reduces its list price to be closer to that of the drug's net price. This dynamic puts pressure on manufacturers to increase list prices, since rebates are based on the difference between list and net prices. However, because patients' out-of-pocket costs are often a percentage of the list prices, not net price, all the rebates provided by manufacturers may not actually help patients pay a lower price for their medicines.

More recently PBMs have been announcing efforts to pass along rebates to many clients. This is likely due to the increased criticism for keeping a portion of rebates as revenue for themselves. In turn, PBMs are increasingly now relying on new administrative fees. These fees are charged to manufacturers, pharmacies, health insurers, and employers as a primary source of profit. These fees can include administrative fees, spread pricing (charging patients more than the PBM pays for the drug), and other hidden fees. Analyses published by Nephron Research found that while the value of rebates paid to PBMs continues to grow, fees and specialty pharmacy now drive a greater share of PBM profits.[2] However, as with rebates, PBMs base administrative and other fees on drug list price. Due to this dynamic, similar to rebates, manufacturers provide more dollars to PBMs, but these fees are not necessarily passed on to plans, client groups or patients. The Nephron Research found that fees that PBMs charge biopharmaceutical companies doubled in the commercial market over five years and were fueled by increases in traditional administrative fees as well the emergence of a new data and PBM contracting entity fees (referred to as "vendor fees").[3]

Health plans and employers may use some portion of the rebates paid by manufacturers to reduce premiums for all enrollees, rather than to directly lower costs for patients facing high cost sharing for their medicines. However, it's becoming an increasingly difficult task to understand the proportion of rebate dollars applied to maintain more affordable premiums versus other uses. Furthermore, requiring patients with high prescription medicine expenditures to pay more out of pocket while rebate savings are spread out among all health plan enrollees in the form of lower premiums results in a system of reverse insurance. Simply put, asking sicker patients with high medicine costs to subsidize premiums for healthier enrollees is the exact opposite of how health insurance is supposed to work.

Without changing the net price to the healthcare system, the lower list price drug is viewed as increasing plan "net cost" because the patient pays less out of pocket at the pharmacy counter. Policymakers may need to consider legislative policy interventions to better address these misaligned incentives which impact list prices. Market-based reforms to improve patient affordability may include a range of approaches involving passing through rebates to patients, and breaking the link between PBM compensation and the price of medicines.

[2] Eric Percher, Nephron Research. Trends in Profitability and Compensation of PBMs and PBM Contracting Entities. Sept. 18, 2023. Available at https://nephronresearch.com/trends-in-profitability-and-compensation-of-pbms-and-pbm-contracting-entities/

[3] Id. at pg. 3.

We believe that innovative biopharmaceuticals are an important part of the solution to the significant burden of serious diseases that impact patients and society. Ongoing investment in research and development have helped to bring innovative biopharmaceuticals to market to significantly improve the quality and length of patient's lives and even cure diseases. We remain committed to working with policymakers to advance market-based reforms that will promote competition and improve patient access to new therapies without stifling innovation in the U.S.