Here's a plan to fight high drug prices that could unite libertarians and socialists

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President Donald Trump and Secretary of Health and Human Services Alex Azar recently introduced American Patients First, a complicated plan intended to make prescription drugs more affordable. It includes many ideas and suggestions, such as requiring drug makers to put the list prices of their products in their advertisements and "working across the administration to assess the problem of foreign free-riding." A few commentators think the plan will materially reduce prices, but we are skeptical.

The plan is a response to bipartisan outrage over drug prices, which have risen dramatically in recent years. The stories about Daraprim, the drug that made Martin Shkreli infamous when he jacked its per-pill price from $13.50 to $750, and the EpiPen, which put Mylan Pharmaceutical in the spotlight when it raised the price of a two-pack from $100 to $600, are probably the best known. But prices have increased for hundreds or thousands of drugs at rates far exceeding the pace of inflation.

Consider Xyrem, a drug for narcolepsy made by Jazz Pharmaceuticals, whose price rose 841 percent over seven years. The price for a twin-pack of Evzio, the naloxone injectors made by Kaleo Pharmaceuticals that are used to treat opioid overdoses, went from $690 to $4,500 in a year. Price hikes for insulin have caused a nationwide panic among diabetics. The list of examples is seemingly endless.

Rising prices mean, of course, that we're spending more on drugs. Americans handed over $457 billion for prescription drugs in 2015 and are on pace to increase that amount by 6.7 percent every year through 2025 — far, far faster than salaries will rise. Is it any wonder the pharma sector regularly outperforms the broader stock market?

Some conservatives defend this system on free-market grounds, arguing that any measure that reduces drug company profits will necessarily reduce innovation. But we are firm believers in the free market, and we think the system is a mess. It is deformed by monopolies and by misguided incentives tied to the payment system.

Because it is such an obviously ungainly monster, the goal of reforming this system has the potential to break down some political walls: Although we are affiliated with the libertarian Cato

Institute, we find ourselves agreeing with Sen. Bernie Sanders, for instance, that the government should experiment with a prize system instead of awarding patents to drug companies.

Monopolies are at the heart of the problem

Why do drug prices keep going up? For branded drugs, the short answer is that patents give drug companies monopolies, which they exploit to the fullest. An added factor is that our payment system often allows manufacturers to charge whatever they want.

Let's start with monopolies. Give a business, any business, a monopoly and it will extract wealth from consumers by charging monopoly prices. And that is precisely what patents for drugs do: They give drug companies monopolies on the sales of new medications.

Even when the original patents have long-since expired, drug companies use various contrivances to keep prices high. The most common tactic is to obtain extensions on marketing exclusivity by means of secondary patents on superficial characteristics, such as pills' coatings or formulas for timed-release.

Consider Lipitor, a cholesterol-fighting statin. An extension of its patent term and a second extension for pediatric testing gave Pfizer, Lipitor's manufacturer, an additional 1,393 days of marketing exclusivity, during which it took in $24 billion more than if the drug had entered the generic category when originally scheduled.

Lockstep pricing — made possible because only a small number of manufacturers compete in many drug categories — is a problem too. Companies don't compete for customers by undercutting other makers' prices; rather, when one raises its prices, the others follow suit. Economic theory suggests we shouldn't see this kind of behavior, but we do.

What can we do about these problems? Let's start with generic drugs, because the problem in that category is the most straightforward. Many of the pricing problems in the generic drug market are directly attributable to insufficient competition. Substantial price hikes occur and stick because only one company makes a drug, or because manufacturers raise prices in lockstep. Illegal, anti-competitive conduct may underlie some of these problems, in which case aggressive antitrust enforcement is the answer.

But the US Food and Drug Administration also bears part of the blame. There is a backlog of pending applications from generic drug manufacturers that want to enter the market. Congress should give the FDA the resources it needs to process these applications more quickly. But until that happens, the FDA should give priority to applications for generics that have experienced price hikes.

Currently, the FDA follows a first-in, first-out approach to applications. A more consumer-friendly arrangement would move applications for drugs that have experienced significant price spikes to the head of the line. A bonus: Once incumbents realize that price hikes will result in fresh competition, they may be deterred from jacking up prices to begin with.

More broadly, policymakers should liberalize access to the US generic drug market by relaxing the FDA's grip on entry. Currently, the FDA requires that it, and it alone, approve the safety of generic drugs. But why not let a company that qualifies to sell a generic drug in Canada, England, France, Israel, or other developed country sell the same drug in the United States — at

least so long as a generic equivalent has already been approved by the FDA, and the 180 days of marketing exclusivity provided to that generic by the Hatch-Waxman Act has expired.

These countries have the expertise needed to protect their citizens from excessive risks and the desire to do so. Sen. Bill Cassidy (R-LA) recently came out in support of a similar idea. If such a policy had been in effect, Martin Shkreli wouldn't have been able to price-gouge anyone.

Martin Shkreli, the former "pharma bro" CEO who raised the price of the drug Daraprim from $13.50 to $750, though it was inexpensive to produce. *AP Photo/Seth Wenig*

What about branded drugs? Here, monopoly is also a problem. Fixing it will be a particular challenge because it requires Congress to undertake patent reform — and the pharma sector is adept at blocking any legislation that would take money out of its pockets.

Consider the fate met by Sen. Sanders's proposals to use prizes instead of patents to encourage pharmaceutical innovation. In 2005, Sanders filed the Medical Innovation Prize Act, which went nowhere, as did the similar bills that he introduced every two years thereafter.

But Sanders is onto something. A well-designed prize regime would lower drug prices by eliminating drug monopolies, yet it would also create the necessary incentives for innovation, including incentives to develop so-called "orphan" drugs (for diseases that afflict relatively few people).

The prize system could also be tailored to encourage drug companies to test the efficacy of old drugs for new uses. Finally, a prize regime would place the costs of drug innovation on-budget, where they would be borne by all taxpayers rather than just by consumers who happen to need drugs (and their insurers).

A prize system might take many forms. One model that we like would link the size of the prize to actual, documented R&D costs — including clinical trials. Companies hoping to obtain FDA approval for new drugs would submit confidential periodic filings outlining all of the drugs they are studying and the associated R&D outlays.

After the FDA approval for a particular drug was granted, a company would apply for a prize and submit an accompanying final statement of its research costs. The company would then receive a check from the US government, the size of which would be a predetermined multiple of the approved research costs, with a larger multiplier in areas where new drugs are especially needed.

This proposal has several important strengths, including transparency. Final cost statements for approved drugs will be audited and available for public inspection. Everyone would know why the government cut the check that it did.

The prize regime would also create clear and focused incentives. Once the multipliers were fixed, innovators would know what they stood to gain before investing in R&D. Incentives could also be periodically retuned. If experience showed that certain types of drugs were needed but not being pursued, multipliers in that space could be increased.

Conservatives may object that regulators are unlikely to size prizes correctly. We agree. A reward system based on prizes will not work perfectly. Nothing does. A prize system just has to

work better than the existing system of patent monopolies, and there are good reasons to think that it would.

For starters, it would keep manufacturers from taking advantage of the inability of the current insurance system to impose meaningful limits on the amounts manufacturers can charge. Second, it would ensure that drug companies are compensated only for the R&D costs and risks they actually bear.

Of course, a prize system will cost taxpayers money; the dollars needed to fund the prizes would come from them. But in light of the many problems existing arrangements generate, it seems better to use the tax system to fund prizes than to use the patent system to impose costs. Today, those costs (and drug-related tax preferences) fall on consumers, insured populations, and taxpayers. Taxing people to fund prizes is simpler, more straightforward, and fair.

Most importantly, a prize system ensures that prices for new drugs are set competitively. Once the FDA approved a new drug or a new use for an old drug, all companies would be free to make it. Competition will force prices down to manufacturers' production costs, which is the efficient, pro-consumer price that emerges naturally when markets are competitive. That will make drugs more affordable for the people that need them.

The fundamental economic problem in the pharma sector is that it costs an enormous amount to create a safe, effective new drug but only pennies to manufacture the actual pills. Pharmaceuticals are not unique in this regard; computer software and blockbuster movies share these characteristics. If drug companies sold pills at their marginal cost, they'd never recoup the billions they spend on R&D.

Our current patent-based regime allows inventors to capture profit by using the power of the government to prevent competitors from duplicating their creations and undercutting their prices. It's a coercive and messy process. It spawns litigation over the validity of patents and their scope. It ties drug companies' returns to their sales, not to the risks and costs they incur. By comparison, even a flawed prize-based system starts to look pretty good.

To create good incentives, we should treat drug companies like trial lawyers who work on contingency. When they produce winners, they should be rewarded lavishly. When they don't, they should get nothing.

There are many other problems with our prescription-drug system — notably insurance systems that insulate people from the cost of the medicines that they purchase. So long as insurance will pay for any medicine, no matter the price, we will not get drug costs under control. But that is a topic for another day.

On the supply side, aggressive antitrust enforcement, revisions to the FDA approval process for generics, and prizes instead of patents provide a solid start for a reform agenda. As a bonus, it may be one that conservatives and liberals alike can rally behind.

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