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Senate Commerce Committee Hearing on Pharmacy Benefit Managers

On Thursday (February 16), the Senate Commerce, Science, & Transportation Committee held a hearing entitled, "Bringing Transparency and Accountability to Pharmacy Benefit Managers." The hearing centered on the bipartisan Pharmacy Benefit Manager Transparency Act (S. 127) reintroduced by Committee Chair Maria Cantwell (D-WA) and Sen. Chuck Grassley (R-IA). The bill would prohibit pharmacy benefit managers (PBMs) from charging health plans more for a drug than they reimburse to pharmacies (also known as "spread pricing") or imposing retroactive clawbacks on pharmacies, and require PBMs to report certain information about payments they receive from health plans and fees charged to pharmacies to the Federal Trade Commission (FTC) on an annual basis.

During the hearing, both Democrats and Republicans cited a need for additional transparency to better understand how money flows through PBMs and the role PBMs play in patients' out-of-pocket drug costs. However, some Republicans, including Ranking Member Ted Cruz (R-TX), raised concerns about the bill's provisions related to the FTC and the potential for the FTC to assume new authorities at a time when there are no Republican commissioners.

The panel heard from two panels of witnesses. First, Sen. Grassley who twice assured Sen. Cruz that the bill would not give the FTC any new authority. They heard next from a panel of providers, including a pharmacist and an oncologist, and two economists. While most of the panelists spoke in favor of increasing PBM transparency. Casey Mulligan, a professor in economics at the University of Chicago, warned about the potential downfalls of increased PBM regulation.

For more information: https://www.commerce.senate.gov/2023/2/bringing-transparency-andaccountability-to-pharmacy-benefit-managers

Opening statements

Commerce, Science, & Transportation Committee Chair Maria Cantwell (D-WA): In her opening statement, Chair Cantwell said the Committee is looking to better understand PBMs' role in the market and how they impact prescription drug prices. She said, "Just three PBMs control 80% of the PBM market. Pharmacy chains and health insurers now own the biggest PBMs, giving independent pharmacies, care providers, and patients nowhere else to turn when PBMs increase their price." Chair Cantwell said she and Sen. Grassley have worked on the Pharmacy Benefit Manager Transparency Act to increase transparency in the PBM market to better understand how money moves between players. She noted that the bill passed out of the Committee last year by a vote of 19-9 and was hopeful that both the Committee and the full Senate could advance the bill this Congress. Full statement

Ranking Member Ted Cruz (R-TX): In his opening statement, ranking member Cruz raised concerns about provisions in the Pharmacy Benefit Manager Transparency Act that would give the FTC additional statutory authority, particularly in light of Commissioner Christine Wilson's recent resignation and the lack of a Republican voice at the FTC. He also raised concerns about passing the bill before the FTC completes its current study on the economic effects of PBMs. He said, "In short, I think we need to think carefully about advancing legislation to

dramatically expand the FTC's power - especially with no Republican counterweight - and to do so before the agency has even completed its PBM study." Full statement

Witness Testimony: Panel 1

U.S. Senator Chuck Grassley (R-lowa): In his testimony, Sen. Grassley said his past investigations on the Senate Finance Committee found "that the PBM scheme encourages drug makers to spike the drug's list price in order to offer a greater rebate, and in turn, secure priority placement on covered meds, at the expense of many patients." He raised concerns about market concentration among PBMs and said that the Senate Judiciary Committee last week passed a bill by voice vote to require the FTC to study pharmaceutical intermediaries. But he said more needs to be done to stop anti-competitive behavior now and that his and Chair Cantwell's bill, the Pharmacy Benefit Manager Transparency Act, would be a start by spotlighting PBM practices while placing guardrails on the FTC. He said that the bill "doesn't give the FTC any new power or regulatory authority." Full Testimony

Witness Testimony: Panel 2

Ryan Oftebro, CEO of Kelley-Ross Pharmacy Group, PharmD: In his testimony, Dr. Oftebro shared his experience running an independent pharmacy and dealing with PBMs. Specifically, he discussed the impact of direct and indirect remuneration (DIR) fees tied to adherence rates and retroactive Generic Effective Rate (GER) fees tied to "overpayments" that PBMs levy on pharmacies. Dr. Oftebro said pharmacies often have no way to combat the fees and have little power when negotiating contracts. He said his company was forced to close one pharmacy as a result of the "unpredictable fees." Dr. Oftebro said the Pharmacy Benefit Manager Transparency Act "is a crucial piece of legislation to prevent PBM abuses." Full Testimony

Debra Patt, Oncologist, Texas Oncology: In her testimony, Dr. Patt said PBMs can block patients from receiving the medication that she, as the provider, believes will best suit the patient's individual needs. Dr. Patt described a patient whose condition deteriorated as Dr. Patt waited for an appeal decision on a drug she believed could have helped the patient retain her quality of life and slow the progression of disease. Ultimately, Dr. Patt said she was forced to start a more aggressive treatment that required her patient to stop working. Dr. Patt also raised concerns about policies related to mail-order pharmacies, noting that they often require 90-day supplies, when oncologists may need to adjust medications after just 1-2 weeks of treatment. She said, "PBM transparency and accountability is critical because patients being able to get their oral cancer drugs in a timely, effective, and sustainable way allows them to realize the benefits of modern cancer therapy." Full Testimony

Erin Trish, Co-Director and Associate Professor of Pharmaceutical and Health Economics, Schaeffer Center, University of Southern California: In her testimony, Dr. Trish said PBMs historically were "independent from health plans and added value by reducing prices, encouraging uptake of generics, and expanding mail-order services. However, a wave of consolidation in the last few years-including health insurers buying up PBMs and PBMs expanding their footprint in pharmacy markets—and other activities have distorted behavior." She said that rebates have been well studied and have been shown to produce "distributional issues" and to "distort market incentives." She said, "PBM issues expand beyond rebates," adding that "it is clear that reforms are needed to improve the functioning of the pharmaceutical distribution system and ensure that the system works to benefit patients and drive value." Full Testimony

Casey B. Mulligan, Professor in Economics, University of Chicago: In his testimony, Dr. Mulligan raised concerns about the impact of regulating PBMs and defended the "buyers' club" model. Dr. Mulligan posed Costco as an

example of an effective buyers' club that saves consumers money and said PBMs offer a similar benefit. However, Dr. Mulligan said the Pharmacy Benefit Manager Transparency Act jeopardizes the economic gains of PBMs. Dr. Mulligan said the bill would "restrict pricing in business-to-business transactions and require disclosure of proprietary information. This by itself does not say whether the Act would have net benefits or net costs, but particularly the price controls are a warning that the unintended consequences may be numerous and profound." Full Testimony

A&Q

Committee Maria Cantwell (D-WA) Cantwell said while she supports Costco-style models, PBMs do not appear to be passing the discount for buying in bulk on to the consumer, and this is creating an issue for patients at the counter and employers trying to predict and control drug spend. Sen. Cantwell asked about the role of market concentration in PBMs' practices. Dr. Trish said data shows that in recent years PBMs are no longer freestanding entities. Instead, most are integrated or owned by a health insurer, which creates incentives to benefit the owner. Dr. Trish said there are areas where vertical integration is beneficial, but we need to better understand the incentives it creates in the realm of PBMs to understand how it is playing out in the market. Dr. Trish said we've learned from insulin that PBMs can be effective in lowering the net prices that manufacturers receive, but the data suggest consumers are not benefitting from those discounts.

Ranking Member Ted Cruz (R-TX) reiterated concerns about the tradeoffs associated with increasing federal regulation and FTC authority. When asked whether the Pharmacy Benefit Manager Transparency Act's requirements could lead to more or less consolidation among PBMs, Dr. Mulligan said it could lead to more consolidation and noted that the bill does not have any exemptions for smaller PBMs. Dr. Mulligan estimated that health care costs could go up if the bill were enacted and that it could increase the federal deficit by \$10 to \$40 billion annually depending on the final language, which he criticized as being overly vague.

Sen. Peter Welch (D-VT) asked about the impact of PBMs' "clawback" policies on local pharmacies and said he is working with Sen. Jon Tester (D-MT) on a proposal to protect local pharmacies. Dr. Oftebro said the fees are causing real harm and directly contributed to the closure of one of his pharmacies. Dr. Patt said DIR fees are not meaningful measures of quality and have grown in recent years. Dr. Trish said she agrees with Dr. Mulligan that PBMs need to have the tools to negotiate, but they are doing so in an opaque environment and issuing fees that do not reflect quality and that needs to be addressed. Dr. Mulligan said lawmakers should consider the tradeoffs when considering regulating contract negotiation between businesses.

Sen. Ted Budd (R-NC) spoke about patients in his state struggling to pay for prescription drugs and the concerns that patients are not seeing the savings from PBMs. When asked about the impact of clawbacks on pharmacies, Dr. Oftebro reiterated, "We have to close our pharmacies." He explained that independent pharmacies are not able to negotiate the DIR fees in their contracts and have no recourse but to pay them. He noted the fees can run hundreds of thousands of dollars. Sen. Budd also asked about the type of data that is needed to better understand if PBMs are favoring drugs with high list prices. Dr. Trish said the rebate data would shine light on that issue, but it is considered confidential. Dr. Mulligan agreed that the data is proprietary.

Sen. Jon Tester (D-MT) said there is no transparency in the PBM market and asked about the anti-competitive tactics PBMs use when working with independent pharmacies. Dr. Oftebro said PBMs steer patients toward mailorder pharmacies and leverage DIR and GER fees that are hard for pharmacies to predict. He said virtually all drugs are impacted by PBM practices. When asked whether the bill's new transparency requirements would place burdens on independent pharmacies, Dr. Oftebro said he did not believe they would place new burdens on independent pharmacies, unless the PBMs could use it to extract more fees.

Sen. Shelley Moore Capito (R-WV) noted that she voted for the bill when the committee passed it last year. She asked whether Dr. Oftebro's pharmacies have ever had success in negotiating some of these contracts to which he said they have not. Asked whether Washington state has passed laws to address the concerns, Dr. Oftebro said the state has passed some laws but they exempted ERISA plans. As a result, Dr. Oftebro said the state laws only cover about 10-20% of the prescriptions they dispense. Sen. Moore Capito also asked Dr. Trish about the shift in PBM practices. Dr. Trish said she believes the consolidation and integration, as well as increased complexity in the market have contributed to higher drug prices.

Sen. Dan Sullivan (R-AK) asked the panelists whether the bill contains the right solutions to increase transparency among PBMs and whether the FTC is the correct federal agency to address the issue. Dr. Oftebro and Dr. Patt said more transparency is needed. Dr. Trish said lawmakers also should consider other factors, such as the role of benefit consultants working for employers who may be compensated by a PBM. She added that in addition the FTC, there are other agencies such as the Government Accountability Office that could be involved in addressing the PBM industry. Dr. Mulligan said he is concerned that the bill currently does not have clearly defined terms, which could give the FTC broad authority.

Sen. Marsha Blackburn (R-TN) asked how PBM policies affect patients' access to drugs. Dr. Pratt said PBMs' vertically integrated relationships can determine which therapies can be given first, even if those are not the therapies recommended by the provider to best meet that individual patients' needs. She also cited cases in which patients have been able to pay lower prices by not using their insurance. Dr. Oftebro agreed and added that mandatory mail order for drugs is another issue that can delay patients' access to drugs.

Sen. John Hickenlooper (D-CO) said we need greater transparency in the PBM market to understand where the money is going and why costs are so high. He asked the panel how to ensure PBMs provide information that is accessible and understandable to patients. Dr. Patt said pharmacist and doctor interactions with patients are invaluable in helping patients navigate the complex system, noting that there are instances in which a patient who is steered toward a mail-order pharmacy may opt to forgo medication because they see a high price.

Sen. Raphael Warnock (D-GA) focused his questions on the costs of insulin, noting that his guest at the State of the Union was a person with diabetes who due to the cost of insulin turned to the black market. Sen. Warnock said while it was important to cap the price of insulin for Medicare beneficiaries, there is a larger root cause driving the price increases and asked how PBMs contribute to those increases. Dr. Trish said PBMs are positioned to make more money as list prices rise because they get a percentage of the rebate or fee that is based on the list price. This creates an incentive for PBMs to leave lower priced drugs off of their formulary, she explained. Warnock said he voted for the bill last year and plans to vote for the bill again this year.

Sen. Amy Klobuchar (D-NM) asked panelists whether the Preserve Access to Affordable Generics and Biosimilars Act, which she co-sponsored with Sen. Grassley and passed out of the Judiciary Committee last week, help lower drug prices. Sen. Klobuchar also asked whether brand name drug manufacturers are using larger rebates in contract negotiations with PBMs to keep potential competitors off the market. Dr. Trish said the greater concern is whether contract negotiations between PBMs and drug manufacturers provide value and benefit to the consumer. Dr. Oftebro said speaking as an employer and a pharmacist that the industry needs more transparency as it's hard to get the visibility into drug spend.

Sen. Jacky Rosen (D-NV) said she is happy to see the committee working to build on the Inflation Reduction Act's provisions limiting drug prices for Medicare beneficiaries to lower drug prices for all consumers. She raised concerns about independent pharmacy closures in Nevada and nationwide and asked about the impact of those closures. Dr. Oftebro said independent pharmacies, particularly those in rural areas, can be the only pharmacy access point for communities.

When asked about how to ensure rebate savings are actually passed onto the consumer at the counter, Dr. Trish said there are policies that could encourage rebate savings but without transparency solving one issue could give rise to a new problem. For example, she said we now have contracts that require rebate sharing with the plans, but that spurred new fees and offshore rebate aggregators, so we need true transparency to better understand how the dollars flow.

If you have questions, please contact <u>Heather Meade</u> or <u>Heather Bell.</u>

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