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Senate Commerce Subcommittee Hearing on Ensuring Fairness and Transparency in the Market for Prescription Drugs

On Thursday (May 05), the Senate Commerce, Science, & Transportation Subcommittee on Consumer Protection, Product Safety, and Data Security held a hearing entitled, "Ensuring Fairness and Transparency in the Market for Prescription Drugs." The hearing, which is one of several Subcommittee Chair Richard Blumenthal (D-CT) plans to hold on lowering consumers' prescription drug costs, focused on the role pharmacy benefit managers (PBMs) play in consumers' drug costs.

Witnesses at Thursday's hearing included a representative from the Pharmaceutical Care Management Association (PCMA), which represents PBMs; an antitrust attorney and former Federal Trade Commission (FTC) policy director; and academics. During the hearing, committee leaders raised concerns about a lack of transparency regarding PBM practices, market consolidation and competition, and the impact on consumers.

- *For more information*: https://www.commerce.senate.gov/2022/5/ensuring-fairness-and-transparency-in-the-market-for-prescription-drugs

Opening statements

Committee Chair Maria Cantwell (D-WA): "Price increases for prescription drugs have outpaced wages, gas, telephone, internet services, food, tuition, transportation, and personal care." She cited an investigation by Sens. Charles Grassley (R-IA) and Ron Wyden (D-OR), which found prescription drug price increases are due in part to business practices of PBMs. She said, "We want to shine a bright light here and we want to understand how PBMs affect drug prices for consumers." She cited concerns with the way rebates can provide an incentive for higher drug list prices and the role of spread pricing on drug prices. She explained, "Spread pricing occurs when a PBM charges an insurer a higher cost for the drug than the amount it is reimbursed by the pharmacy, with PBMs keeping the difference. … The lack of transparency in the PBM market makes this possible."

Subcommittee Chair Blumenthal (D-CT): "PBMs' stated goal is to lower health care costs for consumers … The problem is that patients rarely see the benefits. Drug costs continue to rise, insurance costs continue to eat into incomes and more and more often the drugs patients need are not covered by their health plans. … PBMs benefit from high prices they receive; rebates and administrative fees from drug companies that are often based on the initial list price of a drug, which means the higher the initial cost of the drug the higher the profits for the PBM. PBMs will argue rebates lower the cost of your insurance and they pass them on to insurers, but we have no idea if this is accurate because they are shrouded in secrecy. … PBMs also limit choice … Hundreds of drugs are excluded by PBMs every year. … Let's be clear: PBMs are just part of a broken system. … The biggest and most important priority we have is to lower the cost of prescription drugs … and we can't ignore the role of PBMs."

Subcommittee Ranking Member Marsha Blackburn (R-TN): In her statement, Sen. Blackburn also cited the investigation by Sens. Grassley and Wyden, which found PBMs have hindered transparency into the rebate negotiation process and "have an incentive for manufacturers to keep list prices high." She highlighted actions several states, including Tennessee, have taken to protect citizens from anticompetitive practices by PBMs and criticized the Centers for Medicare and Medicaid Services' (CMS) recent decision to delay until 2024 a policy to

end retroactive direct and indirect remuneration (DIR) fees imposed by PBMs on pharmacies. Sen. Blackburn said, "It is time for more transparency about the impact of potentially anticompetitive PBM practices on patients, small pharmacy businesses, and taxes," citing the Pharmacy Benefit Managers Accountability Act, which would require the Government Accountability Office to submit a report to the Department of Health and Human Services and Congress on PBMs and their role in the pharmaceuticals supply chain.

Witness Testimony

Juan Carlos "JC" Scott, President and CEO, Pharmaceutical Care Management Association (PCMA): "PBMs are proud of the work they do to reduce prescription drug costs, expand affordable access to medications, and improve patient outcomes." During his testimony, Mr. Scott urged Congress to look at the entire pharmaceutical supply chain when looking for ways to lower costs. For example, he said that retail pharmacies, "which are essential to serving patients and providing access to medications, … generally speaking, argue for higher payments, which lead to higher drug costs," and drug manufacturers "argue for higher, not lower, prices. … The PBM industry is the only stakeholder in the chain dedicated to seeking lower costs." He also noted that PBMs have taken steps to improve transparency and provide consumers and providers with real-time tools to access their drug cost information. Finally, he outlined several policies PCMA supports to increase patient access to medications, including improving Medicare's online cost comparison tools, "eliminate patent system abuses" in the pharmaceutical market, and prevent pay-for-delay patient settlements. Full Testimony

Robin Feldman, Professor and Researchers, University of California Hastings College of Law: "Historically, PBMs operated mostly as claims processors, just handling the paperwork flow. However, when Medicare expanded in 2006 to include prescription drugs, PBMs took on an expanded role. … rather than act as honest brokers for health plans, PBMs, unsurprisingly, act in their own interests." She discussed an illustrative example of a store that raises the price of a dress before putting it on sale. She said, "Imagine if the price jump is higher than the sale discount. That's what is happening in the case of medicine. Prices are rising faster than the rebates are rising. … Trying to reform the system — or even talk about it — is like shadow boxing" because rebates and other negotiated details between PBMs and drug companies are considered trade secrets. Full Testimony

David Balto, Antitrust Attorney, David Balto Law Offices: Balto, who from 1995 to 2001 served as policy director of the FTC's Bureau of Competition and attorney advisor to the FTC chair, said "the PBM market is broken" and "the Department of Justice Antitrust Division ("DOJ") and the FTC have failed to take any meaningful enforcement actions." He recommended that the Committee "consider amending the FTC Act to specify certain practices that harm consumers and competition as 'unfair or deceptive acts or practices' and 'unfair methods of competition,'" such as failing to pass on 100% of rebates, clawbacks to payers or consumers, and schemes that prevent lower priced drugs from being included on a formulary or being placed in a disadvantageous position." Full Testimony

Craig Garthwaite, Ph.D., Professor and Director of Program on Healthcare at Kellogg School of Management, Northwestern University: In his testimony, Dr. Garthwaite discussed "the relationships between plan sponsors (i.e. third party payers such as insurers and employers), PBMs, and manufacturers" and "policy options that exist to more directly confront potentially undesirable features of the current pharmaceutical market without generating unintended consequences." For example, he discussed the role PBMs play in securing discounts on drugs for payers, the increased use of strict formularies and exclusion lists, and how the value of rebates are captured. He also discussed the lack of transparency in financial relationships between PBMs, pharmaceutical companies, and insurers. He recommended Congress takes steps to increase transparency and learn about these financial relationships and adopt policies to address cost sharing price negotiations within Medicare Part D plans. Full Testimony

Q&A

During the hearing, witnesses heard questions from Committee Chair Cantwell, Subcommittee Chair Blumenthal, and Subcommittee ranking member Blackburn. Sen. Blumenthal invited other senators on the subcommittee to submit written questions for the record.

Subcommittee Chair Blumenthal directed several questions at Mr. Scott**,** including asking about an increase in drugs being excluded from formularies and its impact on patients. Mr. Scott clarified that PBMs develop and recommend the formularies, but ultimately the plan sponsor makes the final decision. He explained that PBMs develop their formularies based on the clinical need of patients and the economics to ensure the lowest cost drug is placed on the formulary. Mr. Scott said there are processes in place to address instances in which a patient requires a drug not on a formulary, but acknowledged PBMs, and the health care industry at large, could do a better job of leveraging electronic tools to ensure those processes happen in real time.

Sen. Blumenthal also raised questions about the lack of transparency in rebate sizes and how they are applied. He asked whether the consumer sees any direct benefits from drug manufacturer rebates to which Mr. Scott said yes. Mr. Scott explained, "In Medicare, those rebates are negotiated and fully passed on to the plan sponsor and then the plan sponsor makes the determination how to use those savings," whether that be applying them at the pharmacy counter or through lower premiums. When pressed on whether PCMA would support the bipartisan Prescription Pricing for the People Act, which requires the FTC to examine PBM practices, Mr. Scott declined to say yes, but said PCMA "would not be opposed to that study." Mr. Scott also noted that PBMs already report a lot of information to CMS, supported legislation to make that information available to Congress through MedPAC, and will comply with recently enacted legislation for additional information from the commercial market.

In addition, Sen. Blumenthal asked about market competition, noting that while Mr. Scott's testimony states 70 PBMs are active today, three of those players account for 85% of the market. Further, Sen. Blumenthal noted that those three PBMs are owned by health insurers and have relationships with pharmacies and medical providers. He said, "This is a vertical integration in a consolidated industry." Mr. Scott said they've seen about a 10% increase in new entrants into the marketplace in recent years with additional interest from other big names like Amazon and that in his experience employers feel they have the choices they need. However, Mr. Balto, who said he represents union plan sponsors, said most believe they only have three main options.

Finally, Sen. Blumenthal asked about the practice of PBMs pocketing 340B discounts intended to go to the provider. Mr. Scott said his association does not focus on 340B but noted the importance of claims modifiers to distinguish between 340B and non-340B drugs.

Ranking Member Blackburn asked Mr. Garthwaite and Ms. Feldman whether the costs the PBM inserts into the marketplace outweighs the benefit they provide. Mr. Garthwaite said there is not enough information available into PBMs' practices to answer that question, while Ms. Feldman said the fact that prices are rising even after rebates suggests PBMs are not fulfilling their mission to bring prices down. Mr. Garthwaite, additionally, said lawmakers considering policy proposals will need to discuss the trade-offs. "If you'd like to get list prices lower, if you'd like to get rebates removed from the system, if you'd like to get drug prices lower, access is going to be impinged somewhere."

Committee Chair Cantwell directed several questions to Mr. Balto, asking about the FTC's ability to take action against PBMs. Mr. Balto said he believes "the FTC has made some major errors in terms of enforcement in this area," noting that FTC studies have focused on PBMs' impact on the plan sponsor and not on the individual consumer. He recommended Congress pass legislation clarifying unfair methods of competition that FTC should examine, such as gag clauses that prevent pharmacists from sharing information about lower cost drugs. He also

recommended Congress act immediately to restore the FTC's authority under Section 13(b) of the FTC Act to recover money for consumers harmed by anticompetitive practices, noting that this authority was struck down last year in a court case. On Thursday (May 5), Sen. Cantwell and others introduced the Consumer Protection Remedies Act of 2022, which would restore that authority.

Sen. Cantwell also asked about so-called "spread pricing" to which both Ms. Feldman and Mr. Balto said it requires more transparency to understand and address.

If you have questions, please contact Heather Meade or Heather Bell.

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