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BLOG

House Antitrust Subcommittee Addresses Consolidation in Health Care Markets

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On April 29, 2021, the U.S. House of Representatives Subcommittee on Antitrust, Commercial, and Administrative Law met to discuss consolidation in health care markets. The hearing resulted in broad agreement that, despite the bitter partisan divide on Capitol Hill, Democrats and Republicans could work together to prioritize the passage of legislation with the aim of increasing the competitiveness of the health care market.

The hearing, which largely focused on prescription drug pricing and possible legislative solutions to rising prices, included testimony from a bipartisan group of lawmakers, health care experts, and antitrust experts. The testimony and the questions posed by members of the committee revealed a broad bipartisan consensus on the need to act against alleged market consolidation by pharmaceutical companies.

Many of the witnesses shed light on the some of the industry practices pharmaceutical companies purportedly use to maintain market dominance—including "product hopping," "pay for delay," and sham citizen petitions—all meant to delay the entry of generic medications into the market:

- Product hopping occurs when a pharmaceutical company's patent on a specific drug is about to run out and the company tweaks the drug in a certain way—such as by changing a capsule to a tablet or providing a different dosage—reportedly to maintain its exclusivity over that type of prescription. Whenever a brand changes a drug like this, generic drugs cannot be substituted, and the pharmaceutical company can extend its market dominance for several more years—causing patients to pay higher prices for prescriptions, according to the hearing's participants.
- Pay for delay occurs when a branded pharmaceutical company shares its profits with generic pharmaceutical companies in exchange for delaying the introduction of any generic medications into the marketplace.
- Participants at the hearing accused pharmaceutical companies of using a mechanism that the FDA had established for concerned citizens to raise legitimate issues about medication to delay the entry of generic drugs into the marketplace. Instead of being used by citizens, pharmaceutical companies have ostensibly co-opted the system for their own use. For example, when a pharmaceutical company's exclusivity on a certain drug is about to run out, it will petition the FDA to take the drug off the market, citing safety concerns. Until the FDA can review the petitions, which often include piles of complicated scientific documentation, the generic drugs cannot be

introduced. These petitions drain the resources of the FDA and enable brands to maintain their market dominance over a type of drug.

Many of the legislators referenced proposed legislation that they have introduced to combat these problems, including:

- **Affordable Prescription for Patients Act of 2021**: Introduced by Sen. Blumenthal (D-CT) and Sen. Cornyn (R-TX), this bill would prohibit pharmaceutical companies from so-called product hopping and would give the FTC power under Section 5 to challenge hard switches—where a branded drugmaker pulls its product from the market before introducing a tweaked product—and soft switches—where a branded drugmaker introduces a similar product prior to the end of its patent on the original drug and encourages doctors and their patients to switch to this new medication. The bill would also prevent patent thicketing, where an inventor uses multiple overlapping patents or patents with identical claims to create a high barrier to entry.
- **Preserve Access to Affordable Generics and Biosimilars Act**: Introduced by Sen. Klobuchar (D-MN) and Sen. Grassley (R-IA), this legislation would declare any generic receiving anything of value for delayed entry presumptively unlawful.
- **Stop STALLING Act**: Introduced by Sen. Klobuchar (D-MN) and Sen. Grassley (R-IA), this bill would help prevent the abuse of the FDA-petitioning process and would deter branded companies from filing unfounded petitions to delay the approval of generic drugs.

The lawmakers and witnesses also discussed two broad categories of solutions that could help bring down the cost of prescription drugs: enforcement and competition. Dr. Leemore Dafny proposed more reporting of health care transactions, removing limitations on the FTC's authority to investigate anticompetitive conduct by nonprofit organizations, and studying the business of insurance. According to Dafny, increased reportability of transactions—through increased filing requirements and lower asset value threshold, among other things—would assist the FTC's ability to recognize potentially anticompetitive transactions. Additionally, granting the FTC the ability to study the business of insurance would enhance the agency's efforts in health care enforcement because of the blurred lines between the provision of care and insurance. Moreover, she stated that because the FTC does not have the authority to investigate nonprofit entities, the agency cannot enforce the nation's antitrust laws against mergers involving nonprofit hospitals—something she states has been shown to increase prices.

Witness Robin Feldman proposed that the bills discussed be approved by the committee and urged that there be an implementation of a "second look" policy after the completion of a merger to ensure that it is not anticompetitive. She stated that while consideration of mergers is forward-looking, most legal actions, such as torts or contracts, are backward-looking. Allowing for a "second look" would allow for courts to reassess whether the predicted procompetitive outcome of a transaction ultimately occurred. Michael Carrier and Alden Abbott agreed that mergers between large firms ought to be presumptively unlawful. Carrier specifically stated that there is "no good reason" for two large companies to merge if they both have entrenched advantages in areas such as financing, marketing, sales, and insurance reimbursement. Additionally, he said that there are no innovative reasons for two large firms to merge.

Abbott also believes that existing antitrust statutes are "fully adequate" to address health care antitrust issues but said that narrowly targeted legislation could help address gaps in the law that do not cover the alleged abuses that the experts testified about. He specifically highlighted the CREATES Act, passed in 2019, which attempts to prevent pharmaceutical companies from blocking generic drug companies from producing generic versions of the branded drugs, as an example of the type of thing Congress can do. Finally, he agreed with Dafny that the Federal Trade Commission Act should be modified to give the FTC authority over nonprofit entities. He stated that it places "major, if not insurmountable, obstacles before the FTC's ability to investigate and, where necessary, take enforcement action against a wide range of monopolizing or otherwise anticompetitive conduct in the health care sector."

Sen. Klobuchar discussed allowing Medicare Part D to negotiate drug prices and importing prescription drugs from Canada to force competition and bring down the cost.

Finally, there appeared to be broad consensus on the need to increase funding for enforcement agencies, such as the FTC and the Antitrust Division of the Department of Justice. One potential solution included Sen. Klobuchar's

Merger Filing Fee Modernization Act, which would fund a $135 million budget increase for antitrust enforcement, split between the FTC and the Antitrust Division.

While not the main focus of the hearing, lawmakers also spoke out against diminishing competition among hospitals as a result of the large amount of hospital mergers in recent years. Potential solutions discussed included increased antitrust scrutiny of hospital mergers, as well as the repeal of state certificate-of-need laws that currently prevent the entry of would-be competitors into the health care market in a particular state unless the state agrees—sometimes with the input of incumbent firms.

As previously mentioned, the lawmakers who participated in the hearing, both as witnesses and on the committee, all recognized that there is a bipartisan consensus that Congress needs to act to maintain competition in the health care markets and prevent future consolidation that will harm consumers.

Takeaway

While the health care industry has been subject to particularly intense scrutiny by antitrust regulators, especially over the past few years, the hearing on April 29 makes clear that the crosshairs are now set on pharmaceutical companies. Lawmakers on both sides of the aisle are seeking out and promoting a variety of legislative measures that aim to increase and protect competition in the pharmaceutical sector, with an ultimate goal of making prescription drugs more affordable and accessible to Americans. Pharmaceutical companies, medical device manufacturers, and other healthcare industry participants must continue to tread carefully when it comes to pricing, obtaining patents, and contemplating mergers and acquisitions to ensure that they are not opening the door to negative attention that could make them a target for regulators.
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