





Correction, Please!

Pols Eye Risky Prescription: Price Controls for Drugs

Item: "Congressional liberals," reported the Associated Press for January 10, 2019, have offered legislation to lower prescription drug prices. One major effort, noted the wire service, was being pushed by "Sen. Bernie Sanders, I-Vt., Rep. Elijah Cummings, D-Md., and others. Cummings leads the House Oversight and Government Reform Committee, which is expected to take a major role on drug pricing."



Their "newest idea would essentially apply to any U.S. patent-protected brand-name drug, whether or not government programs are bearing the cost."

Drugs, the AP continued, that were "found to be 'excessively priced' by the government could face generic competition. A medication's cost would be deemed 'excessive' if its price in the U.S. was higher than the median, or midpoint, price in Canada, the United Kingdom, Germany, France and Japan. If the manufacturer was unwilling to cut its U.S. price, then the government could allow generic companies to make a more affordable version of the medication."

Item: Massachusetts Democrat Senator Elizabeth Warren, reported the Intercept on December 18, wants to establish a "publicly run office to manufacture prescription drugs — to control the means of production, so to speak."

The bill "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."

Item: The Campaign for Sustainable Rx Pricing (CSRxP) — a project of the National Coalition on Health Care — decries on its website that "dozens of pharmaceutical companies rang in the new year by increasing hundreds of drug prices by up to 15 times the rate of inflation — despite the fact that their profits continue to far exceed spending on research and development."

The group cites various increases of certain drugs ranging from 6.2 to 10 percent, pronouncing that "at a time when one in four Americans can't afford their medications, these price hikes are staggering."

Adds CSRxP: "It's time for Congress to hold these companies accountable."

Correction: We would be better off if there was less government in business and more business in government, preferably smaller, constitutional government.





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This is not to say, of course, that certain companies are without fault. There are indeed problems with pharmaceuticals. Still, we might also grumble, for example, that running shoes are "excessively priced" (thus hurting the well-being of hard-pressed exercisers), but that does not mean that the solution is establishing the U.S. Office of Sneaker Manufacturing.

As it is, we are not dealing with anything approaching a free market with pharmaceutical drugs when one considers how deeply Washington is already involved, including countless levels of regulations.

Regulations cost in terms of both production and delivery time for patients. This has been a challenge for some time, as addressed last June in an analysis by Charles Silver and David Hyman. Silver is an adjunct scholar at the Cato Institute and a law professor at the University of Texas at Austin; Hyman is an adjunct scholar at Cato and a professor at the Georgetown University Law Center. They rightfully pointed a finger at the U.S. Food and Drug Administration for "a backlog of pending applications from generic drug manufacturers that want to enter the market." The writers urged Congress give the agency the resources needed "to process these applications more quickly" and to give "priority to applications for generics that have experienced price hikes."

When it comes to generic drugs, it is government policies that "allow big drug companies to obtain long-term monopoly protection by keeping their generic competitors out of the marketplace," as was noted by Dr. Ron Paul last year in a piece for the Foundation for Economic Education. Too many drug companies, the former congressman wrote, do exploit

the complexity of the post-patent rules to make it very time-consuming and costly for competitors to enter the marketplace. They can even withhold supplies of their drugs from companies that — under Food and Drug Administration (FDA) rules — must obtain them to make sure they're copying them correctly. The result is the big drug companies are able to extend their de facto monopolies well beyond the intent of Congress, thus keeping the supply of the drugs artificially low and prices artificially high.

In late October, the Council of Economic Advisers outlined how HHS and FDA policies had already helped decrease the prices of prescription drugs for American patients. Its report shows that "relative annual price growth for prescription drugs has slowed since January 2017, and estimate that lower prices from new generic drug products saved consumers \$26 billion through July 2018."

Under FDA Commissioner Scott Gottlieb — as described in a November piece in E21, the economics portal of the Manhattan Institute for Policy Research — "the FDA has slashed regulatory barriers to new and generic drug development, allowing the FDA to approve a record number of new drugs in FY18, beating the record they set the previous year." This is a positive step.

But it is part of the progressive creed to disdain business "greed" even while seeking to concentrate power with the central government. Let's concede that even well-intentioned capitalists are not generally altruistic saints. That said — and this is assuredly not because the American pharmaceutical industry is unselfish — this country accounts for more than half of new "wonder drugs" developed in recent decades, according to the Milken Institute.

The industry is not a charity. It has major expenses and is sustained by profits. As explained by Chris Pope of the Manhattan Institute: "The average cost of developing a new drug, demonstrating its safety and efficacy, and bringing it to market has been estimated to be as high as \$2.9 billion. Patents allow drug firms to recoup their investment by temporarily restricting competition."





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At the same time, Big Pharma, as it has been widely labeled, is an attractive target for populist attacks — in part because it is easy to blast someone for raising prices now rather than giving them credit for providing cures down the road. As John Tierney put it in a balanced, perceptive piece in the *City Journal* last year, "Developing a new drug often takes more than a decade — an eternity to a politician. Lowering prices for today's voters is far more appealing than saving the lives of voters in 2030."

The U.S. pharmaceutical industry is, as Tierney observed, "the most innovative in the world and saves more lives than any other institution." And it is denounced by many in both political parties as a major villain for profiteering.

Tierney noted that even Donald Trump, in a press conference as president,

accused drug companies of "getting away with murder," and Bernie Sanders has called the industry's greed a "public-health hazard to the American people." A central plank in the "Better Deal" that Democrats are promising ... is for the federal government to "negotiate" drug prices, and some progressives don't even make that semantical pretense. They call for outright price controls, if not the "deprivatization" of the industry, on the grounds that Big Pharma is too powerful to be constrained by market forces.

Both parties say the industry needs reforming because companies can game the system. And what government has deformed, it could reform — either for the better or the worse. The *Wall Street Journal* has looked, very dubiously, at some of the solutions that fall in the latter category. Democrats in the House, the paper's editors wrote on January 8,

are pushing a bill to let Medicare "negotiate" drug prices, an idea President Trump tossed around as a candidate. The reality is that Medicare's prescription benefit known as Part D is run by commercial payers that already negotiate steep discounts. The real Democratic goal isn't "better deals" but political control over what government pays for medicine. In other words they want price controls, which sap the incentive to innovate.

There has also been an alignment, of sorts, between socialist Bernie Sanders and Trump administration proposals. One Sanders bill "would peg what the U.S. pays for drugs to what other industrial countries pay — Canada, the United Kingdom, Japan and so on. Earlier this year the Health and Human Services Department proposed trying a similar model for drugs in Medicare Part B." Under the Sanders legislation, as the *Journal's* editors wrote, the HHS secretary "could break the patent of any drug that is 'excessively priced,' which judging by the political pique would include all of them."

Warren, Sanders, and Trump administration officials, among others, have complained about (or looked jealously at) what occurs in foreign countries, many with single-payer health systems. Some of those countries are apparently freeloading, as critics complain, from American drug companies, and those companies have been accepting the prices set there (and making up by charging more in this country). Economic columnist Stephen Moore, who served as a senior economic advisor to the Trump campaign, says that HHS Secretary Alex Azar has assured him the administration's plan "is designed to limit the price controls in foreign countries and bring American drug prices down so they are in line with other nations."

One might hope so. Yet, as Moore cautions, if price controls are the problem, "effectively importing them to these shores can't also be the solution."





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There could also be unforeseen consequences. If, under political pressure, the prices in foreign nations for a certain drug are forced up, that does not necessarily mean that Americans are going to pay less. Companies might just pocket the foreign increase and wind up with more money at the expense of patients on both sides of the Atlantic.

The history of those relying on government price controls is a sad one (and not just in Venezuela, though the shortages caused there should be instructive). Dr. Joel Zinberg, a surgeon who is now on the White House's Council of Economic Advisers, previously summarized the effects of price controls imposed by European countries in the 1980s. The doctor noted that in the middle of that decade, "European drug R&D was 24% higher than in the U.S. After price controls, European pharmaceutical R&D grew at half the U.S. rate" and substantially trailed American R&D by 2016.

Yes, Americans do gripe about their drug costs, but there are plenty of complaints in Europe too. We should not fall victim to the "grass is always greener on the other side" syndrome. Yes, there are numerous individual horror stories about the cost of prescription drugs in this country, often related to innovative treatment. Let's assume each is true. How should we respond? After all, there are reasons for the maxim that hard cases make bad law.

On the one hand, we have politicians pushing industry nationalization. On the other hand, here are some actual statistics: The latest data from the Centers for Medicare & Medicaid Services reveal that spending on prescription drugs in this country increased 0.4 percent in 2017. Does this reflect a devastating crisis? The Association for Accessible Medicines, the generic-drug lobby, points out that generics provide Americans "with nine out of 10 of their prescriptions at only 23 percent of total spending on drugs." Moreover, as the *Wall Street Journal* has pointed out, countries in Europe make

trade-offs that are severe but often not transparent. Britain's National Health Service routinely puts conditions on which patients can receive oncology drugs, for instance. Some drugs are denied approval on grounds that they don't produce results worth the cost, a judgment most American patients might prefer to make themselves. The Food and Drug Administration doesn't consider cost, at least not explicitly.

As for Elizabeth Warren's essential nationalization push of generic drugs, even the left-wing Washington Post sent up smoke signals in warning — pointing out that it is almost impossible to find a state-owned enterprise that can really pursue innovation and social welfare rather than profit. The Post's Megan McArdle called Warren's idea

particularly silly given that so many of the problems that make it harder for generic drug-makers to enter the market are created by government regulations in the first place. Unless the government enterprise bypasses the regulatory hurdles constraining supply, it will face much the same difficulties that private firms do. And if the government is going to relax regulatory requirements, wouldn't it make more sense to just retool the way the market works for everyone?

Sure, but there's an election coming. If you want to lead the Democrats into battle, you need more than the DNA of a 1/1,024th statist, you must display the headdress of a full-fledged socialist chief.

- William P. Hoar

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