Waxman

DATE: August 20, 2018

TO: Chairman Joseph Simons, Federal Trade Commission

FROM: Former Congressman Henry Waxman, Chairman of Waxman Strategies

RE: Competition and Consumer Protection in the 21st Century Hearings, Project Number P181201

Dear Chairman Simons,

Thank you for the opportunity to comment on competition and consumer protection. We are encouraged that the Federal Trade Commission (FTC) wishes to tackle these important topics. At Waxman Strategies, my team and I have a great interest in competition and market consolidation within the pharmaceutical supply chain, specifically mergers and acquisitions involving Pharmacy Benefit Managers (PBMs). I believe in order for a market to operate effectively, we should strive to find the appropriate balance between competition, choice, and access.

As an author of the Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the Hatch-Waxman Act), I am deeply concerned about Americans' access to affordable prescription drugs. The intent of the Hatch-Waxman Act was to achieve a balance between innovation in pharmaceutical development and price competition. The legislation achieved that goal. However, for several reasons, including the complexities of the supply chain and market consolidation, the balance of incentives and competition has become distorted over time contributing to higher prescription drug prices. I am increasingly concerned that the current market dynamics will leave patients without access to affordable prescription drugs and undermines the balance we found in passing the Hatch-Waxman Act.

In recent years, mergers and acquisitions have led PBMs and other intermediaries to consolidate both horizontally and vertically, creating a pathway for less competitive oligopolies and affecting prescription drug pricing. The FTC has always had a key role in monitoring the market and conducting analyses to determine the impact of market changes. I strongly encourage the FTC to study the horizontal and vertical consolidation involving PBMs and other intermediaries, including payers, in the prescription drug market.

The Role of PBMs

PBMs currently play a critical role in the pharmaceutical supply chain as they are largely responsible for negotiating the price of prescription drugs for employer health plans and providing retail pharmacy benefits for health insurance carriers in Medicare, Medicaid, and the private insurance market. PBMs are currently responsible for drug benefits for more than 266 million Americans with health insurance coverage.[1]

PBMs obtain discounts on prescription drugs for group health plans, health insurance plans, Medicaid, and Medicare Part D by using their market power to negotiate directly with drug manufacturers and wholesalers. The savings they are able to generate from these negotiations may be passed through to employers, insurance carriers, and patients through lower priced drugs and prescription drug rebates. However, I am concerned whether the savings are truly being passed on to the plans and patients due to the lack of transparency and the increasing number of reports that suggest they are not. In fact, a number of lawsuits have been brought against PBMs on these charges, discussed below.

PBMs are also given the power to determine a formulary, tiering of the formulary, and cost sharing for patients for the employer health plan, and health insurance carriers, with the assistance of physicians and other clinical experts, referred to as a pharmacy and therapeutics (P&T) committee. This means that PBMs have direct influence on which drugs are covered, and therefore more likely to be prescribed. This control coupled with the lack of transparency gives PBMs influence over determining the affordability of drugs while creating perverse incentives for the PBMs to place higher priced drugs on the preferred formulary to receive greater rebates from manufacturers, dispensing, and administrative fees.[2]

Today's role as a PBM has been influenced by the consolidation that has recently occurred. In 2014, the top three PBMs, Express Scripts, CVS Health, and Catamaran (which was later purchased by UnitedHealth Group's Optum Rx)[3], managed pharmacy benefits for more than 180 million individuals, nearly 80 percent of the total number of insured covered by PBMs.[4]

In 2016, these three largest PBMs – CVS Health, Express Scripts, and Optum Rx – accounted for about 70 percent of market revenues. The two largest accounted for almost 52 percent of market revenues. [5] All three of these PBMs have participated in mergers. CVS Health merged with Caremark in 2007, as well as acquired Omnicare in 2015. Express Scripts merged with MedCo Health Solutions, another PBM, in 2012. And as mentioned above, Optum, owned by UnitedHealth Group, acquired Catamaran in 2015.[6]

[1] C. Werble, "Pharmacy Benefit Managers," Health Affairs, September 2017. DOI: 10.1377/hpb2017.13, accessed at: https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/full/
[2] R. Feldman, "Perverse Incentives: Why Everyone Prefers High Drug Prices – Except for Those Who Pay the Bills," SSRN, April 2018, accessed at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3162432
[3] Ibid
[4] Ibid
[5] "Letter to Chairman Simons," U.S. House of Representative Committee on Energy and Commerce, July 27, 2018, accessed at: https://energycommerce.house.gov/wp-content/uploads/2018/07/20180727FTC.pdf
[6] Ibid

The Impact of Consolidation Involving PBMs Should be Carefully Studied

One of the main factors that led to consolidation of the PBM market is that the more covered lives PBMs are able to represent the greater the discounts to be achieved and the larger the rebate from the manufacturer who will gain that market share. The incentive to increase size and number of covered lives has led to consolidation in the PBM industry in the past decade.[7]

I am concerned with the consolidation among the PBM industry, as well as the vertical integration occurring today. In addition to the mergers discussed above, CVS Health is in discussion to merge with Aetna, and Cigna is considering acquiring Express Scripts. These mergers and acquisitions could lead to reduced competition and higher prescription drug prices for patients and the health care system. With the lack of information and transparency, the FTC can play an important role in studying the horizontal and vertical integration and pinpointing the specific issues and impact.

PBMs Under Scrutiny as a Result of Anti-Consumer Behaviors

A recent lawsuit filed against CVS/Caremark alleges that CVS/Caremark is price gouging consumers to increase profits.[8] The plaintiff sued CVS/Caremark when she purchased a generic drug through her insurance for $165 at a CVS pharmacy, yet the drug would have cost $92 if she had not used her insurance. The lawsuit alleges that the increase in price was claimed as a copay, but in fact were payments for PBMs. Since the agreements between PBMs and pharmacies are confidential, many have highlighted these pricing discrepancies as kickbacks for PBM profit. There is a lack of transparency related to these agreements between PBMs and other stakeholders among the pharmaceutical supply chain. This lack of transparency can trickle down to the consumer level with what are known as pharmacy gag clauses, where pharmacists, due to the pharmacy's agreement with the PBM, cannot disclose to patients that their drug may be cheaper if they pay out-of-pocket and do not use their insurance.[9] A similar lawsuit was filed against Walgreens with the plaintiff alleging Walgreens is overcharging consumers for generic prescription drugs.[10]

Another similar suit alleges that Cigna, which contracts with OptumRX, a PBM owned by UnitedHealth Group, overcharged their members by artificially inflating prescription drug prices, violating the Employee Retirement Income Security Act (ERISA) and the Racketeer Influenced and Corrupt Organizations (RICO) Act by charging members more than 10 times the amount that Cigna paid the pharmacy for drugs.[11] The plaintiffs claim that Cigna required

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[7] C. Werble, "Pharmacy Benefit Managers," Health Affairs, September 2017. DOI: 10.1377/hpb2017.13, accessed at: https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/full/

[8] E. Chuck, "CVS Charges More for Generic Drugs Paid for With Insurance, Lawsuit Claims," August 2017, accessed at: https://www.nbcnews.com/news/us-news/cvs-charges-more-generic-drugs-paid-insurance-lawsuit-claims-n791156

[9] "Prohibiting PBM 'Gag Clauses' that Restrict Pharmacists from Disclosing Price Options: Recent State Legislation 2016-2018," July 2018, ! accessed at: http://www.ncsl.org/Portals/1/Documents/Health/Pharmacist_Gag_clauses-2018-14523.pdf !

[10] J. Berr, "Walgreens gets sued for generic-drug overcharges," May 2017, accessed at: https://www.cbsnews.com/news/walgreens-sued-for-generic-drug-overcharges/ !

[11] E. Sweeney, "Drug pricing lawsuit proceeds against Cigna as lawmaker calls for a closer look at Express Scripts Deal," March 2018, accessed at: https://www.fiercehealthcare.com/payer/cigna-drug-pricing-lawsuit-express-scripts-congress

pharmacies to collect higher copays and then took the spread between the contract fee and copay. These types of allegations have received attention from Members of Congress, who have called for hearings on PBM consolidation and tactics.

Recommendations

The FTC plays an important role in identifying the specific issues related to PBM consolidation. I urge the FTC to conduct a comprehensive, retrospective analysis of the prescription drug supply chain industry. This study should include a review of the horizontal and vertical consolidation in the industry to understand the effects on competition, prescription drug prices, patients, and the pharmaceutical industry. In addition, the study should also review the agreements and contracts between PBMs and intermediaries, including pharmacies, wholesalers, manufacturers, and payers, to understand the role PBMs play, how these arrangements impact patients and payers, and the effect on prescription drug prices.

FDA Commissioner Scott Gottlieb has stated that his agency will be working with the FTC to identify anti-competitive behaviors among the pharmaceutical supply chain. We believe the FTC and FDA together should proactively monitor the market for anti-competitive behaviors and proactively identify failures in the market that lead to high prescription drug prices or barriers to patient access. This type of increased market monitoring should address issues related to vertical and horizontal consolidation and encompass monitoring of manufacturers, PBMs, various intermediaries, and any relationships among those intermediaries that lead to anti-competitive practices.

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We hope to continue this conversation with you, your staff, and other federal agencies involved in this issue. Please do not hesitate to reach out to myself or Kristi Martin at kristi@waxmanstrategies.com with any questions.

Regards,

Henry Waxman
Chairman, Waxman Strategies
Henry@waxmanstrategies.com