PHARMACISTS UNITED FOR TRUTH AND TRANSPARENCY
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December 8, 2018

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

Scott Gottlieb, MD
Commissioner
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: U.S. Small Business Pharmacy Owners' Response to the FTC's November 8th workshop, "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics"

Dear Acting Chairwoman Ohlhausen and Commissioner Gottlieb:

We are Pharmacists United for Truth and Transparency (PUTT), a growing coalition of U.S. independent pharmacy owners. We have seen and experienced first-hand the damage caused by big business Pharmacy Benefit Managers (PBMs), the 3 largest of whom command as much as 79 percent market share according to testimony by Mark Merritt, CEO of the Pharmaceutical Care Management Association (PCMA).[1]

As you know, the PCMA is the trade and lobbying association for PBMs, and Mr. Merritt represented the interests of his organization's clients as a member of the Federal Trade Commission's panel on November 8th. A cross-section of our members were also represented at the meeting - in the audience, wearing gags over their mouths to symbolize what has happened to the care and practice of pharmacy since PBMs have taken control.

Pharmacists are considered among the most trusted members of a patient's healthcare team. We are our patients' last line of defense and who they turn to for answers. **PBMs compromise that trust by forcing the use of contractual "gag clauses"** that mandate our silence when we see a patient being taken advantage of by their prescription drug plan.[2]

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[1] Testimony of Mark Merritt, Pharmaceutical Care Management Association before the United States House of Representatives Committee on Oversight and Government Reform. February 4, 2016.
https://oversight.house.gov/wp-content/uploads/2016/02/Merritt-PCMA-Statement-1-26-Prescription-Drugs.pdf

[2] You're Overpaying for Drugs and Your Pharmacist Can't Tell You. By Jared S Hopkins
February 24, 2017, Bloomberg 3:00 AM MST Corrected February 27, 2017, 9:21 AM MST
https://www.bloomberg.com/news/articles/2017-02-24/sworn-to-secrecy-drugstores-stay-silent-as-customers-overpay

Contractually obligating a healthcare provider to remain silent when a patient's best interest is at stake is unconstitutional, but PBMs get away with this practice because they hold the power of access to patient networks in the proverbial palm of their hand. Pharmacies would have few or no patients to serve without networks, so withholding access to those networks - or worse, threatening to expel a pharmacy from a network for so-called "contract breaches" which can include mailing a patient prescription out of state, telling a patient about a cheaper generic alternative to a prescribed medication or simply being an independent pharmacy when a new PBM takes over - is a bona fide concern for pharmacy owners.[3, 4]

Gag clauses are not the only tactic PBMs utilize in order to the bend the system to their benefit. At this time, the nation's 7th largest corporation - the $153 billion CVS Health - is planning to merge with Aetna, effectively determining where 20 million Aetna patients can go for care, which medications are available to them, and how much those medications will cost.[5] PBMs already have too much power and too little oversight or regulation.

We are asking the FTC to intervene in the enormous, unchecked power PBMs hold over pharmacy care. A small number of healthcare organizations presiding over tens of millions of lives should never have that much power over an individual's personal health care choices or the shaping of the overall healthcare delivery system.

PBMs portray themselves as helpful, cost-savings third-party administrators. In fact they are industry middlemen profiting at every stage of the prescription drug supply chain from the manufacturers and the dispensers to the plan payers and patient. PBMs engage in questionable, non-transparent activities that can best be described as anti-competitive and designed to bully independent pharmacies out of business.

Examples of the kinds of PBM anti-competitive practices we are referring to include:

> **PBM-owned pharmacies.** The largest PBMs own mail order, retail and specialty pharmacies that compete directly with the pharmacies PBMs contract through Pharmacy Services Administrative Organizations (PSAOs). The most familiar example is CVS/Caremark, with its 9,700 locations across the U.S. It is estimated that 70 percent of Americans live within a 3-mile radius of a CVS

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[3] Express Scripts, Pharmacies Collide Over Network Cuts. By Mary Anne Pazanowski, Bloomberg BNA. March 2, 2017 https://www.bna.com/express-scripts-pharmacies-n57982084674/

[4] Teresa's Story. Teresa Stickler, Pharmacists United for Truth and Transparency. November 25, 2015 http://www.truthrx.org/2015/11/25/teresas-story/

[5] 4 ways CVS-Aetna merger could change your health care, By Jacqueline Howard and Paul La Monica, CNN. Updated 11:58 AM ET, Tue December 5, 2017 http://www.cnn.com/2017/12/05/health/cvs-aetna-merger-health-care/index.html

pharmacy[6], but CVS also holds mail order and specialty pharmacies. Express Scripts, the second-largest PBM behind CVS/Caremark owns several mail order and specialty pharmacies. PBMs offer special pricing incentives to their plan participants to use PBM-owned pharmacies, offering special deals (e.g. "3 months for the price of 2") that network pharmacies are specifically prohibited by PBM contract from offering.

Non-transparency in the determination of "MAC" lists. MAC refers to Maximum Allowable Cost" and is the PBM-generated list of products that includes the upper limit or maximum amount that a plan will pay for generic drugs and brand name drugs that have generic versions available. Currently there is no standardization in the industry as to the criteria for the inclusion of drugs on MAC lists or for the methodology as to how the maximum price is determined, changed or updated. PBMs can alter their MAC lists at any time without the courtesy of professional notice to their pharmacy networks, which makes it difficult, if not impossible, for most pharmacies to plan for future costs, predict margin and prepare for changes that are a normal part of the business cycle.

Non-transparent reimbursement policy, spread pricing and appeals process. PBMs reimburse pharmacies weeks or months after the pharmacy has dispensed the medication, and do not share with pharmacies the rate of reimbursement they can expect for the dispensed drugs. Because PBMs employ a tactic called "spread pricing" - in which they charge the plan sponsor an agreed upon rate for a MAC list drug while reimbursing the pharmacy for that same drug at a significantly less rate, <u>often below cost</u> - pharmacy owners frequently lose money on the transaction. PBMs do not share this information with plan sponsors or pharmacies, citing "proprietary" or "trade secrets" but the result is small business pharmacies closing by the hundreds each year.[7] And while many states have MAC appeal laws, most PBMs reimburse less than 1 percent of appeals, and often at rates equivalent to pennies on the dollar.[8]

Clawbacks. Clawbacks happen when the cost of a prescription is less than the co-pay charged to the patient — the insurance company "claws back" the difference, which is then paid back to the insurance company's PBM. For example, a $50 prescription drug co-pay on a drug that costs $12 to fill would result in a "claw back" of $38 to the PBM, not the patient, who not only paid the copay but also pays a monthly premium for the insurance "discount" in the first place. Pharmacies are prohibited by the PBM "gag clause" from disclosing the true cost (or loss) of prescriptions to patients, but pharmacies are implicated in the crisis of skyrocketing drug costs because of their forced silence.

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[6] Q&A: How would $69B Aetna bid for CVS change your healthcare? The Associated Press. December 4, 2017 at 12:25 pm http://www.whittierdailynews.com/2017/12/04/qa-69b-aetna-bid-pushes-cvs-deeper-into-consumers-lives/
[7] Source: National Community Pharmacists Association. 1,752 independent pharmacies closed between 2005-2014
[8] Interview with PBM Executive, M. Whitney. November 2017

DIR Fees. Associated with Medicare Part D, DIR stands for "direct and indirect remuneration" and was originally created by the Centers for Medicaid and Medicare (CMS) as a way to track the annual amount of drug manufacturer rebates and other price adjustments applied to prescription drug plans impacting the total cost of Medicare Part D medications.[9] It was presumed the savings from rebates received by the PBM would be returned to CMS. DIR fees now can mean the price a pharmacy pays to participate in a PBM/plan's network; the contracted rate the PBM reimburses the pharmacy for a medication, or the reimbursement or fee to a pharmacy for meeting or failing to meet certain quality measures.[10] DIR fees do the most damage to small, independent pharmacies, who experience this type of clawback long after prescriptions have been filled.

Pocketing manufacturer rebates. Manufacturer rebates are supposed to help defray the rising costs of prescription drug but evidence suggests not only do rebates contribute to rising prices[11], but rebates are not finding their way back to health plan sponsors or patients. Rebates are actually incentives provided to the PBM in return for formulary placement. It is estimated nearly 3 million Americans generate the highest number of rebates - some $50 billion from the purchase of medications to treat the most serious of illnesses (cancer, multiple sclerosis, HIV and autoimmune diseases) but no one is clear where, exactly, the rebates are going, except to the PBMs.[12] Rebates are relabeled as "administrative fees", "grants" or "discounts", allowing PBMs by contract to reimburse themselves for the prices they purport to negotiate on behalf of the client.[13]

These are just a few of the practices PBMs engage in that make it difficult, if not impossible, for America's independent and community pharmacies to compete. Even the PSAOs cannot help America's pharmacies navigate the slippery slope PBMs have created for patients, providers and taxpayers when it comes to containing costs while providing care.

You would think PBMs would want to partner fully and completely with America's pharmacies. Instead, because PBMs can set up their own pharmacy distribution networks and keep their practices opaque and above question, they can threaten, bully, intimidate, dismiss and push around the patient, the insurance payer, the manufacturer and the pharmacy - while simultaneously profiting off of each. **This is why PBMs are a multi-billion dollar industry.**

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[9] The Dirt on DIR Fees. Blair Thielemier, PharmD. Pharmacy Times, July 25, 2016. www.pharmacytimes.com/contributor/blair-thielemier-pharmd/2016/07/the-dirt-on-dir-fees

[10] Thielmier, Pharmacy Times. July 25, 2016

[11] Rebates to pharmacy benefit managers are a hidden contributor to high drug prices. By B. Douglas Hoey, STAT. November 28, 2016 https://www.statnews.com/2016/11/28/rebates-pharmacy-benefit-managers-contribute-high-drug-prices/

[12] Reduce drug prices by eliminating PBM rebates. By Robert Goldberg, Opinion Contributor, The Hill. 02/14/17 01:35 PM EST 9 http://thehill.com/blogs/congress-blog/healthcare/319479-reduce-drug-prices-by-eliminating-pbm-rebates

[13] Don't Get Trapped By PBMs' Rebate Labeling Games. Linda Cahn. Managed Care Magazine, January 2009 https://www.managedcaremag.com/archives/2009/1/don-t-get-trapped-pbms-rebate-labeling-games

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The FTC's mission is to protect consumers and prevent anticompetitive business practices. On behalf of everyone who depends on a fair, working healthcare system, we urge you to dial back the power PBMs currently exploit and abuse. To do so would be to create a system in which there is room for accountability, transparency and equity for all participants.

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