## FTC Cracks Down Anticompetitive Tactics from All Sides of Prescription Drug Supply Chain

As public outcry against healthcare costs, in particular prescription drug prices, continues to dominate the national spotlight, the Federal Trade Commission (FTC) is stepping up its efforts to regulate anticompetitive conduct in various markets of the healthcare supply chain. In this month's Litigation and Enforcement Highlights, we take a look at FTC enforcement actions that target 1) the e-prescription market, 2) reversepayment agreements between drug manufacturers, and 3) pharmacy benefit managers.

## FTC Targets Monopoly in Electronic Prescription Market in Antitrust Action Against Surescripts

As the country faces building pressure to rein in rising healthcare costs, the FTC is broadening its efforts and turning the focus on the other side of the healthcare market: healthcare information providers. In April, FTC filed a lawsuit against Surescripts in the U.S. District Court for the District of Columbia,[1] alleging the health information company engaged in illegal exclusionary contracts to deter competition in the electronic prescription (e-prescription) market, resulting in fewer choices and higher prices for consumers. E-prescribing processes prescriptions by transmitting patient information and prescriptions among insurers, doctors, and pharmacies. It is an efficient tool used to streamline the prescription process and reduce costs compared to traditional paper prescription.

According to the <u>complaint</u>, Surescripts possesses at least 95% market share both in the market for routing e-prescriptions to pharmacies[2] and the market for determining patients' eligibility for prescription coverage. [3] Leveraging its "musthave" network status, Surescripts pressured vendors into terminating relationships with competitor platforms and to enter into exclusive agreements with Surescripts for network access and favorable prices. Electronic health record (EHR) vendor Allscripts "lamented that it had 'no choice' but to enter into [the exclusive] agreement as Surescripts was a "must-have" connectivity vendor, and without a contract, Allscripts would be unable to connect to pharmacies and PBMs and thus be unable to e-prescribe." As a result, "Surescripts's web of loyalty contracts prevented competitors from attaining the critical mass necessary to be a viable competitor in either routing or eligibility... [and] [t]hose effectively exclusive contracts foreclosed at least 70% of each market."

The FTC said in a press release that Surescripts's conduct "denied patients the benefits of competition—including lower prices, increased output, thriving innovation, higher quality, and more customer choice," in violation of Section 2 of the Sherman Act.[4] The Agency seeks to undo and prevent Surescripts' unfair methods of competition, restore competition and provide monetary redress to consumers.

## FTC Doubles Down on Regulation of Pharmaceutical Pay-for-Delay Schemes in Latest Ruling Against Impax

In a more direct effort to rein in anticompetitive behavior in the pharmaceutical industry to reduce drug prices, the FTC is honing its target on pharmaceutical pay-for-delay schemes, the popular practice in which a brand drug manufacturer pays a generic drugmaker to stay off the market. Most recently, the FTC reversed an administrative court's ruling and found that generic drugmaker, Impax Laboratories, participated in an unlawful payfor-delay or reverse payment agreement with brand manufacturer Endo, in violation of antitrust laws.

The FTC <u>alleged</u> that Impax accepted a "large and unjustified" payment of more than \$100 million to abandon its patent challenge and delay its release of the generic version of Opana ER, an opioid pain reliever manufactured by Endo, until January 2013. As a result, the complaint further claimed that "patients" were denied the opportunity to purchase lower-cost generic versions of Opana ER, forcing them and other purchasers to pay hundreds of millions of dollars a year more for this medication." However, as previously covered on The Source, the administrative law judge (ALJ), in a May 2018 decision, held that the procompetitive benefits of the agreement outweighed the anticompetitive harm and dismissed all of FTC's claims. In the reversal, the Commission found that plaintiffs established a prima facie case of the existence or likelihood of substantial anticompetitive harm. Specifically, it held that sufficient evidence existed to show that Impax could have launched a generic product before the agreed-upon date, had it not entered into the reverse payment settlement with Endo. Additionally, Impax failed to show "cognizable procompetitive benefits" for its reverse payment. The final order bars Impax from entering any other reverse payment agreements with drug companies.

As experts expected, the FTC's <u>latest ruling</u> confirms the 2013 landmark U.S. Supreme Court decision in <u>FTC v. Actavis</u> that a brand name manufacturer's payment to a generic competitor to settle patent infringement claims could potentially violate antitrust laws.[5] This development is also the latest victory in a string of FTC enforcement actions against similar pay-fordelay tactics. In February 2019, the FTC reached a large-scale settlement in lawsuits in three separate federal courts, prohibiting generic manufacturer Teva Pharmaceuticals from engaging in reverse-payment patent settlement agreements that impede consumer access to lower-priced generic drugs.[6] The FTC also scored a <u>record monetary award</u> against pay-for-delay schemes in June 2018, when a federal court in Philadelphia ordered AbbVie to pay \$448 million in illegal profits to consumers for delaying the entry of generic versions of the testosterone replacement drug AndroGel. These milestones in FTC enforcement efforts are promising developments to help rein in schemes to delay generic competition in the prescription drug industry.

## FTC Urged to Scrutinize PBM Practices for Antitrust Concerns

To add to the FTC's plate of enforcement actions, Congress is urging the Commission to not forget about the middlemen in the pharmaceutical supply chain, pharmacy benefit managers (PBMs). The House and Senate are considering <u>H.R. 2376</u>, the Prescription Pricing for the People Act of 2019, which would require the FTC to study PBMs and whether their practices in negotiating drug prices with drug manufacturers are anticompetitive. PBM practices have come under increasing scrutiny, as the nation's three largest PBMs (CVS, Express Scripts, and OptumRx) control 85 percent of the PBM market. The string of recent vertical mergers of PBMs with health insurers, including Aetna-CVS and Cigna-Express Scripts, further exacerbated concerns of market concentration. Given its bipartisan support, the bill has a good chance of passing both houses and would enable new government reports to shed light on the PBMs' notoriously secretive business practices.

Litigation and enforcement actions serve as a formidable weapon to keep anticompetitive practices in check in the healthcare industry, and the FTC is at the forefront of that effort. As the FTC expands its actions to all sides of the healthcare supply chain, the precedents it sets will prove important in attaining the ultimate goal of encouraging competition and reducing healthcare prices.

[1] Federal Trade Commission v. Surescripts, LLC, D. Wash., # 1:19-cv-01080, complaint filed 4/17/19.

[2] A routing technology that allows healthcare providers to send electronic prescriptions directly to pharmacies.

[3] A service that allows healthcare providers to electronically check patients' eligibility and benefit for prescription coverage through access to insurance coverage and benefits information (usually through a pharmacy benefit manager).

[4] FTC Charges Surescripts with Illegal Monopolization of E-Prescription Markets: https://www.ftc.gov/news-events/press-releases/2019/04/ftc-charg es-surescripts-illegal-monopolization-e-prescription (last visited May 11, 20

[5] FTC v. Actavis Inc., 133 S. Ct. 2223, 2013 BL 158126 (U.S. 2013).

[6] FTC Enters Global Settlement to Resolve Reverse-Payment Charges against Teva: https://www.ftc.gov/news-events/press-releases/2019/02/ftc-enter <u>s-global-settlement-resolve-reverse-payment-charges</u> (last visited: May 11, 2019).