

## Health Agency Could Make Generic Drugs Under Democrats' Bill (1)

By Shira Stein

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- Intended to counter generic drug shortages, high drug prices
- Has little chance in the Senate, good chance in the House

The federal government could step in to make generic prescription drugs that have high prices or are in short supply under legislation offered by two Democrats in the Senate and House.

Sen. Elizabeth Warren (D-Mass.) and Rep. Jan Schakowsky (D-Ill.) introduced companion bills aimed at lowering the cost of prescription drugs that would establish an Office of Drug Manufacturing in the Department of Health and Human Services. The bill would need to be reintroduced in the next session of Congress to get full consideration with this session ending in a few weeks.

The bill is unlikely to pass a Republican-led Senate, where conservative lawmakers are more inclined to rely on the market to lower drug prices. But it has a good chance next year in a House led by Democrats who want to push for strict drug pricing measures and call in pharmaceutical executives for investigations.

### Fixing Drug Markets

"The solution here is not to replace markets, but to fix them. The Affordable Drug Manufacturing Act will introduce more competition into the prescription drug market, and bring down prices for consumers," Warren said in a statement.

The Department of Health and Human Services would be authorized to make generic drugs in certain situations where they aren't being manufactured, are in shortage, there's little competition, or the price has spiked.

The majority of generic drugs are made by a few companies, including Teva Pharmaceuticals and Mylan Inc., according to a 2017 National Bureau of Economic Research study, and many drugs whose patents have expired aren't being produced at all.

The new HHS office would be able to sell its manufacturing rights to any company that commits to keeping a drug on the market at a fair price, and any revenue from the sale of these drugs would be used to make the office self-sustaining.

Scott Gottlieb, the head of the Food and Drug Administration, recently told Bloomberg Law the agency is looking into how it can increase Medicare reimbursement for certain generic drugs that are often in shortage.

"With generic drug market failures increasingly prevalent, consumers are suffering from price gouging and essential drug shortages," Robert Weissman, president of Public Citizen, said in a statement. "This common sense bill will address shortages, lower prices, aid consumers and advance public health."

### **Focus on Insulin**

Warren and Schakowsky's bill would also require the new office to begin the production of generic insulin within one year of its enactment.

High insulin prices have been getting extra attention lately because of the financial strain put on Americans with diabetes and the prevalence of stories about patients dying because they rationed their insulin due to its high cost.

The FDA is also focused on making it easier to create a substitutable generic version of insulin to drive down costs, Gottlieb said at a recent event. The agency is changing the definition of insulin starting in 2020 to make the regulatory pathway easier to navigate.

Starting in March 2020, insulin will fall under a narrower definition of "biologic," making it easier to create a substitutable generic and drive down insulin costs, Gottlieb said Dec 11.

### **Drug Industry Concerns**

Drugmakers are unhappy about the possibility of this bill passing.

"It is hard to fathom why anyone would call this system broken or insist that the government commandeer the business of developing, manufacturing, and distributing these medicines," a spokesperson for the Association for Accessible Medicines said in a statement. "At best, this legislation is an unrealistic distraction from policies that would meaningfully reduce drug prices, such as combating patent abuse and cultivating a robust biosimilars market."

Branded drug industry group the Pharmaceutical Research and Manufacturers of America believes "there is a right way and a wrong way to spur competition in the marketplace for biopharmaceuticals. We welcome the opportunity to work with Congress and the administration to build upon existing efforts at the FDA to improve generic competition for patients," Andrew Powaleny, a spokesperson for PhRMA, said in a statement to Bloomberg Law.

"CSRxP is reviewing the legislation, as we do with all drug=pricing proposals," Lauren Blair, a spokesperson for the nonpartisan Campaign for Sustainable Rx Pricing, said in an interview. CSRxP supports bipartisan, market-based solutions to lower drug pricing, the campaign's website said.

Patients for Affordable Drugs had no comment.

## Pricing Fixing Inquiry

Warren also sent a letter to the expected chairmen in the next Congress of the Senate Health, Education, Labor, and Pensions Committee, Lamar Alexander (R-Tenn.), the Finance Committee, Chuck Grassley (R-Iowa), and the Judiciary Committee, Lindsey Graham (R-S.C.), to ask them to open investigations into allegations of price fixing by generic drug manufacturers.

Over 300 generic drugs had at least one "extraordinary" price spike of over 100 percent from 2010 to 2015, according to a 2016 Government Accountability Office report.

"It's always been a priority for Sen. Grassley to shine a light on anticompetitive behavior and ensure that bad actors are held accountable. In the next Congress, Sen. Grassley will continue his work to protect American consumers from abuses in the system that help drive drug costs higher," Michael Zona, communications director for Grassley, said in a statement to Bloomberg Law.

(Adds additional content throughout.)

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