Congress Proposes Legislative “Fixes” to Drug Industry Rules Believed to Be Contributing to High Costs

Thursday, June 30, 2016

We spend a lot of time covering prescription drug costs, and even convened a Pharmacy Industry Summit earlier this year focusing on the various pressures that are contributing to higher drug prices. Although Congress has not been sitting on the sidelines of the drug pricing debate – having conducted three separate committee investigations, which included subpoenas of top executives and the most well-known of them, Martin Shkreli, getting boot ed from the committee room for refusing to answer any questions – Members of Congress are finally beginning to roll out legislation with the end goal of increasing prescription drug competition and decreasing the costs of drugs.

CREATES ACT

Earlier this month, two separate, bipartisan pieces of legislation intended to address competition and drug pricing were introduced in the United States Senate. First, Senator Patrick Leahy (D-VT), Ranking Member of the Senate Judiciary Committee, along with fellow Chairman Chuck Grassley (R-IA), introduced the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2016. The CREATES Act would enable a generic drug manufacturer to challenge a pharmaceutical company in federal court for injunctive relief if the company prevents the generic manufacturer from obtaining samples of the branded product or refuses to allow generic competitors to participate in a restricted distribution system. These restricted distribution issues have peaked since the passage of a 2007 law that authorized FDA to require a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits of a drug outweigh its risks, because one possible component of a REMS can be a restricted distribution model for the drug. Tightly controlled distribution has led to situations in which a generic manufacturer (or biosimilar developer) has been unable to secure samples of the branded product or refuses to allow generic competitors to participate in a restricted distribution system. These restricted distribution issues have peaked since the passage of a 2007 law that authorized FDA to require a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits of a drug outweigh its risks, because one possible component of a REMS can be a restricted distribution model for the drug. Tightly controlled distribution has led to situations in which a generic manufacturer (or biosimilar developer) has been unable to secure samples of the reference product needed to conduct basic testing to support their own follow-on applications. In addition, we have seen disputes related to the issue of a shared distribution system (that is, shared between the innovator and the generics), which the 2007 law authorizes but which are not always freely agreed to by the original pharmaceutical company when generics begin to enter the market. Each of these practices are referred to as “REMS abuse” by the generic pharmaceutical industry as well as the Federal Trade Commission.

PRICED ACT

Second, Senators Sherrod Brown (D-OH) and John McCain (R-AZ) introduced the Price Relief, Innovation and Competition for Essential Drugs (PRICED) Act just last week. The PRICED Act would shorten the exclusivity period for brand name biological products from twelve to seven years. The current 12-year exclusivity period was created under the Biologics Price Competition and Innovation Act, or BPCI A, which also created the abbreviated licensure pathway for biosimilars to take advantage of after the 12-year period of protection for the innovator
biologic has passed. The PRICED Act’s amendment to current law would thus enhance competition by giving biosimilar applicants the ability to enter the market seven years after the innovator biologic is first licensed. Importantly, the 2017 budget request from the Department of Health and Human Services says that reducing exclusivity of biologics to seven years would save the federal government and taxpayers $6.9 billion over the next 10 years. A companion bill was also introduced in the House by Rep. Jan Schakowsky (D-IL). It is worth noting that Sen. McCain is in cycle and facing a tough reelection bid, but this is not his first foray into addressing prescription drug costs - he is the lead Republican sponsor on the Safe and Affordable Drugs from Canada Act, which would allow individuals to legally import certain prescription drugs from Canada.

The likelihood of these bills passing this year are slim to none. But given a new incoming Administration in 2017, with the two leading candidates both talking prescription drugs and the unsustainability of their high costs, it’s important to be aware of the types of proposals being floated. Any one of these proposals could be taken up individually next year or could end up being tacked on to a larger legislative vehicle. One such vehicle could be next year’s reauthorization of the Generic Drug User Fee Amendments, which is set to expire September 30, 2017 and will likely be a priority for the Senate HELP Committee, regardless of who is in the majority.

©1994-2019 Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. All Rights Reserved.

Source URL: https://www.natlawreview.com/article/congress-proposes-legislative-fixes-to-drug-industry-rules-believed-to-be