

Sen. Elizabeth Warren, D-Mass., during a post-midterm election meeting on Capitol Hill on Nov. 13, 2018, in Washington, D.C. Photo: Chip Somodevilla/Getty Images

ELIZABETH WARREN PLAN WOULD ALLOW THE GOVERNMENT TO MANUFACTURE ITS OWN GENERIC DRUGS

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If I told you that there are two major efforts on the left to reform the pharmaceutical industry, and one relies

on market competition while the other establishes a publicly run office to manufacture prescription drugs – to control the means of production, so to speak – you might assume that the first comes from [capitalist-to-her-toes](#) Sen. Elizabeth Warren and the second from [honeymooned-in-the-USSR](#) Sen. Bernie Sanders.

It's actually the opposite.

Warren introduced legislation on Tuesday with Rep. Jan Schakowsky, D-Ill., that would create an Office of Drug Manufacturing within the Department of Health and Human Services. That office would have the authority to manufacture generic versions of any drug for which the U.S. government has licensed a patent, whenever there is little or no competition, critical shortages, or exorbitant prices that restrict patient access.

Last month, Sanders and Rep. Ro Khanna, D-Calif., released their own bill to tackle high drug prices, which would require the government to identify any excessively priced drugs (relative to an international index of list prices) and grant a license to private companies to provide competition with a generic version.

The two bills from Warren and Sanders, who are [both likely running for president](#), are actually complementary efforts that deal with different elements of a system that results in Americans paying more for medications than anywhere in the industrialized world. And

they reflect a broader attack on the industry from multiple angles.

“Sanders-Khanna and Warren-Schakowsky are two absolutely complementary bills,” said Alex Lawson of Social Security Works, who has worked extensively on drug prices and was involved in both efforts. “It’s important that you’re seeing multiple, transformative big ideas.”

The Sanders-led legislation seeks to reform the monopoly patent system for prescription drugs, which virtually assures high prices and incentivizes the exclusive drugmaker to restrict competition. But the bill relies on a functioning generic drug market that can drive down prices by mass-producing alternatives that steal customers from brand-name treatments.

About 90 percent of all prescription drugs filled are for generic medications. But recent events have revealed that the generic market is also broken. A 2017 National Bureau of Economics Research [paper](#) found that generic competition has weakened over time, as fewer firms compete to make alternatives. By 2016, 40 percent of all generics were [made by a single manufacturer](#).

A Government Accountability Office [report](#) identified price spikes of 100 percent or more in the generic drug market in one out of every five drugs studied between 2010 and 2015. There is even an active [investigation into cartel behavior](#) among 16 different generic drug

manufacturers, which allegedly divvied up the market and fixed prices for more than 300 drugs.

This trend toward monopoly providers of generics creates fragile supply chains that can lead to [widespread drug shortages](#) in the event of a disruption, something that almost never happens in a well-functioning, wealthy market economy.

Even with multiple generic options, the effect on prices can be illusory. Last month, Teva Pharmaceuticals, a powerful generic drug company, released a generic version of the EpiPen, the price spirals of which have angered patients. But the Teva-made generic [costs the exact same amount](#) as a generic EpiPen released by Mylan, maker of the brand-name drug.

Warren's bill, the Affordable Drug Manufacturing Act, attempts to address that market failure by having the government pick up the slack. The Office of Drug Manufacturing would acquire rights to manufacture generic drugs or contract them to be manufactured by an outside entity. The legislation explicitly states that those generic drugs must be offered at a "fair price" that covers manufacturing and administrative costs while ensuring patient access. The office could strip a contractor of its ability to make and sell the drug if the price point is too high. Proceeds for these sales would go back to covering agency costs, making it a self-sustaining entity.

The government would also be authorized to manufacture active ingredients for medications. This has become a problem, as major drug companies **routinely deny rivals** samples of their products, which are used in testing to determine whether the generic is an equivalent treatment.

One drug is listed specifically: Generic insulin treatments would have to be produced within the first year of the legislation's passage. **Prices for insulin have skyrocketed** in recent years and shortages are common.

“In market after market, competition is dying as a handful of giant companies spend millions to rig the rules,” Warren said in a statement. “The solution here is not to replace markets, but to fix them.”

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Except the means to fix those markets is a government-directed option that puts the Department of Health and Human Services into the pharmaceutical manufacturing business. That's the primary action in the legislation that allows competition to take root and prices to fall. In this sense, competition policy can work hand in hand with targeted nationalizations or public options.

Another section of the bill highlights Warren's preoc-

cupation with the notion that personnel matters as much as policy. Former drug company lobbyists would be banned from holding the position of director of the Office of Drug Manufacturing under the proposed legislation, as would any senior executive of a drug company subject to regulatory enforcement for wrongdoing.

Advocates generally welcomed the concept of a public drug manufacturer. “Anyone who is serious about controlling costs and ensuring more patients have access to life-saving drugs should be supporting this legislation,” said Richard Master, chair of the Business Initiative for Health Policy, in a statement.


But some experts believe that more work must be done to reform the entire supply chain for prescription drugs. Phil Zweig, a former journalist who works with [Physicians Against Drug Shortages](#), believes that group purchasing organizations, or GPOs – collections of hospitals that contract to provide medical supplies and medications – are at the heart of the exorbitant pricing and shortages. GPOs are a key gatekeeper for drugs administered at hospitals. “Generic drugmakers simply stop making the drugs if they don’t get a sole-source contract,” Zweig said. “It’s a winner-take-all game.”

GPOs have an exception to the anti-kickback statute that allows them to give exclusive contracts to drug companies in exchange for cash, some of which flows back to hospital executives and administrators.

Zweig wants to remove the safe harbor. “All we’re trying to do is remove obstacles to competition,” he said.

Pharmacy benefit managers, or PBMs, which negotiate prices for drugs sold in pharmacies on behalf of health plans, have also [been accused](#) of skimming off the top and artificially creating higher drug prices. The Trump administration has [proposed taking away](#) the anti-kick-back safe harbor for PBMs.

Warren spokesperson Ashley Woolheater agreed that “there is bad behavior up and down the supply chain,” adding that this bill specifically focuses on the generics and active pharmaceutical ingredients markets.

“It’s going to take a multi-pronged effort,” said Lawson. “This is not a silver bullet, it’s just one piece of it.”
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