Comment of the American Economic Liberties Project regarding the Pharmacy Benefit Manager Transparency Act of 2022

June 21, 2022

We write with respect to the Pharmacy Benefit Manager Transparency Act of 2022 (the PBMTA), the bi-partisan bill introduced by Sens. Grassley (R-Iowa) and Cantwell (D-Wash) that would empower the Federal Trade Commission (FTC) to increase drug pricing transparency and hold pharmacy benefit managers (PBMs) accountable for practices that drive up costs of prescription drugs at the expense of consumers. The American Economic Liberties Project is a non-profit think tank and advocacy organization dedicated to understanding and addressing the problem of concentrated economic power in the United States.

We commend Sens. Grassley and Cantwell for building on the Senate's decade-long investigation into rising drug costs, and for putting forth a bill that will have demonstrable, immediate impacts. We also offer suggested mark-ups that would enhance the intent of the PBMTA, while creating an administrable law conducive to compliance and enforcement, as follows:

- Remove language requiring that claw backs or off sets by PBMs of reimbursement payments be "arbitrary, unfair, or deceptive," thereby acknowledging the *per se* harm of these practices to pharmacies and patients.

- Eliminate the exception for PBMs who return price concessions to health plans, which threatens to swallow the rule against illegal claw backs and price increases, and further incentivizes consolidation of PBMs and health plans.

- Remove the affirmative defense allowing PBMs to plead that illegal claw backs and price increases were necessary to "protect patient safety or access," which is an unreasonably vague standard and will result in barriers to enforcement against *per se* harmful conduct.

- Provide pharmacies with a private right of action so that they may hold PBMs directly accountable, outside the context of years-long, under-resourced public investigations and enforcement actions.

We expand on each of these points below:

1. **Remove vague "arbitrary, unfair, or deceptive" qualifiers on illegal claw-backs and price increases, and render these actions illegal *per se*.**

A 2021 Senate investigation into rising insulin costs found that PBMs have "used their size and aggressive negotiating tactics, like the threat of excluding drugs from formularies, to extract more generous rebates, discounts and fees from insulin manufacturers."[1] This dynamic, investigators found, contributed to skyrocketing insulin prices and discouraged price decreases for the drug. As the sponsors of the PBMTA are aware, PBMs have become so ubiquitous in the pharmaceutical industry that self-dealing and so-called "spread pricing" are the norms, leaving pharmacies and plan beneficiaries on the hook for dramatically increased prices.

The PBMTA seeks to end PBM self-dealing by prohibiting PBMs or their affiliates from reducing, rescinding, or clawing back any reimbursement payment to a pharmacy or payer for a prescription drug's ingredient cost.[2] The PBMTA also prohibits PBMs from increasing fees or lowering reimbursements to pharmacies in order to offset reimbursement changes under Medicare, Medicaid, or any other health plan funded by the Federal Government.[3] Prohibiting this conduct outright will have an immediate impact on soaring drug prices.

The PBMTA would be improved, and its intent more assuredly met, by eliminating the additional burden on enforcement agencies to demonstrate that unlawful conduct is also "arbitrary, unfair, or deceptive." These vague qualifiers will result in inconsistent judicial opinions, compounded litigation costs, impediments to enforcement, and inadequate deterrence. Even if the actual harm to pharmacies and plan beneficiaries is clear – as it often is – enforcement actions will be derailed and delayed by premature fact-finding and inconsistent analyses of what makes a claw back or price increase "unfair, arbitrary, or deceptive." For PBMs, the cost of protracted litigation will be well worth it to continue extracting billions of dollars from pharmacies and people in need of low-cost drugs.[4]

We can reasonably anticipate this result because it has played out in other contexts. Take, for instance, the rule of reason, the traditional antitrust framework under which courts must determine whether a specific restrictive practice poses an "unreasonable restraint on competition." This discretionary determination and balancing act has created confusion for market participants seeking to comply with the law, reduced accuracy and objectivity (both in bringing enforcement actions and adjudicating disputes), and prevented courts from enforcing antitrust laws quickly

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[1] https://www.finance.senate.gov/chairmans-news/grassley-wyden-release-insulin-investigation-uncovering-business-practices-between-drug-companies-and-pbms-that-keep-prices-high

[2] *See* PBMTA Sec. 2(a)(2)

[3] *See* PBMTA Sec. 2(a)(3)

[4] "The Secret Drug Pricing System Middlemen Use to Rake in Millions," Bloomberg: https://www.bloomberg.com/graphics/2018-drug-spread-pricing/ (A Bloomberg study of the 90 best-selling generic drugs used by Medicaid managed-care plans, revealed that PBMs siphoned off $1.3 billion of the $4.2 billion Medicaid insurers spent on drugs in 2017 alone.)

and inexpensively.[5] These deficiencies have long supported revisions to the law that enumerate commonplace, objective restraints. Under the PBMTA, that would be the enumerated unlawful conduct set forth in Section 2(a), absent any vague or subjective qualification.

Whether a claw back or price increase is "arbitrary, unfair, or deceptive" is a question that sidesteps the actual, tangible harm caused to pharmacies and consumers that the PBMTA seeks to prevent. We recommend removing this language.

2. Eliminate the loophole for PBMs who return price concessions to health plans.

The PBMTA includes an exception for PBMs who return price concessions (e.g., any rebate or discount) to a health plan or payer.[6] Traditionally, as distinct but related interests, PBMs make money when health plan beneficiaries purchase drugs, and health plans make money when they attract new customers by ensuring efficient care. The natural assumption is that this relationship is structured to benefit the end user.

This has changed in the past decade, as PBMs and health plans have merged with each other, thereby eliminating structural market incentives to provide efficient and affordable care to health plan beneficiaries. When UnitedHealth merged with Optum in 2011 and set up its own PBM, other health plans took notice. In November 2018, pharmacy benefit manager CVS Corp. agreed to a $70 billion merger with health plan Aetna. In December 2018, Cigna closed a $67 billion purchase of Express Scripts, one of the largest pharmacy benefit managers in the country.

In 2014, prior to the near-complete merger of PBMs and health plans, the top three PBMs – CVS Caremark, Express Scripts, and OptumRx – controlled 80 percent of the market, or 180 million people whose pharmacy benefits were administered by PBMs.[7] As PBMs and health plans have become one and the same, that market share has continued to grow.

The phenomenon of PBM and insurer consolidation also appears in the context of government-funded plans, which are also operated by private insurers. Centene, the nation's largest Medicaid managed care organization, providing coverage in 29 states to nearly 15 million enrollees, was engaged in a fraudulent scheme with its own subsidiary PBM, Envolve Pharmacy Solutions. As of the date of this memo, Centene has entered into a string of no-fault settlements totaling

[5] "Does the Rule of Reason Violate the Rule of Law?", 42 U.C. Davis L. Rev. 5

[6] *See* PBMTA Sec. 2(b)(1)

[7] U.S. Senate Finance Committee, "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug," January 14, 2021 (at p. 29)

$250 million – just a portion of the reported $1.1 billion they've set aside to resolve future settlements.

Under the PBMTA pass back exception, as long as a PBM discloses the return of price concessions to its subsidiary or affiliate health plan, no unlawful conduct has occurred – even though the harm to beneficiaries has still occurred. The exception creates an internal accounting loophole that threatens to swallow the rule itself.

We recommend deleting this exception.

3. Remove the affirmative defense allowing PBMs to plead that illegal clawbacks and price increases were necessary to "protect patient safety or access."

Under the PBMTA as presented, even if a party bringing suit can make the case that an unlawful claw back or price increase has occurred, extremely well-resourced PBMs will still avoid liability by pleading that the unlawful conduct was necessary to "protect patient safety or access."[8] As with the burden of proving that clawbacks and price increases were "arbitrary, unfair, or deceptive," what it means to "protect patient safety or access" opens an unnecessary and vast field of dispute that will delay relief for the patients most in need of those protections.

PBMs have already launched robust lobbying campaigns to argue that they "help patients safely navigate their health care coverage." [9] They argue, without evidence, that excessive claw backs and price increases, from which they derive hundreds of billions of dollars in revenue, are justified by, e.g., the prevention of unspecified "medication errors." PBMs have lobbied against the rebate rule on the vague basis that it hampers their ability to "negotiate increased access" to medications for seniors. "Patient safety" and "access" have become meaningless buzzwords in the campaign by PBMs to stave off regulation, or to neuter regulatory efforts like the PBMTA.

These lobbying efforts provide a window into the representations and effective laundering of unlawful conduct that parties seeking redress will face in court. Will costly mark-ups on system maintenance be used to justify the 8.8% spreads that cost pharmacies in Ohio $223.7 million between March 1, 2017 and March 30, 2018? How will under-resourced pharmacies rebut an argument that PBMs "protected access," when there is scant alternative access outside of the 85% of the market controlled by PBMs and their affiliate health plans?

[8] PBMTA, Sec. 6(c)(2)-(3)

[9] "How PBMs Help Patients Safely Navigate their Health Care Coverage," Pharmaceutical Care Management Associationhttps://onyourrxside.org/how-pbms-help-patients-safely-navigate-their-health-care-coverage/

Answers to these questions should not be relegated to expensive litigation. As with the "arbitrary, unfair, or deceptive" threshold for pleading unlawful conduct, the "patient safety or access" affirmative defense presents a costly barrier to relief – involving expensive experts that PBMs will be able to easily afford – and threatens to render the PBMTA toothless.

We recommend the removal of this affirmative defense.

4. **Allow pharmacies who are harmed by anti-competitive PBM practices to bring private rights of action.**

In 2015, the State of Arkansas adopted Act 900 in response to concerns that the reimbursement rates set by PBMs were often two low to cover pharmacies' costs, and that many pharmacies, particularly independent pharmacies in rural communities, were at risk of losing money and closing. The parties most likely to be harmed by PBMs serve the most vulnerable communities with the least access to redress. They are also most susceptible to harm from under-enforcement and, even when actions are initiated, by the delays of under-resourced agency investigations. The most direct path to redress for these parties is a private right of action, which the PBMTA should be amended to include.

Private rights of action tend to be met with unfounded concerns that independent, private enforcement actions will result in *over*-deterrence or duplicative damages. These concerns are easily assuaged by the dearth of evidence that this has been the case as to violations of the Sherman Act or the Clayton Act. To the contrary, despite the availability of treble damages, disgorgement, *and* criminal fines, which could theoretically result in sixfold damages, settlements are typically negotiated at below net harms and ultimately provide inadequate deterrence.[10]

The PBMTA's success at deterring unlawful conduct will depend on the ability of impacted parties to enforce it. A private right of action provides that direct path to relief, and avoids the possibility of a PBMTA rendered toothless by delayed investigations and under-resourced enforcement actions.

Conclusion

Pharmacy Benefit Managers – and their revenue – have grown exponentially over the past decade, coinciding with a period of consolidation resulting in just three PBMs controlling 85% of the market. Senate leaders have simultaneously undertaken expansive investigations to fully understand the harm caused by PBMs.

[10] "Multiple Enforcers and Multiple Remedies: Why Antitrust Damage Levels Should Be Raised," 16 Loy. Consumer L. Rev. 329

The mark-ups recommended in this memo will ensure that the Pharmacy Benefit Manager Transparency Act accomplishes its stated goals while addressing thoroughly understood harms. There is no reason to wade through years of litigation and additional agency reporting requirements to tell policymakers what they already know.

The American Economic Liberties Project reiterates its support for the PBMTA and appreciates your consideration of the changes described herein.