Comments on How Pharmacy Benefit Managers (PBMs) affect Smaller Pharmacies and Consumers (ID FTC-2022-0015-0001)

By William Smith, PhD, and Robert Popovian, PharmD, MS

Pioneer Institute, Boston MA

Pioneer Institute is a non-profit 501(c)3 think tank. Our mission is to develop and communicate dynamic ideas that advance prosperity and a vibrant civic life in Massachusetts and beyond. Pioneer has a specific focus on issues around the life sciences, and the practices of pharmacy benefit managers (PBMs) is an area of our research.

Given that payments to PBMs from drug manufacturers, such as rebates and fees, probably exceeded $200 billion in 2021, there is little doubt that some PBM business practices are reducing the drug costs of health plans, employers and some consumers. These reduced drug costs can assist in keeping health insurance premiums lower and allow employers to continue offering subsidized healthcare to their employees.

However, PBMs' practices impact consumers in different ways depending upon a patient's health condition, medication regimen and health insurance benefit design. For a relatively healthy patient who is taking few medications and is covered by a health plan with low coinsurance and deductible requirements, PBM practices may keep premiums lower.

An increasing number of patients, however, find themselves covered by health plans with higher coinsurance and deductible requirements. For patients in these plans–and who also find themselves prescribed a specialty medicine by their physician—PBM practices can make their medications unaffordable. This is because the PBM system of structuring discounts as rebates and fees tends to drive list prices for drugs higher. By raising list prices, drug manufacturers can create more "headroom" to provide more generous rebates and fees without lowering net prices.

Under this system, higher list prices adversely impact patients who are forced to pay list prices in the deductible and coinsurance phases of their healthcare benefit. Many health plans do not allow their PBMs to pass along negotiated discounts to patients who are paying out-of-pocket for their medicine. *This should change, and we strongly recommend that PBMs be required to pass along negotiated discounts to patients in the deductible and coinsurance phases of their coverage; this policy change would save patients billions in out-of-pocket costs.*

This change is even more urgently required because the mix of medicines being approved by the Food and Drug Administration is increasingly composed of specialty medicines, many for rare orphan diseases, that tend to be more expensive because they treat a smaller universe of patients. During 2020, 58 percent of FDA's approvals were for orphan drugs and that figure was 52 percent for 2021. Policy makers can argue about the pricing practices of pharmaceutical companies and whether, in individual cases, prices for some of these orphan drugs are too high. It is an economic fact, however, that newly launched orphan drugs will always be more expensive than small molecule drugs that treat millions of patients.

Therefore, the three converging trends of rising out-of-pocket costs, increases in drug list prices, and approvals of higher cost orphan and specialty drugs are going to create a cohort of patients who will find it increasingly difficult to afford their medicines. While the trends in FDA approvals are being driven by advances in science, the trends in out-of-pocket costs and rising list prices are being driven by PBM business practices that need closer scrutiny by policy makers.

If passing rebates and fees at the point of sale to patients is not feasible, at a minimum the federal government should have audit rights of PBMs ledgers to find out the exact amount they are extracting from the biopharmaceutical industry. Such a policy will guarantee that PBMs and insurers are not hiding any concessions from the largest payer of pharmaceuticals in the U.S. – the federal government. Once and for all we will know the exact amount of rebates, fees, discounts, or any other compensation from the biopharmaceutical industry provided to the PBMs and insurers.

While we are sympathetic to the plight of independent pharmacies and how PBM contracts are making their business model unsustainable, we are most concerned about patients who need access to life-saving drugs who are failing to fill their prescriptions because PBM business practices have made their medicine unaffordable.

Finally, some policy makers will blame pharmaceutical manufacturers for rising patient out-of-pocket costs. While, as we discussed, increases in drug list prices do have adverse impact upon patients, the higher list prices are unquestionably driven by the desire of drug manufacturers to provide more generous rebates and fees and to achieve more generous formulary status for their medications. In fact, while we continue to see list price growth, average net prices for brand-name drugs have seen declines for the last four years. For example, the CEO of Sanofi, one of the largest makers of insulin, testified to the Senate that net prices for their portfolio of drugs declined by 8 percent in 2019, and the average net price of all Sanofi's insulin products had declined by 25 percent between 2012 and 2019. Due to growing rebates and patent expirations, average prices are declining.

We hope that the Federal Trade Commission will examine how PBM business practices can make medicine unaffordable for many patients. Thank you.