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Maureen K. Ohlhausen
Acting Chairwoman
Federal Trade Commission
400 7th St., SW
Washington, DC 20024

Re: Federal Trade Commission Workshop, "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics"

Dear Acting Chairwoman Ohlhausen:

On behalf of the members of the Tennessee Pharmacists Association (TPA), I greatly appreciate the opportunity to provide insight and proposed solutions, from the perspective of practicing pharmacists in Tennessee, to the rising costs of prescription drugs. As the only 501(c)6 professional organization in Tennessee representing approximately 3,000 pharmacists, student pharmacists, pharmacy technicians, and associate members in all pharmacy practice areas, TPA's mission is to advance, protect, and promote high-quality pharmacist-provided patient care in Tennessee. TPA would like to acknowledge and thank the Federal Trade Commission (FTC) for conducting this workshop on "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics" addressing how the current pharmaceutical supply chain and delivery system may contribute to the rising costs of prescription drugs. TPA applauds your ongoing commitment to addressing this issue and ensuring the future sustainability of our health care system. In general, greater patient access to pharmacist-provided care, mitigation of market-driven barriers to safe and effective prescription drugs, and increased transparency and accountability within the prescription drug benefit process, will help ensure that our patients have appropriate access to affordable prescription drugs.

TPA's comments will largely focus on issues that arise due to pharmacy benefit managers' (PBMs) business practices. But first, we would like to emphasize pharmacists' role in and the importance of efficient medication selection and use.

Fully integrate pharmacists to promote more appropriate and efficient utilization of prescription drugs

TPA strongly advocates for changes at the federal level to formally recognize pharmacists as providers under the Social Security Act. Fully integrating pharmacists as providers will drive more appropriate and efficient medication selection and use, increase prescription drug-related health outcomes, decrease overall costs of care, and ensure that patients have access to pharmacist-provided care and services.

Prescription drug costs are rising at an incredible rate and many factors have contributed to this crisis, including persistent and crippling drug shortages and greater use of specialty drugs. Emphasizing appropriate prescription drug use and incentivizing providers who work with patients to improve health outcomes through optimal prescription drug use will lead to decreases in overall costs to the health care system, including prescription drug costs.

Pharmacists contribute to efficient medication selection.

Pharmacoeconomics is the comparison of one medication to another, weighing the costs and benefits.[1] Pharmacoeconomics is an entire subspecialty of pharmacy but also is a concept that permeates pharmacists' work in a variety of settings. Pharmacists consider the costs (financial and the potential for side effects) and benefits (health outcomes) of a medication when assessing the appropriateness of a prescription, conducting a comprehensive medication review, or examining a coverage policy for a class of medications. Pharmacists, in all practice settings, are often the primary member of the healthcare team who is able to add the financial layer of analysis to patient medication regimens. Hospital pharmacists lead efficient formulary development, [2] community pharmacists make recommendations for cost effective therapeutic substitutions, [3] and managed care pharmacists design coverage policies to guide effective medication use at the population level, but also allow for patients with unique needs to get the best medication for them.[4]

Pharmacists' medication management services ensure efficient medication use.

TPA broadly encourages FTC and other policy makers to recognize the value that pharmacists bring to the continuum of medication use. While efficient medication selection is important to controlling the growing costs of medications, it is also important to consider the value medications bring to healthcare. When taken correctly, medications provide the most effective way to manage chronic conditions, prevent future, and costly, complications, and even cure some diseases. Unfortunately, medications are often not taken as directed—a problem that leads to costly complications and prevents medications from delivering on their promise for improved outcomes.[5,6] If medications do not deliver on their potential for improved outcomes, their value significantly decreases. Pharmacists' medication management services are critical to ensuring patients use their medications correctly.[7] Investing in pharmacists' medication management services has been shown to significantly decrease overall healthcare costs and must be discussed in parallel with drug pricing considerations.[8,9]

Enact greater transparency and accountability with regard to pharmacy benefit managers

TPA strongly supports initiatives which ensure the pharmacy benefit manager (PBM) industry is appropriately regulated and stop practices that raise prescription drug costs without adding value to the healthcare system.

As costs continue to rise, patient access to prescription drugs has been restricted and system-wide incentives have been misaligned. To maintain profit margins, pharmacy benefit managers (PBMs) continue to demand greater rebates from manufacturers for the inclusion of their prescription drugs on

[1] https://www.ncbi.nlm.nih.gov/pubmed/16120204
[2] http://www.pharmacytimes.com/publications/health-system-edition/2017/september2017/hospital-formulary-management
[3] http://www.pharmacytimes.com/news/therapeutic-substitution-could-curb-skyrocketing-drug-costs
[4] http://www.amcp.org/InformationForTertiary.aspx?id=9045
[5] www.nehi.net/writable/publication_files/file/pa_issue_brief_final.pdf
[6] www.ncbi.nlm.nih.gov/pmc/articles/PMC3934668/
[7] www.accp.com/docs/positions/misc/improving_patient_and_health_system_outcomes.pdf
[8] www.aphafoundation.org/sites/default/files/ckeditor/files/Our%20Work/MP7-PSMP-Diabetes-JAPhA-Final%20Report.pdf
[9] www.aphafoundation.org/sites/default/files/ckeditor/files/Our%20Work/201101_ImPACT_Depression_JAPhA.pdf

drug formularies-pushing costs to consumers, and the health care system, even higher. Misaligning incentives by placing greater emphasis on prescription drug rebates and increasing prescription drug costs, without regard to the value to the patient or the overall costs to the health care system, significantly disadvantages patients, providers, and taxpayers. PBMs entered the market as prescription drug claims processors and as specialists in designing drug benefits for cost efficiency. One of the original core functions of PBMs was to assist health plans with understanding pharmacoeconomic data and designing evidence-based drug benefits that encouraged consumers and prescribers to utilize prescription drugs that were most clinical and economically effective. Since the 1990s, their business model has evolved to include complex rebate negotiations within the supply chain, in-house fulfillment of prescription drug orders through mail-order, contracting practices that often result in narrow networks and force pharmacies to take a loss on a prescription drug in order to provide their patients with needed medications, copayment differentials between pharmacies, and monopolistic market consolidation. Throughout this time, PBMs have continued to be unregulated and have enjoyed ever increasing profit margins.

Rebates

Manufacturer rebates are negotiated between PBMs and pharmaceutical manufacturers to induce PBMs to include certain drugs on the prescription drug formulary or to include them at a lower co-pay tier. A fraction of the same rebate is then given to PBM clients to induce the same drug to be included on their individual organization's formulary. This practice results in prescription drugs being placed on a higher copay tier in order to incentivize consumer use of an equally effective but less expensive alternative. These rebates often result in higher costs for prescription drugs in the long run, even exceeding the financial benefit the PBM's client receives from the rebate. Since the PBM is not designated as a fiduciary to their clients, they have no legal obligation to stop this from happening—and benefit greatly from the portion of the rebate that goes to the PBM's bottom line.

In-house mail order

Though mail order programs tout high patient adherence scores, these are based only on data that shows the prescription drug was delivered, not that it was taken. Since the prescriptions are often sent automatically, hundreds or thousands of dollars are wasted on prescription drugs that the patient may no longer be taking but continue to be billed and sent. Additionally, the mail order pharmacy—usually owned by the PBM—often is paid more than a local community pharmacy, even though there is little or no patient contact or counseling involved.

Disproportionate contracting power

Because the PBM industry has consolidated into three primary organizations that make up nearly 80% of the market, contracts with providers are essentially take-it-or-leave-it and losing just one PBM's market share of patients can have devastating effects on a pharmacy's business. Within the contracts are provisions such as direct and indirect remuneration (DIR) fees (sometimes called "clawbacks"), maximum allowable cost drug lists that change much slower than market prices, and other provisions that result in the pharmacy losing money on many of the prescription drugs dispensed. The pharmacist is then in a position where he or she must decide between providing good care to the patient and risking their long-term ability to care for their community as their business model crumbles over time.

Patient copayment differentials

There have been many reports in the media about so called "clawbacks," when patients are charged (as a copayment) an amount higher than what the pharmacy would charge were the patient uninsured.[10] Unfortunately, the pharmacist is often prohibited from disclosing this discrepancy due to "gag clauses" in their contracts with PBMs.[11] Because the consumer does not know about the opportunity for a lower cost without insurance, she ends up paying the higher copayment.[12] States are responding with laws that aim to prohibit contractual "gag clauses."[13,14]

Market Consolidation

Consolidation within the health care market, and especially related to PBMs, harms competitive pharmacy bargaining power and leads to decreased access. With three large companies now making up nearly 80% of the market, pharmacies (especially those that are independently-owned, but also chains) are faced with "take-it-or-leave-it" contracting. The terms pharmacies are forced to accept sometimes include:

- Negative reimbursements (payments for products that are lower than the cost the pharmacy pays for the product)
- Vague fees (such as direct and indirect remuneration or DIR) that are assessed months after a particular prescription is filled – giving the pharmacy with little opportunity to predict their effect on the business
- Dispensing fees that are vastly lower than the true cost to dispense a prescription
- Administrative burdens such as harsh auditing procedures, "gag clauses" (discussed above), etc.

Private contracting is usually not the concern of policy makers—even if the party with less bargaining power cannot negotiate better terms, they can walk away from the deal. However, PBM consolidation creates a unique problem. If a pharmacy rejects a PBM's contract because a particular term will not work for their business, it could result in nearly 30% of their patients being forced to find another pharmacy, undermining patient choice, and potentially limiting access.

Consider a small town where there is only one pharmacy—if that pharmacy stops taking one of the three big PBMs – up to 30% (or more if one of the PBMs has a larger share of the local market) will have no local pharmacy from which they can access covered medications. The pharmacy is then in the impossible position of deciding between their bottom line and harming the community they serve. As trusted healthcare advisors, pharmacists often choose to protect their patients and take the PBMs terms—to the detriment of their bottom line. Overtime, accepting negative reimbursements can result in the pharmacy closing altogether; consequently the entire community is left without access to a pharmacy.

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[10] http://www.ncpanet.org/advocacy/pbm-resources/lack-of-transparency-and-higher-costs
[11] https://www.bloomberg.com/news/articles/2017-02-24/sworn-to-secrecy-drugstores-stay-silent-as-customers-overpay
[12] An odd twist on moral hazard – the consumer has incomplete information (does not know the cash price is lower because the pharmacist is prohibited from telling her) so the PBM charges a higher copayment, knowing the consumer will pay it because she need the medication and do not know there is a lower cost option available to her.
[13] http://www.legis.la.gov/legis/BillInfo.aspx?i=229167
[14] https://www.thecppc.com/single-post/2017/07/12/Connecticut-Enacts-Law-to-Stop-PBM-Clawbacks

Pursue strategies to resolve prescription drug shortages to reduce market volatility and prevent unsustainable increases in prescription drug costs

TPA urges FTC to investigate and implement practical strategies which identify, resolve, and prevent prescription drug shortages which continue to affect patients on a daily basis.

Drug product shortages place patients at risk for adverse health outcomes and negatively impact prescription drug costs every single day. Pharmacists and providers practicing in critical care units, emergency rooms, and other pharmacy practices across the country continue to spend a significant amount of time and resources navigating the pharmaceutical supply chain to try to maintain access to life-saving prescription drugs which are either unavailable or are in limited supply. These prescription drug shortages are difficult to predict and may occur overnight, leaving patients at risk for adverse events due to factors outside of the control of the providers. Specific to this hearing, when these essential prescription drugs become unavailable or are in short supply, hospital operational costs to mitigate these prescription drug shortages, as well as their actual costs to purchase the prescription drugs, significantly increase. The American Society of Health-System Pharmacists (ASHP) has taken important steps to help pharmacists to navigate current and impending prescription drug shortages. ASHP has cited several precipitating factors which continue to contribute to ongoing drug shortage issues: unavailability of raw and bulk materials; manufacturing difficulties and regulatory issues; voluntary prescription drug recalls; changes in product formulation or manufacturer; manufacturers' production decisions and economics; industry consolidation; restricted drug product distribution and allocation; inventory practices at all levels; unexpected increases in demand and shifts in clinical practice; non-traditional distributors; and natural disasters such as the devastation caused by recent hurricanes.

Pharmacists work daily to mitigate prescription drug shortages through early identification and assessment, preparation, and contingency planning, and while some shortage issues are not preventable, others may be resolved with the help of FTC. Specifically, the Food and Drug Administration (FDA) is responsible to assist with prescription drug shortages to the extent of its authority. Its responsibilities are dispersed among several components of the Center for Drug Evaluation and Research (CDER). FDA intervenes in the case that a shortage meets "medical necessity" criteria. In this scenario, the FDA will work to either prevent or ease shortages for prescription drugs that are medically necessary. However, in current pharmacy practice, the FDA's determination of "medically necessary" may be inconsistent with the pharmacist's professional judgement and clinical evaluation of what prescription drugs are "medically necessary" for their patients. In these cases, pharmacists are left to work through their own mechanisms to identify and secure suitable alternatives to the needed prescription drugs, including substitution of other prescription drugs, compounding alternative formulations, working with other hospitals and practices, or in the most severe instances, having to go without providing some essential prescription drugs because there are no suitable options for the patient. While inconvenient and costly to the patient, institution, and manufacturer may not be considered as sufficient reasons for the FDA to classify a product as "medically necessary," TPA urges FTC to investigate potential strategies which will ease prescription drug shortages. Easing prescription drug shortages will ensure that patients have access to life-saving prescription drugs and lead to decreased prescription drug costs.

Ensure patient access to safe prescription drugs approved through nationally-accepted standards for prescription drug safety and quality

TPA opposes cost-saving proposals, such as the importation of drugs from other countries, which do not meet nationally-accepted patient safety, efficacy, and quality standards for prescription drugs.

The landscape of the prescription drug supply chain is a dynamic and changing environment, and weighing the risk and benefit of prescription drug therapies is essential to the clinical decision-making process. Pharmaceutical manufacturers continue to pursue new and innovative prescription drug therapies which diagnose, prevent, treat, and cure acute and chronic conditions. However, the challenge exists in maintaining affordability for these prescription drugs, and each prescription drug's benefit versus it's cost must be considered. However, the affordability of medications must also be weighed in terms of patient safety and quality, both of which should not be sacrificed in an attempt to decrease prescription drug costs. Proposed cost-saving proposals, such as the importation of drugs from other countries, which circumvent the rigorous and nationally-accepted patient safety, efficacy, and quality standards cause great concern to pharmacists. Without accountability, tracking, monitoring, and oversight through the complete journey of a prescription drug from manufacturing all the way through dispensation to the patient, professional confidence in the quality and safety of prescription drugs is undermined. Permitting the importation of prescription drugs that have not been appropriately monitored and tested to ensure that they are safe, effective, and high-quality will likely lead to increased prescription drug adverse events, suboptimal health outcomes, increased visits to providers, increased hospitalizations, and potentially, preventable deaths, all of which will ultimately drive up health care costs.

I appreciate this opportunity to submit comments in advance of this FTC workshop and also applaud your efforts to ensure that patients, including those in our home state of Tennessee, have affordable access to safe, effective, and high-quality prescription drug therapies. Thanks again for the opportunity to submit comments for your consideration, and please feel free to contact me if you have any questions.

Sincerely,

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