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Analysis: The Good, the Bad and the Ugly of the Trump Administration’s Drug Pricing Measures from its FY 2019 Budget Proposal

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In December 2016, then [President-elect Trump said](#) he was “going to bring down drug prices.” He reiterated that message in his State of the Union speech last month when he said “[o]ne of my greatest priorities is to reduce the price of prescription drugs,” and added, “[t]hat is why I have directed my Administration to make fixing the injustice of high drug prices one of our top priorities. Prices will come down.”

But the drug pricing measures in the Administration’s [FY 2019 budget proposal](#) released on February 12, 2018, are far short of living up to this promise. The budget includes some limited positive proposals. But the Trump Administration fails to target the root causes of high U.S. drug prices by leveraging government negotiating power, putting an end to price spikes and curbing the monopoly abuses of industry; foregoing the most effective and obvious reforms that are needed to make a real difference in the lives of Americans struggling to afford their medicines. And beyond its limited positive proposals, the White House budget nods towards measures that instead of lowering drug prices at home, would impose hardship abroad. This analysis will break down the good, the bad and the ugly of the White House budget drug pricing measures.

The Good

First, the President’s budget proposal included some positive albeit modest measures that would help provide some consumers with relief and yielding modest government savings.

“Address abusive drug pricing by manufacturers by establishing an inflation limit for reimbursement of Medicare Part B drugs”

The proposal to establish an inflation limit for Part B reimbursements, similar to the inflation-indexed rebate under Medicaid, could provide significant savings to the program. Currently, under Part B, Medicare reimburses for drugs administered in physician offices and hospital outpatient departments at a rate of the Average Sales Price (ASP)¹ plus six percent. As the ASP of a drug increases, so too does the amount that Medicare reimburses, no matter how drastic the increase. After meeting a deductible, patients pay a 20% coinsurance of this price.

An inflation limit for Medicare Part B reimbursements, under the Administration’s proposal, would establish that Medicare pay the lower of the actual ASP+6% amount or an ASP+6% amount limited by

¹ Average Sales Price (ASP) is a manufacturer’s sales of a drug (with certain exceptions) to all purchasers in the United States in a quarter divided by the number of units of the drug sold by the manufacturer in that same quarter, net of certain price concessions and discounts. The statutory definition is available in Section 1847A(c) of the Social Security Act.

inflation. Such a measure would lower Medicare payments for Medicare Part B drugs with ASPs that rise faster than inflation, and lower what patients pay through coinsurance.

The Department of Health and Human Services (HHS) Office of Inspector General (OIG) issued a [report](#) late last year finding that if an inflation-indexed rebate were in place for Medicare Part B in 2015, it would have saved \$1.4 billion or \$1.8 billion on 64 high-expenditure drugs that represented 81 percent of total Part B drug expenditures that year, depending on whether the rebate was calculated based on ASP or Average Manufacturer Price (AMP), respectively. The rebates would have represented 7% and 9%, respectively, of program spending on these 64 drugs. To provide context, Medicare Part B and its beneficiaries spent a total of \$20.8 billion dollars on these drugs and \$25.8 billion on prescription drugs overall in 2015.

“Reduce Wholesale Acquisition Cost (WAC)²-based payments” and “Improve manufacturers’ reporting of average sales prices to set accurate payment rates”

Under Medicare Part B, drugs for which there is no ASP information available, either due to the drug newly entering the market or because of lack of reporting of ASP information, are reimbursed at WAC+6%. WAC is generally higher than ASP, because it does not include price concessions and discounts. Additionally, HHS OIG found that a number of Part B drug manufacturers were not required to report ASP data and that some that are required to submit ASP data fail to do so, and that such omissions can result in Part B calculating reimbursement based on WAC instead of ASP, which is more costly.

Last summer, the Medicare Payment Advisory Commission (MedPAC) [proposed](#) to reduce the WAC+6% payment calculation in Medicare Part B to WAC+3%, require that all manufacturers of Part B drugs report ASP data, and to increase penalties for companies that fail to report ASP. Reducing the WAC add-on percentage would help ensure that the program does not over-reimburse for prescription drugs that lack ASP information, while requiring ASP reporting and increasing penalties for those that don’t report would help ensure that Part B is calculating reimbursement based on prices available rather than list price. The Trump Administration seems to be reflecting these recommendations in its proposal. Both of these changes would be positive, albeit modest reforms to the program.

The Obama Administration proposed a demonstration reducing the ASP add-on percentage to help counter the perverse incentive to physicians under the current ASP+6% system to furnish more expensive medicines when equally effective, lower-price alternatives are available and prevent Part B drug price inflation. For example, under the ASP+6% system, a physician may be more inclined to administer a \$10,000 drug rather than a \$1,000 drug because the add-on percentage would be \$600 rather than \$60. Additionally, the time it takes for reported ASP information to be incorporated into Part B reimbursement calculations means that reimbursements are effectively based on reimbursement from six months earlier. Lowering the ASP add-on percentage could [help prevent inflation](#) by reducing the room that drug companies have to raise prices without putting physicians’ offices underwater because the reimbursement add-on percentage is insufficient to cover the price increase and physician overhead

² [Wholesale Acquisition Cost \(WAC\)](#) is the list price paid by a wholesaler, distributor and other direct accounts for drugs purchased from the wholesaler’s supplier. Generally, it is the price established by the manufacturer before any rebates, discounts, allowances, or other price concessions are offered. The statutory definition is available in Section 1847A(c) of the Social Security Act.

and profits. It is disappointing that the Trump Administration failed to include this commonsense reform in its proposal.

“Clarify definitions under the Medicaid Drug Rebate Program to prevent inappropriately low manufacturer rebates”

Under Medicaid’s basic rebate, brand name drug manufacturers are required to provide a rebate of at least 23.1% of AMP and generic drug manufacturers are required to provide a rebate of at least 13% of AMP. The HHS Office of Inspector General issued a [report](#) in December estimating a potential loss of \$1.3 billion for Medicaid from 2012-2016 from reduced reimbursements of 10 drugs with highest total reimbursement in 2016 that were potentially misclassified. These 10 drugs accounted for 68% of Medicaid reimbursement for potentially misclassified drugs in 2016. OIG’s calculation under that report included rebates that would have been lost under both the basic and the inflation-adjusted rebate due to potential misclassification. To provide context, in the five years analyzed, 2012-2016, Medicaid [spent](#) \$109.9 billion on prescription drugs, including rebates; \$1.3 billion is just 1.2% of net spending of Medicaid on prescription drugs over this period. The Administration estimates that its proposal would produce \$319 million in savings over ten years, an extremely small amount relative to 10-year Medicaid prescription drug spending.

The OIG report recommendations differed from those of the Administration, however, calling for CMS to “follow up with manufacturers associated with potentially-misclassified drugs [...] to determine whether current classifications are correct”, “improve its Drug Data Reporting for Medicaid System to minimize inconsistent data submissions and track potential misclassification errors for follow-up”, and “pursue a means to compel manufacturers to correct inaccurate classification data reported to the Medicaid rebate program” – CMS does not currently have the authority to compel manufacturers to correct inaccurate classification data. The Administration could improve its proposal by recommending legislation to provide CMS with this authority.

The Bad

Beyond the Trump Administration budget’s [assaults on access to health care](#) more broadly, which in turn impact patients’ access to medicines, the worst part of the President’s budget measures relating to prescription drug pricing are in its omissions.

Trump’s budget proposals fail to leverage government negotiating power to get lower prices for seniors

While he was on the campaign trail, then-candidate Trump [backed](#) allowing the government to negotiate Medicare Part D drug prices directly with pharmaceutical companies. He [reiterated support](#) for the policy at his first news conference as President-elect. While this policy change would not save the \$300 billion per year that the President estimated (which is more than the \$99.5 billion spent under Medicare Part D on prescription drugs in 2016), it would produce substantial savings.

The President was correct that we are not properly [leveraging the negotiating power](#) inherent in Medicare Part D; [Part D expenditures](#) on prescription drugs represented an estimated 9% of [global](#) prescription drug spending in 2016. If through government negotiations, the government realized the same prices on brand name drugs as Medicaid or the Veterans Health Administration, it would save

\$15.2 to \$16 billion per year, respectively. However, even those U.S. government programs that achieve lower prices than Medicare Part D still pay more than many other OECD countries.

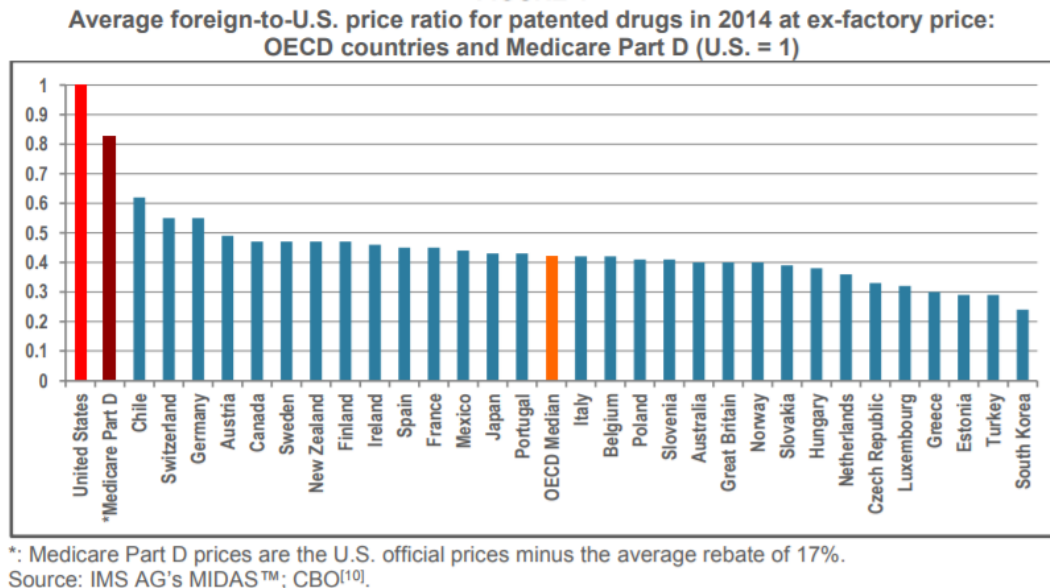


Figure retrieved from: Gagnon MA, Wolfe S. *Mirror, mirror on the wall: Medicare Part D pays needlessly high brand-name drug prices compared with other OECD countries and with U.S. government programs.* Available at <https://www.citizen.org/sites/default/files/2269a.pdf>

Trump's budget proposals fail to put an end to price spikes

While the Trump Administration proposed to put in place an inflation-indexed rebate for Medicare Part B, it fails to propose any solution that would provide consumers across our health care system relief from sharp year-over-year [price spikes just below 10%](#) that have become commonplace for prescription drug corporations across the industry.

The Trump budget should have embraced Sen. Brown and Gillibrand's [Stop Price Gouging Act](#) (S. 1369), which penalizes drug manufacturers when they raise the price of a medicine beyond the level of medical inflation over a one-to-five year period, with penalties proportionate to the level of price increase. Experts from Harvard University [estimate](#) that enacting this legislation could result in initial tax receipts through penalties of up to tens of billions of dollars annually, with "[t]he burden of [the] price spike tax [...] borne by those companies that rely disproportionately on price increases, rather than innovation, to drive returns." Further, the experts believe this measure could slow price increases and compress gross-to-net spreads to the benefit of patients.

Trump's budget proposals fail to curb the monopoly abuses of prescription drug corporations

The root problem of high U.S. drug prices is the monopoly power of the pharmaceutical industry. Government-granted monopolies provide incentive for prescription drug corporations to engage in a range of abusive behaviors, ranging from [fraudulent reimbursement schemes](#) to efforts to inappropriately extend monopolies through [patent evergreening](#), [Risk Evaluation and Mitigation Strategy \(REMS\) abuse](#) and [pay-for-delay deals](#). Yet absent from the Trump Administration's proposals are any measures to address these monopoly abuses. Here are measures that the Trump Administration should have included to address these abuses:

Evergreening

Extending monopoly periods through patent evergreening is accomplished by making minor changes to old medicines in order to obtain a longer term of patent protection. This is possible through granting of [low-quality, secondary patents](#) that is permitted under weak, overly broad U.S. patent rules. More stringent patentability standards should be put in place to reward true innovation instead of rent seeking.

REMS Abuse

The CREATES Act (S. 974, H.R. 2212) would help ensure that brand-name companies aren't able to use REMS systems to prevent generic manufacturers from bringing competing products to market. *CREATES* would allow a generic drug manufacturer that is being prevented by a brand company from obtaining samples of a branded product necessary to conduct testing necessary for FDA approval to bring an action in federal court for injunctive relief (i.e. to gain access to the sample) and for a judge to award damages to deter future delaying conduct. Additionally, it would allow the FDA more discretion to approve safety protocols rather than require parties to develop shared safety protocols in order to address another delaying tactic engaged in by brand name companies.

Pay-for-delay

The *Preserve Access to Affordable Generics Act* (S. 124) and the *Competitive DRUGS Act* (H.R. 4117) would help give the Federal Trade Commission (FTC) the tools it needs to prevent brand-name and generic drug companies from entering into anticompetitive deals to delay competition. These bills would authorize the FTC to initiate proceedings against parties to any agreement resolving or settling a patent infringement claim in connection with the sale of a drug. Such an agreement, with exceptions, would be presumed to have anticompetitive effects and be a violation if the filer of the generic application receives anything of value and agrees to forego research, development, manufacturing, marketing, or sales of the generic drug.

Existing Authorities to Remedy Monopoly Abuses

Moreover, the Trump Administration has thus far failed to make use of or indicate any intention to use its existing authorities to remedy drug company abuses of their government-granted monopolies. 35 U.S.C. § 203 provides federal agencies with the authority to 'march-in' on U.S. government-funded inventions to allow for generic competition when a patent holder fails to make a product available on reasonable terms. When U.S. taxpayers are paying more than other wealthy countries for an invention developed through taxpayer dollars, it is inherently unreasonable. When that is the case, the National Institutes of Health (NIH), the Department of Defense (DOD) and other agencies should exercise their march-in authority.

In cases of drug industry price gouging of government health programs, the government should exercise its authority under 28 U.S.C. § 1498, also known as 'government use'. Section 1498 permits the government to use a patented invention without permission of the patent holder, so long as it provides reasonable compensation. The Trump Administration could exercise this authority to ensure that medicine prices do not act as barriers to the national response to the opioid addiction epidemic or to pursuing a robust hepatitis C eradication strategy.

A [recent article](#) in the Yale Journal of Law and Technology showed that the government routinely relies on exercising its authority under § 1498 to procure a wide array of patented inventions from non-patent holders, ranging from electronic passports to genetically mutated mice and fraud detection software to waste removal methods. In the 1960s, the DOD used § 1498 on numerous occasions to procure generic drugs at steep discounts. While the authority has not been exercised to procure medicines in recent years, in 2001, then Secretary of HHS Tommy Thompson raised the prospect of using § 1498 to procure generic ciprofloxacin; in response, Bayer cut its price of the brand-name drug in half.

The Ugly

The Administration is right that there are significant disparities between U.S. drug prices and those in other wealthy countries, but draws a faulty conclusion. Foreign drug prices are lower than those in the U.S. because their health care systems have rules in place to better limit prices charged by prescription drug corporations. Better deals achieved by other countries are not “at the expense of the American people”, as the Administration states, but because we do far too little in the U.S. to restrain the high prices set by industry under monopoly conditions.

Unfortunately this is not the first time the Administration has put forth this [flawed narrative](#), and it’s unlikely to be the last. But claims that high prices in the U.S. are rooted in high research and development (R&D) costs that the rest of the world does not sufficiently support do not stand up to scrutiny. The U.S. Department of Health & Human Services [found](#) that pharmaceutical corporations set prices not because of R&D spending, but to maximize profits.

Similarly, the [bipartisan investigation](#) into Gilead’s pricing of the hepatitis C treatment sofosbuvir (brand name Sovaldi) found that “[a] key consideration in Gilead’s decision-making process to determine the ultimate price of Sovaldi was setting the price such that it would not only maximize revenue, but also prepare the market for Harvoni and its even higher price.”

Prescription drug corporations [receive 176 percent of their global research and development costs](#) from the pricing premium that Americans pay for prescription drugs beyond prices in other wealthy countries alone. Pharma firms regularly [spend more on sales and marketing](#) than they do on research and development. And even by their own measures, [pharma’s corporate profits exceed what they spend on R&D](#) – in 2015, the 20 largest pharmaceutical corporations recorded profits (not revenues) of 134 percent what they spent on R&D.

Even predating the Trump Administration, the United States government has a history of pressuring other countries to lengthen and strengthen drug patents and restrict government reimbursement systems’ abilities to combat high prices. It is wrongheaded to claim that other countries are at fault for the U.S. drug pricing problem, and simply cruel to the extent that the Administration translates this claim into pressures on other countries to alter their policies so they pay more and face U.S.-style medicines affordability problems. Doubling down on such policies will not do anything to provide people living in the United States relief from high drug prices.

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