

Here's How Trump Should Address The High Cost Of Prescription Drugs

Jeffrey Singer

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President Donald Trump has expressed concern about prescription drug prices. During a cabinet meeting, he remarked that "the drug companies are getting away with murder. . . as usual, the world is taking advantage of the United States. They're setting prices in other countries, and we're not."

In a tweet announcing former Eli Lilly CEO Alex Azar as his nominee for secretary of Health and Human Services, the president exclaimed, "He will be a star for better healthcare and lower drug prices." Yet at Senate confirmation hearings late last year, Azar offered no specifics on how he plans to do that.

Here's a solution: stop focusing on trying to control drug prices, and start paying attention to who's paying them. Tax and regulatory policy, such as the exemption for employer-provided insurance or mandated-benefits laws, have led to a third party—often the government—paying the vast majority of medical bills. With the consumer out of the loop, costs to the third party—and consequently premiums—continue to rise.

There's no denying that rising drug prices are having an outsized impact. The uproar over the \$600 EpiPen has barely faded from memory. A recent *Washington Post* articlecited the staggering growth in the price of naloxone, an antidote for opioid overdoses in use since 1971. Soaring prescription drug prices strain state and local budgets and fuel insurance premiums.

Some politicians clamor for price controls on prescription drugs. Some think the rise of pharmacy-benefit management firms, middlemen that negotiate prices with manufacturers on behalf of insurers, might provide relief. But drug makers charge outrageous prices because they can, largely by gaming the third-party-payer system. PBMs only insert another layer into it.

Drug makers take advantage of the third-party-payer system, where they quote a price to a deep-pocketed third party, not the consumer. This results in high, often imaginary prices charged to the third party, with the understanding that the third party will likely negotiate the price down. Not everyone can negotiate, however. For example, Medicare is not legally permitted to negotiate drug prices. Medicaid, by contrast, is required by law to pay the lowest price negotiated by a private insurer. Veterans Affairs is allowed to negotiate drug prices like private insurers do.

Yet none are negotiating from the standpoint of the end-user consumer. This means that even relatively inexpensive drugs fetch a higher price than they would if there was a direct producer-to-consumer market.

To help defray patients' out-of-pocket drug costs for high-priced drugs, many pharmaceutical companies offer coupons or contribute to charities called Patient Access Programs, which help cover copays and other coinsurance requirements. These tax-deductible charitable donations are a small price to pay to remove consumers' cost concerns from the transaction with the third party.

The maker of Evzio, the only auto-injectable naloxone, said one of the reasons it quintupled its price to \$4,500 since 2014 was to cover its donation to a "charitable" patient assistance program that covers all the out-of-pocket costs for those with private insurance, and provides the drug free to those without insurance who earn less than \$100,000 per year. This makes the auto-injectable naloxone attractive to the patient while leaving the insurance company to pick up the bulk of the bill.

High drug prices are also buttressed by the pharmaceutical regulatory regime. Entrenched manufacturers are gaming this system too.

When a drug maker introduces a new product, it enjoys monopoly status, letting it charge high prices until its patent expires. Taking advantage of a scheme created by the Hatch-Waxman Act of 1984, drug makers often extend monopoly status by tweaking their products, like a change in pill coating, and obtaining a secondary patent—a process called "ever-greening."

One government study found that from 1989 to 2000 54 percent of all Food and Drug Administration-approved drugs were these so-called "incrementally modified drugs." Drug makers also take advantage of the FDA's onerous drug approval process by requesting greater scrutiny of competing generic or new drug entrants, delaying their introduction. The makers of Narcan nasal spray, another opioid antidote, recently used this ploy to throw sand in the gears of a generic effort by Teva Pharmaceuticals.

Competition from new entrants is also deterred by the slow and complicated FDA approval process. A September 2016 report showed a backlog of more than 4,000 generic drugs awaiting approval, with a median time to approval of 47 months.

None of this is meant to indict the pharmaceutical companies. They are in business to make a profit. It's the system that is ailing. The tax laws that favor employer-based insurance over individual insurance must be reformed. So must mandates that result in bloated and intrusive third parties wedging themselves between consumers and providers. Regulatory reforms must address the "gaming of patent and exclusivity agreements" Azar acknowledged at the confirmation hearings.

If President Trump wants to bring down drug prices, he should avoid new layers of regulations and controls that will only make matters worse, and focus on bringing consumer-driven market forces and competition to this broken system.

Jeffrey A. Singer, MD, practices general surgery in Phoenix, Arizona and is a senior fellow at the Cato Institute