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April 25, 2022

The Federal Trade Commission
Washington, DC

RE: Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers

Why the FTC should Act to Force Change on the PBM Industry

Introduction:

Americans pay the highest prices in the world for drugs. Still, the argument by all parts of the supply chain, including manufacturers, pharmacy benefit managers, health plans, and providers, is that they all provide invaluable services and, as a result, that we have the best healthcare system in the world. If we were to ask if we could construct a more efficient system in which many of the participants in the current system would be obsolete, the answer would be yes. While our existing system construct is an artifact of legacy vs. intrinsic necessity, inadequate or incorrect market regulation has led to these inefficiencies. As consumers, taxpayers, and employers who pay for all healthcare services in the US, it is pretty clear that the primary reasons for these high costs are 'market' inefficiencies created by an effectively one-sided market. The root cause of the inefficiency is the regulated demand side (health insurance coverage requirements mandated at the federal and state level) devoid of any price controls, either implicit (market) or explicit (government control) on the supply side.

While the scope of this request for comments pertained to the PBM industry, the actual implications of the PBM model are broader. It would be difficult to understand the role that PBMs play without understanding the overall supply side of the drug industry. Any review of competition should consider all of the participants and the broader competition implications, which start with the drug manufacturer and end with (or without) an outcome for a patient.

Drugs in the US are generally priced based on a manufacturer-supplied price referred to as Average Wholesale Price (AWP). The name is misleading as this quantity is neither average nor wholesale; rather, it is simply the equivalent of what we commonly refer to outside of healthcare as an MSRP. Almost all drug contracting today, including every major PBM, health plan, or pharmacy, is based on discounts to AWP. The supply side of drugs falls into three general categories, Specialty, Brand, and Generics, each of which

has completely different supply-side economics and, therefore, should be considered independently.

Generics represent about 90% of the volume and about 15% of the cost of all drugs sold in the US. These drugs are usually multi-source drugs for which patents have expired. These drugs also have the most extended history and data surrounding their use. They are typically sold at a multiple of the actual acquisition cost. For example, a common drug such as Atorvastatin is generally available at wholesale for less than $2.00 for a 30-day supply and often sold for > $10.00. What is important to note for the generic is that its high AWP is based on the brand drug, even though its supply side is entirely different than the brand originator drug, which in the case of Atorvastatin is Lipitor. It is typical for generics to have discounts greater than 90% from AWP. Americans would likely benefit the greatest if we were to give away this 90% of truly commodity drugs. If so, we estimate that it would cost us approximately 5% of the current annual drug spend as we could obsolete much of the existing supply chain as it would be unnecessary. To put this into perspective, consider there are more pharmacies in the US than Starbucks and McDonald's combined. Clearly, this is an inefficient system that is driven by supply driving demand rather than the opposite.

Brand drugs represent about 8% of the volume and about 35% of the cost of all drugs sold in the US. These drugs either have no generic competitors or may have a generic equivalent such as Lipitor. They are typically sold at a discounted AWP, generally less than 30%. If there are therapeutic equivalents to the brand drug, then it is likely that there may be a manufacturer rebate associated with the drug. A manufacturer rebate is a post-sale discount that the manufacturer pays to the PBM, who then pays some portion of that back to their customer, who originally paid for the drug. A rebate is analogous to 'paying for shelf positioning' in the retail space. This would be the equivalent of not only having a preferred shelf position in retail but also being able to dictate that a competitor's product not be allowed to be sold at all. Likewise, the critical difference is that these rebate agreements require using the preferred drug while preventing the offering of a competitive product.

From a population health perspective, most public health-related therapies (diabetes, heart disease, simple infections) fall into the categories of generics and brands.

Specialty drugs represent ~2% of the volume and ~50% of the cost (and rising) of all drugs sold in the US. What makes specialty drugs 'special?' Nothing; they are simply brand drugs that target tiny populations with conditions such as inflammatory diseases, MS, cancer, etc. If you were to review the 10-Ks of the top drug manufacturers and PBMs, most of their profits have shifted from generics and brands to specialty drugs over the last five years. As a result, both pharma and PBMs are trying very hard to control every aspect of the specialty markets and thereby limit any real competition.

The upshot of the previous discussion is that these categories have different markets and, therefore, competitive dynamics and require independent analysis. Unfortunately, it is challenging to do that since the Big 3 PBMs control almost 100% of these markets. While the understanding is that they control 80% of the market through rebate contracts, it isn't apparent that they effectively control 100% of the market as almost every other PBM uses a rebate contract that is a derivative of one of the Big 3.

Impediments to Competition:

- The Big 3 PBMs control virtually 100% of the market. Rebates control what drug and where it gets dispensed. As a result of the 3 PBMs controlling nearly all brand drug rebates, they control and, in this case, restrict competition in two major ways. The first is that they prevent new entrants from being on the formulary as the incumbent brands generate higher fees due to larger market share. The second and more insidious issue is that clinical steerage rules both require certain drugs to be dispensed in specific orders and prohibit the FUTURE selection of a competitor's products. For example, suppose 100 patients are currently on a product A and competitor product B is excluded. In that case, one can lose rebates on the 100 EXISTING patients on Product A simply by dispensing product B. This would not even pass the competition test for 'cereal,' but we consider it acceptable in healthcare.

- The Big 3 PBMs are owned by health plans which now steer their members to their own PBM. Vertical integration removes more competition by blurring the line between what is supposed to be the financial intermediary that represents the buyers and the suppliers of healthcare products and services. What used to be a conflict of interest in the pharmacy space has now become a conflict that encompasses all healthcare services with vertical integration strategies of health plans through their purchases of healthcare services such as pharmacies, infusions centers, and primary care.

- PBMs prevent new competitors through 'dumping' by lowering prices below the market to lock out competition. With their enormous scale, they 'buy' the business by lowering their prices to effectively prevent any new entrants into the market when new competitors are present. Effectively this preserves their dominance and prevents even large companies that are billion-dollar companies from competing against them.

- Pharmacies cannot be in business today without being 'in-network' of a PBM as they control reimbursement. They are also told how they will price to be part of the network. They are restricted by channel, so they cannot sell through the mail-order channel to prevent competition with the PBM's own mail-order channel.

- The big health and benefits consultants in the market all have coalitions in which the PBMs compensate them to recommend and steer employers to their own coalitions. PBMs further restrict competition by paying kickbacks to the large consulting firms that operate their own 'coalition' contracts. While there is the perception of independence, in reality, their advice is largely a funnel to their own highly profitable coalitions. Most of the large group purchasing organizations are similarly steered and funded.

- Larger pharma companies control markets by paying for positioning through formularies preventing newer competitors (by drug class) from being able to compete. i.e. Mavyret. These formularies also allow bad pharma actors to prevent competition by blocking the sale of competitors such as biosimilars in the US.

- PBMs all claim to be managers but 'self-deal' with supplier networks, most often owned by them. All of the Big 3 PBMs sell the most profitable drugs directly (specialty) and even own the retail networks in some cases.

- PBMs also generally require 'Most Favored Nation' status in their contracts with pharmacies and pharma. This type of clause effectively prevents competition on both the price and reimbursement of drugs.

- PBMs not only have gag clauses to pharmacies that prevent pharmacists from offering lower-cost solutions, but they also try to 'gag' the consumer under a cloak of confidentiality claiming the adjudicated claims data (what a consumer paid for something) is also confidential.

- They have a business model that is focused on higher prices and utilization rather than the best outcome for the patient and payer.

- Today, PBMs provide an unneeded service for almost all drug purchases, similar to what travel agents did decades ago. Today, 90% of drugs are generics, and open market competitors such as Walmart, Costco, Amazon Pharmacy, Mark Cuban Drug Company, Health Warehouse are examples that have prices that approximate cost plus. These generic drugs (90% of transactions) only require a simple transaction processing network for reimbursements.

- PBMs and pharmacies also own other auxiliary infrastructures such as the largest prescription transfer network, which controls almost every prescription transfer in the US. Most importantly, they control price information shown in EMRs which, even today, doesn't show the net price of drugs, so even prescribers don't know what drugs cost.

- They often charge excessive fees to prevent customers from breaking out services and classes such as specialty. VIVIO, as a specialty therapy management company, has had many experiences where customers of PBMs have either been forced to pay or have been threatened with carve-out penalties that are more than the fees that VIVIO charges for their services.

Recommendations:

We recommend that the FTC consider the following to increase competition which will result in better and cheaper medications for all Americans:

- If intermediaries such as PBM's and Health plans own suppliers of healthcare services, they should

    - Support an 'any willing service provider' model without penalties, channel restrictions such as mail order, accumulation limitations for high deductible plans, or any other artificial barriers to competition.

    - Allow customers to choose any combination of the services/service providers without penalties, technical barriers, or any other artificial barriers to competition.

- Prevent rebate contracts from stipulations that competitor products be prevented from being sold, and that market share agreements be based only on actual market share.

- Prevent the use of MFN contract clauses that effectively prevent competition.

- Prevent the limitations on access (formulary choices) to drugs based on profitability for the PBM rather than reduction of the net cost of the drug.

- Remove all confidentiality claims on prices paid by consumers, or on their behalf, for drugs.

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Drug therapies are the highest frequency and most important intervention in the history of medicine. The FTC has an obligation to ensure that companies compete fairly. The result of a fair and competitive market will be better therapies that cost less. This is the outcome that all Americans deserve rather than paying inflated prices on artificially buoyed therapies by industry participants with economic interests that dictate otherwise. Competition cannot exist without transparency of information, especially on actual pricing. Please help remove the veils that protect the current incumbents from the competitive forces that they should experience.

For further information or details on PBM practices and business model implications, please contact:

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