June 3, 2025

The Honorable Chuck Grassley
Chairman
U.S. Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Dick Durbin
Ranking Member
U.S. Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Grassley and Ranking Member Durbin:

Thank you for the opportunity to testify before the U.S. Senate Committee on the Judiciary at your May 13, 2025, hearing on behalf of the Pharmaceutical Care Management Association (PCMA). Please view PCMA's responses to Senators Amy Klobuchar and Mike Lee below.

**Response for Senator Klobuchar**

1. **How does the market power of pharmaceutical companies affect the ability to negotiate for lower prescription drug prices?**

The prescription drug market is unique, with patent and exclusivity protections designed to incentivize innovation by creating monopolies, which grant manufacturers virtually unlimited pricing power for specific periods of time. When drug companies extend monopolies beyond the intended period, competitors are prevented from coming to market on the timeline intended by policymakers, resulting in higher drug costs.

A drug company's market power affects a pharmacy benefit manager's ability to negotiate for lower prescription drug costs by skewing the leverage of the negotiating parties. When manufacturers hold valid patents or regulatory exclusiveness, their products face no competition, giving the companies monopoly pricing power. This is especially true for brand-name drugs with no other brand, generic, or biosimilar alternatives available. Combined with the fact that manufacturers are solely responsible for setting and increasing list prices, manufacturers hold an enormous amount of control over the cost of prescription drugs.

Policies that enhance competition will make drugs more affordable. Direct competition between brand-name drugs lowers costs, and the introduction of generic versions of brand-name drugs is proven to be effective at reducing costs. The Food and Drug Administration found that as few as six generic competitors lowers prices by 95%.[i]

PCMA commends Sen. Klobuchar's efforts to address drug company patent abuse and support the *Stop Significant and Time-wasting Abuse Limiting Legitimate Innovation of New Generics (Stop STALLING) Act,* which will reduce drug prices by promoting competition.

Ultimately, the more market power a drug manufacturer holds, the less room there is to negotiate, and the more important it becomes to preserve PBMs' ability to drive competition and

manage costs. PCMA strongly supports the bipartisan work of this committee to address patent abuse, including the recent advancement of legislation that would substantially support greater competition and stop drug companies from wrongfully extending monopoly pricing and imposing higher costs on American patients and taxpayers. We hope the full Senate will swiftly take up and pass these bills to lower drug prices through greater competition and reduce some drug companies' patent abuses.

**Responses for Senator Lee**

1. **Why do drug manufacturers raise list prices on existing brand-name drugs annually when no clinical improvements have been made?**

Drug companies have the power and control of the market to increase or decrease the price of a drug as frequently as they desire. Prescription drug costs continue to soar due to drug companies' aggressive pricing strategies, particularly for specialty and brand-name drugs. New brand-name drug prices are increasing: According to Reuters, the median launch price was $300,000 in 2023[ii] and $222,000 in 2022.[iii] Most recently, a 2025 Reuters report found that the median annual list price for a new drug was over $370,000 in 2024.[iv]

Drug companies raise prices to maintain high profit margins and at times in coordination with one another. In addition to arbitrary price increases to increase profitability, drug companies sometimes engage in a practice called shadow pricing. Shadow pricing is used to keep prices as high as possible for a group of competing products. In this arrangement, drug companies closely monitor the pricing behaviors of competitors, and as prices increase on related brands of competing products, prices are adjusted in a synchronized fashion.

2. **Do drug manufacturers employ strategies to delay the entry of generics and biosimilars into the market? If so, describe the strategies in which this occurs.**

Yes. Drug companies employ patent and exclusivity extension strategies, product manipulation, and payments to keep competitors at bay.

Some common anticompetitive practices to extend a drug product's exclusivity include product hopping, patent thickets, secondary patents, and pay-for-delay agreements. One study found that practices like these cost U.S. consumers an additional $40.07 billion in a single year.[v] **Product hopping**, a common tactic used to maintain market share, is a process by which drug companies make menial changes to a drug. Common examples of product hopping include changing a pill from a capsule to a tablet or creating an injectable that lasts only slightly longer and discontinuing the original product, forcing patients onto the new product, which has its own patent and exclusivity protections.

Another common tactic, known as a **patent thickets**, involves acquiring as many patents as a drug company can attain on a single drug. Patent thickets are linked through terminal disclaimers and secondary patents creating patents on each component of a drug. A terminal disclaimer allows a drug company to make small changes to the drug. An example of this could be a small change to a label's wording such as stating "seven days" as opposed to "a week." Drug companies also strike deals with potential competitors, paying them to keep their products off the market for a specified period. These arrangements are called pay-for-delay agreements. Additionally, drug companies are major offenders when it comes to filing false petitions to delay the approval of generic drugs, essentially abusing the Food and Drug Administration's **Citizen Petition** (CP) process. CP petitions are designed to give the FDA time to address safety

concerns with a particular drug, however, drug companies may file a CP with the sole goal of prolonging a drug's monopoly power.

PCMA advocates for reducing incentives for drug company patent holders to file CPs to delay competition by simplifying the process the FDA uses to penalize filers if it determines that the CP was submitted with the purpose of delaying the approval of an application and the petition does not raise valid scientific or regulatory issues.

To that end, we commend Sen. Lee for his leadership in introducing the Biosimilar Red Tape Elimination Act aimed at streamlining the biosimilar approval process and increasing biosimilar competition. Importantly, such a law would remove the need for "switching studies" and deem all approved biosimilars interchangeable with their reference biologics – which would lower drug costs for patients and increase access to these medications.

3. **To what extent have the largest PBMs and their group purchasing organizations (GPOs) begun replacing their rebate take revenue with other fees from drug manufacturers?**

As a trade association, PCMA does not have specific information on individual PBM revenue sources or amounts.

Increasingly, employers and health plans have exercised their choice to move away from pass-through contracting and toward administrative fees. In addition to administrative fees, pharmacy benefit companies provide bona fide services to drug companies for which they are paid fees; for example, PBMs are paid fees for prescription drug market analysis. Some of the drug company fees are for service for which PBMs compete with other vendors in the marketplace to deliver a value to drug companies. These fees are reported to the government for both Medicare Part D and commercial plans.

The $68 billion in commercial rebates negotiated by PBMs lower the costs of prescription drugs for patients and plan sponsors. PBMs pass 99.6%[vi] or rebates to plan sponsors in Medicare Part D and 91%[vii] in the commercial market, and 90 percent of employers that received rebates in the last 12 months applied the savings toward at least one activity to offset the cost of their prescription drug benefits.[viii] Additionally, pharmacy benefit companies retain just 6% of every dollar in the drug supply chain, while drug companies keep 65%.[ix]

All participants in the drug supply and payment chain are compensated based on list prices, including drug companies who are solely responsible for setting list prices.

4. **To what extent do major insurers—parent companies of the vertically integrated PBMs—permit independent PBMs to collaborate with their in-house third-party administrators (TPAs) and provider networks? What fees are imposed in these instances? Are you aware of instances where a PBM's parent insurer prohibits such arrangements?**

As a trade association, PCMA does not have the information requested. However, we do support PBM market diversity and promote policies to maintain a competitive landscape across the drug supply chain.

Very few PBMs are owned by insurers or other companies in the drug supply chain. However, some PBMs have affiliations with insurers or other drug supply chain participants. By in large, PBMs do permit other, independent PBMs to collaborate with their in-house TPAs and pharmacy networks. Many independent PBMs contract with larger PBMs or affiliates of larger PBMs to process claims, for example, and they may lease the pharmacy networks of other similarly sized or larger PBMs. While we are not privy to the cost structure, we do know that network leasing is a very common practice, which leads to the conclusion that the cost must not be prohibitive.

Importantly, PBMs of all sizes and with varying business models compete with one another for business. Some smaller PBMs even partner with larger PBMs to leverage each other's scale and unique capabilities to better serve the needs of employers. There are many examples, as well, where smaller PBMs partner with each other to increase scale and leverage and provide a broader array of expert services.

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[i] FDA. (2019) Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices. https://www.fda.gov/media/133509/download?attachment
[ii] Reuters. 2024. Prices for new US drugs rose 35% in 2023, more than the previous year
[iii] Reuters. 2023. U.S. new drug price exceeds $200,000 median in 2022
[iv] Reuters. 2025. Prices for new US drugs doubled in 4 years as focus on rare disease grows
[v] I-MAK and American Economic Liberties Project. 2023. The Costs of Pharma Cheating. https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.
[vi] Government Accountability Office. 2019. Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization. https://www.gao.gov/products/gao-19-498.
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[viii] https://www.norc.org/research/projects/employers-experiences-managing-prescription-drug-benefits.html
[ix] PCMA. 2023. Share of Drug Dollar Retained by Drug Supply Chain Participants. https://www.pcmanet.org/wp-content/uploads/2023/04/Share-of-the-Drug-Dollar.pdf