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FTC, FDA Team Up to Fight Drug Monopolies, High Prices

By Jacquie Lee and Alexei Alexis | August 3, 2018 10:03AM ET

- FTC and FDA don't traditionally regulate drug prices, but they're stepping into that space now
- It could lead to more scrutiny for some brand drugmakers who have already been accused of gaming regulations

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A partnership to tackle high drug prices is budding between two federal agencies with traditionally separate missions as drug costs rise and the government struggles to rein them in.

The collaboration between the agencies—the Food and Drug Administration and the Federal Trade Commission—could result in even more scrutiny for brand drugmakers as well as pharmacy benefit managers as prices increase and companies merge.

The partnership may be a sign of past promises coming to fruition. Maureen Ohlhausen, the former acting chairman of the FTC, said in November the agency would be keeping an eye on unfair practices within the drug industry, but was cautious about using litigation as a cure-all. Since then, the Trump-nominated FTC chairman, Joseph Simons, has taken over amid rising pressure from Congress to investigate anti-competitive behavior.

Lowering drug prices was one of President Donald Trump's campaign promises. And while some companies, like Merck & Co., have promised to cut prices on some products, 255 brand drugs had increases between Feb. 1 and July 15, according to the latest Bloomberg News analysis of data on the drug pricing website GoodRx. Brand pharmaceutical companies have long been accused of gaming regulatory channels—including Gilead Sciences Inc. and Celgene Corp.—who were frequently cited in a list of possible suspects the FDA published in May.

Neither the FDA nor the FTC is directly responsible for regulating drug prices, but both have stepped up to the plate recently. The FDA regulates which drugs reach patients' medicine cabinets; the FTC spots and shuts down anti-competitive behavior through lawsuits.

Two Agencies, One Goal

The pair offers a rare window of opportunity that could shift the balance of power in favor of generic competitors, competition advocates told Bloomberg Law.

"I would say this is probably the most coordination we've seen between the agencies," Michael Brzica, vice president of federal government affairs at the Association for Accessible Medicines, told Bloomberg Law. The group represents generic drug firms such as Zydus Pharmaceuticals Inc.

Scott Gottlieb, head of the FDA, announced July 18 he planned to meet with Simons to discuss situations where drug companies are infringing on fair competition.

The FTC said in a July 16 filing that it stands ready to partner with the Health and Human Services Department and the FDA on the issue.

"Regulatory barriers and abuse of government processes that delay and constrain competition can lead to higher prices and reduce access to those medicines—all to the detriment of consumers," Simons said in a statement on the project.

The Pharmaceutical Research and Manufacturers of America, the leading industry group representing brand drugmakers, didn't respond to Bloomberg Law's requests for comment.

Working Together

Brand drugmakers have lots of opportunities to use regulations to draw out their patent exclusivity or keep a generic product from hitting the market.

They can tweak their products—like switching up packaging—to extend patents so they can continue to exclusively make money off a drug. And a brand drugmaker also can refuse to sell samples of its branded drug products to a generic makers, which the

generic maker needs to prove to the FDA its new version of the drug is just as effective and safe.

That's where the FTC could intervene.

The agency has the power to investigate and file lawsuits against companies that use "unfair methods of competition" under Section 5 of the Federal Trade Commission Act.

It could also conduct studies on pharmaceutical patent abuse so it can advise Congress on potential legislation, David Balto, a former FTC policy director who helped develop its pharmaceutical enforcement program, told Bloomberg Law. Balto is based in Washington and now practices law independently.

While the FTC has a long track record on drug competition, it has largely been focused on pursuing "pay-for-delay" cases, where branded drugmakers pay their generic competitors to keep cheaper alternatives off the market for a period of time, according to Balto.

"The FDA has the technical and scientific knowledge, and the FTC has the legal expertise as a competition enforcement agency," David Mitchell, founder of Patients for Affordable Drugs, told Bloomberg Law. "The two of them working together can be a mighty force." The group advocates for policy changes to lower the price of prescription drugs.

Both agencies have urged legislative action to address situations where branded drug companies use FDA regulations to skirt competition. The bipartisan CREATES Act (S. 974), approved by the Senate Judiciary Committee in June, would make it easier for generic drug companies to bring federal court cases and receive damages if they believe brand-name firms are thwarting competition.

Tension exists between the two agencies however, Peter Pitts, president and co-founder of the Center for Medicine in the Public Interest, told Bloomberg Law. The center is a nonprofit research and education organization focused on patient-centered health care.

For example, the FTC was critical of the way the FDA names biosimilars in its public comments on President Trump's drug blueprint. At an event at the Brookings Institute in July, Gottlieb told the crowd, "I wish they would focus more on the legal activity and less on the scientific nomenclature."

Much of the tension comes from each agency not understanding what the other does, Pitts said. Good communication going forward will be crucial to any collaboration, he said.

PBMs Next on List?

The role pharmacy benefit managers play in the drug supply chain has gotten more scrutiny the past few years as well. Congress has recently highlighted potential anti-competitive behavior within those business models, which act as middle men that negotiate drug discounts and set up which drugs are covered under health insurance plans.

Republican lawmakers asked the FTC July 27 to take a closer look at PBM mergers. Three major PBMs—CVS Health Corp., Express Scripts Holding Co., and UnitedHealth Group Inc.'s OptumRx unit—make up roughly 70 percent of the market. Meanwhile the Justice Department is reviewing CVS's acquisition of Aetna Inc. and Cigna Corp.'s purchase of Express Scripts. Mergers aren't necessarily better for consumers, Reps. Greg Walden (R-Ore.), Gregg Harper (R-Miss.), and Michael Burgess (R-Texas) said.

Another area related to PBMs where the FTC should direct its attention is in how they create their formularies, Edmund Haislmaier, a senior research fellow at the Heritage Foundation, told Bloomberg Law. Those are the lists that indicate which drugs are covered under a health insurance plan.

For example, a drug company could pay the PBM to prioritize the placement of its drug on the formulary list for multiple indications, which could freeze out other drugmakers who have their own—potentially superior—products they want to put at the top of formulary lists, Haislmaier said. "Is that deal anti-competitive? Is that a restraint on trade?" he asked.

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