Nearly four years ago, “Pharma bro” Martin Shkreli made headlines after his pharmaceutical company raised the price of the brand name drug Daraprim from $13.50 to $750 per pill, seemingly overnight. While the price hike or spike gained notable media attention and congressional public shaming, little evidence was brought forth to explain why the hike had happened. Even now, while Shkreli is incarcerated on unrelated charges, Daraprim still costs a hefty price for its users. While some argue that Shkreli’s company, now rebranded as Vyera Pharmaceutical, should be prosecuted for antitrust violations, mounting such a case against the oft-maligned corporation may not be so successful or even the right approach. Instead, the answer for scrutinizing such price hikes in the future may not be in the courts but a legislative function, a type of congressional initiative that President Donald Trump championed on the campaign trail and one which is being discussed more frequently after the recent midterm election.

One of the main tenets of antitrust law is the need for anticompetitive behavior that is harming consumers or competition generally. In the drug-pricing context, however, it is often difficult to pinpoint an antitrust violation, as sometimes competition is not being pushed out of the market, but instead, ceases to exist in the first place. One of the main sources of competition in pharmaceuticals is the presence of generics, lower cost alternatives to the brand name that help decrease pricing by offering options to the consumer. Of course, a company has to decide whether or not it is profitable to create a generic and sometimes the answer is no, which was the case for Daraprim, the drug at the heart of the Shkreli scandal. As prescribed, Daraprim is used to treat a very rare infection called toxoplasmosis, which can be deadly in those infected with HIV. Relatively speaking, however, the portion of Americans in need of the drug numbers only a few thousand per year, making it less attractive to pharmaceutical companies who might be interested in developing a competitor drug. Without competitors entering the market, the price of the drug is set by one supplier, with little incentive or need to lower the cost to keep pace with other possible competing options. Yet, there is no antitrust violation necessarily there since there is no anticompetitive behavior in the first place because of that singular competition. Competitors are allowed to enter the market unless there are significant barriers to entry but what if they have chosen not to enter a market perceived as not desirable? Does that mean the only player in the market is guilty of an antitrust violation?

Of course, if a pharmaceutical company were to restrict entry to the market by others, that might be a cause for anticompetitive concern. Some argue that Shkreli did just that by enacting an unnecessary restricted distribution program. Restricted distribution programs can be used to limit the dangerous effects of a certain drug on vulnerable populations, such as restricting the availability of a drug that causes birth defects to physicians who are well-educated on its effects and qualified to prescribe it to only those patients who really need it. Because such restricted access programs could actually drive profits down by decreasing the number of patients who can be prescribed the drug, some argue that it is a type of safety protocol that an unsavory businessperson can use as a type of shield to oust competitors from the market, without suggesting that is the motivation for implementation.
For example, for a generic to enter the market, it must prove that it is biologically equivalent to the name brand version of the drug it intends to copy, a process that includes testing the generic against a sample of the original, a sample which can only be acquired through the original distributor. Not only can the original distributor refuse to supply the sample, but in order to perform the requisite bioequivalence studies, the generic producer may need an amount of the drug which can be too difficult to acquire in order to create the appropriate data package for approval. There was no evidence that a generic tried to enter the Daraprim market and failed due to access problems. One could argue that Shkreli’s decision to use the restricted distribution system was enacted against the self-interest of the company in order to erect a barrier to entry for competitors. And yet, while the Sherman Act, by its terms, prohibits every agreement “in restraint of trade” the U.S. Supreme Court has long recognized that only “unreasonable” restraints were intended to be rooted out by antitrust law. Just because trade could have theoretically been strained, if there were a reason for it—such as a valid medical concern—then there would still be no antitrust violation. Thus, the question becomes whether Shkreli did or did not have a valid medical safety concern for enacting the restricted distribution system and, even if he did not, did his actions keep competitors from entering the market or did they fail to enter because the market for the drug was too small to be profitable in the first place?

Finally, antitrust cases are brought against anticompetitive behavior. In order to have competition, there has to be more than one player in the relevant product and geographic markets. It is problematic to mount a successful antitrust case on the basis of unilateral price hikes alone. While there have been a few instances of actionable conduct over the years, antitrust law focuses on the presence of an agreement between key players and evidence of collusion among competitors to fix prices. With only one player involved, an antitrust claim can be merely one of unfair performance versus anticompetitive tactics.

In the case of Daraprim, Shkreli was able to obtain market exclusivity, seemingly legally based on the evidence at hand, which invited controversy but no judicial solutions. Last month, Trump signed a bill into law that would require drug makers to send details of biosimilar deals, essentially drug generics, to the Federal Trade Commission for antitrust scrutiny. Accessing the terms of these deals could allow the FTC to more quickly catch antitrust violations and potentially provide a drug manufacturer with pause before engaging in anticompetitive behavior. The bill also allows the FTC to review “pay for delay” agreements, a type of agreement where a generic manufacturer acknowledges the patent of the originator pharmaceutical company and agrees to refrain from marketing its generic product for a specific period of time. With prescription drug prices being one of the few areas where Trump has suggested he would reach across the aisle, this bill could be the fertile ground for legislative review.

In that vein, potential government tax breaks or subsidies to promote innovation by pharmaceutical companies in areas deemed not profitable may be one answer. And some increased informed oversight by the FTC could potentially manage those companies or executives who cross the line. Bottom line is that not every price hike or spike equates to invoking the heavy weight of the antitrust laws. Stay tuned.

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