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July 16, 2018

**Comments RE: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs  
(Docket No. CMS-2018-0075)**

Public Citizen is a consumer advocacy organization with more than 400,000 members and supporters nationwide. We advocate in an array of issue areas to advance the public interest, including ensuring prescription drugs meet high safety and efficacy standards and are made more affordable both in the U.S. and abroad.

We submit the following comments in response to the Department of Health and Human Services' (HHS) request for information relating to the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs<sup>1</sup>.

In December 2016, then President-elect Trump said<sup>2</sup> he was “going to bring down drug prices.” He reiterated that message in his State of the Union speech in January 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.”

The drug pricing measures proposed by the administration in the Blueprint are far short of living up to President Trump’s promises.

The Blueprint 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 blueprint suggests measures that instead of lowering drug prices at home, would impose hardship abroad.

These comments will highlight some of the modest, positive drug pricing proposals; harmful measures and omissions; and the misguided pursuit of policies that would make medicines more

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<sup>1</sup> Henceforth referred to as “the Blueprint”.

<sup>2</sup> <https://www.vox.com/policy-and-politics/2018/1/30/16896434/trump-drug-prices-year-one>

unaffordable in other countries while doing nothing to lower prescription drug prices in the United States.

However, prior to delving into the substance of our comments, we must note that we are deeply troubled by what seems to be highly inappropriate influence of the prescription drug industry on shaping the administration's drug pricing policies.

### **Concerns over Industry Influence on Administration Drug Pricing Policy**

On March 22, Public Citizen sent a complaint<sup>3</sup> to the ethics officer of the Office of Management and Budget (OMB) expressing concern that the appointment of Joseph Grogan, former lobbyist for Gilead Sciences, Inc., to oversee OMB's health programs posed a conflict of interest and potential violation of ethics rules. President Donald Trump's own ethics executive order prohibits former lobbyists from overseeing the "same specific issue areas" they had lobbied in the previous two years. Public Citizen received no response from OMB's ethics officer.

On July 12, Public Citizen filed a second conflict of interest complaint<sup>4</sup> against Joseph Grogan, who is currently in the midst of a new scandal in which he collaborated in his official capacity with a drug company to develop a cancer treatment therapy, the same therapy his former employer, Gilead Sciences, Inc., was pursuing when Grogan was their lobbyist and continues to pursue today. Meanwhile, Grogan failed to inform OMB of the potential conflicts of interest until the collaboration came to a close.

Public Citizen has requested that the OMB ethics officer examine whether Joseph Grogan is in violation of paragraph 7 of President Trump's own ethics executive order prohibiting a former lobbyist from overseeing "any particular matter on which [the lobbyist] lobbied within 2 years before the date of appointment" as well as paragraph 6 of the executive order which prohibits officials from participating in "any particular matter involving specific parties that is directly and substantially related to [the official's] former employer."

Public Citizen is also deeply concerned by the revelations of ties between Michael Cohen and the Swiss prescription drug corporation Novartis. On May 10, Public Citizen submitted a Foreign Agents Registration Act (FARA) complaint<sup>5</sup> to the FARA Unit of the Department of Justice, as well as the Secretary of the U.S. Senate and Clerk of the U.S. House of Representatives. The request was for an investigation into whether Cohen violated FARA or the Lobbying Disclosure Act by accepting compensation from corporate clients, including Novartis, in exchange for "access" to officials in the Trump administration.

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<sup>3</sup> [https://www.citizen.org/sites/default/files/30\\_ethics\\_complaints\\_.pdf](https://www.citizen.org/sites/default/files/30_ethics_complaints_.pdf)

<sup>4</sup> [https://www.citizen.org/sites/default/files/second\\_complaint\\_to\\_james\\_carroll\\_.pdf](https://www.citizen.org/sites/default/files/second_complaint_to_james_carroll_.pdf)

<sup>5</sup> [https://www.citizen.org/sites/default/files/may\\_2018\\_cohen\\_complaint\\_final.pdf](https://www.citizen.org/sites/default/files/may_2018_cohen_complaint_final.pdf)

On July 13, Sens. Wyden, Murray, Warren and Blumenthal released a report titled, “White House Access for Sale: Michael Cohen, Novartis and the bid to sell access to the Trump administration.”<sup>6</sup> The report revealed even more extensive contacts between former Novartis CEO Joe Jimenez and Michael Cohen, including “[i]n June 2017, three months after Novartis represented it had ceased to engage Mr. Cohen, Mr. Jimenez sent Mr. Cohen a document containing ‘ideas to lower drug costs.’”<sup>7</sup> The report adds that “[s]everal of the suggestions in the ‘Drug Pricing Initiatives’ document provided by Mr. Jimenez to Mr. Cohen are similar to the policies included in the administration’s ‘Blueprint.’” The details outlined in the report are yet another indicator of undue pharmaceutical industry influence over the Trump administration’s policies relating to prescription drug prices.

### **Modest, Positive Proposals**

#### **“Requiring Medicare Part D plans to apply a substantial portion of rebates at the point of sale”**

Cost-related nonadherence (CRNA) that is driven by high out-of-pocket costs results in needless suffering of patients and drives up overall health care spending.<sup>8</sup> To help reduce CRNA among Medicare Part D beneficiaries, the administration has proposed to pass along some negotiated rebates to patients at the point of sale. This would help reduce CRNA and expand access to medicines, but would not do anything to lower drug prices and would result in increased spending for Medicare Part D.

A recent analysis<sup>9</sup> found that the United States ranked the worst among 11 developed countries regarding CRNA among older adults. 16.8% of Americans age 55 and older reported not filling a prescription or skipping doses within the last 12 months because of out-of-pocket costs. While the rate was lower for Americans aged 65 and older, with 12% CRNA, this was still more than twice the next highest rate in any other country for this age group (ranging from 1.5% in France to 5.3% in Canada). Lowering out-of-pocket costs is an important component to expanding access to medicines in the United States.

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<https://www.finance.senate.gov/imo/media/doc/REPORT%20White%20House%20Access%20for%20Sale%20Michael%20Cohen%20and%20Novartis.pdf>

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<https://www.finance.senate.gov/imo/media/doc/REPORT%20White%20House%20Access%20for%20Sale%20Michael%20Cohen%20and%20Novartis.pdf>

<sup>8</sup> <https://jamanetwork.com/journals/jama/article-abstract/2545691>

<sup>9</sup> <http://bmjopen.bmj.com/content/7/1/e014287>

Currently out-of-pocket costs paid by Medicare Part D beneficiaries at the pharmacy counter are based on list prices and do not reflect negotiated rebates conducted by insurers and pharmacy benefit managers (PBMs). Rebates are purportedly passed along to beneficiaries through lower premiums, but this raises two problems: 1) high CRNA for patients that are taking expensive medicines and paying an out-of-pocket cost based on list price and 2) insurance plans failing to fully pass along the benefits of rebates to beneficiaries.

On the latter point, a 2011 report<sup>10</sup> from the Department of Health and Human Services (HHS) Office of Inspector General (OIG) found that plan sponsors underestimated rebates in their bids to the Centers for Medicare and Medicaid Services (CMS), resulting in higher premiums paid by the government and beneficiaries. The government recoups some of the overpayments, but beneficiaries do not. The most recent Medicare Trustees Report<sup>11</sup> found that actual rebates for 2015 “were significantly higher than the plans estimated in their corresponding bid submissions.”

Moreover, to the extent that benefits from rebates primarily accrue to Part D plan sponsors, plans may have a perverse incentive to pursue high-price, high-rebate drugs rather than lower cost alternatives. Ensuring that rebates are passed along to beneficiaries at the point of sale could help dampen this incentive, and may lead to use of more lower-cost prescription drugs for the program.

However, not all of the benefit of rebates is captured by the plan under the current system – some does indeed serve to help lower premiums. Therefore such a policy change would result in higher premiums for Medicare Part D beneficiaries. Further, because of resulting lower levels of CRNA due to lower out-of-pocket costs, utilization of prescription drugs in the program would increase. By the administration’s own estimates<sup>12</sup>, providing point-of-sale rebates in Medicare Part D would reduce overall beneficiary costs by \$10.4 billion through lower cost-sharing partially offset by increased premiums, but increase costs to the government by \$16.6 billion over a period of ten years. So, despite improving access to medicines, there would be more spending on prescription drugs under Medicare Part D if this proposal were to be implemented. That is why such a policy should be advanced alongside measures to lower prescription drug prices charged by pharmaceutical companies, and not in lieu of them.

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

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<sup>10</sup> <https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf>

<sup>11</sup> <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2017.pdf>

<sup>12</sup> <https://www.federalregister.gov/documents/2017/11/28/2017-25068/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare>

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)<sup>13</sup> 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. The proposal to establish an inflation limit for Part B reimbursements could provide significant savings to the program.

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 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.

However, a more direct and more closely analyzed approach to pursue an inflation limit would be to establish an inflation-based rebate for Part B<sup>14</sup>, similar to the inflation-based rebate that is in place for Medicaid. HHS OIG found<sup>15</sup> that more than half the rebates owed by manufacturers to Medicaid for brand name drugs included in its study were attributable to inflation-based rebates.

Implementing an inflation-based rebate would directly limit manufacturer pricing of drugs purchased under Medicare Part B, rather than relying on manufacturers to respond to lower reimbursement rates for physicians administering Part B drugs.

HHS OIG issued a report<sup>16</sup> late last year finding that if an inflation-based 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.

### **“Reducing Wholesale Acquisition Cost (WAC)<sup>17</sup>-based payments” and “Improving manufacturers’ reporting of average sales prices to set accurate payment rates”**

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<sup>13</sup> 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.

<sup>14</sup> <https://www.congress.gov/bill/115th-congress/house-bill/5150>

<sup>15</sup> <https://oig.hhs.gov/oei/reports/oei-03-13-00650.pdf>

<sup>16</sup> <https://oig.hhs.gov/oei/reports/oei-12-17-00180.pdf>

<sup>17</sup> [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

Under Medicare Part B, the government and consumers could be paying less for prescription drugs simply by having reimbursements more closely reflect what physicians pay for drugs that they administer. The White House proposes to better align reimbursement with physician spending on drugs by reducing the WAC-based add-on percentage and by improving ASP reporting, so fewer reimbursements are based on the more-costly WAC. But these measures are much weaker than prior Part B drug pricing reform proposals.

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, resulting in higher costs for the government and beneficiaries.

Last summer, the Medicare Payment Advisory Commission (MedPAC) proposed<sup>18</sup> 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<sup>19</sup> 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 and profits.

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any rebates, discounts, allowances, or other price concessions are offered. The statutory definition is available in Section 1847A(c) of the Social Security Act.

<sup>18</sup> [http://medpac.gov/docs/default-source/reports/jun17\\_ch2.pdf?sfvrsn=0](http://medpac.gov/docs/default-source/reports/jun17_ch2.pdf?sfvrsn=0)

<sup>19</sup> [https://drugpricinglab.org/wp-content/uploads/2017/05/Part-B-Phase-1-Report\\_Phys-and-Hosp.pdf](https://drugpricinglab.org/wp-content/uploads/2017/05/Part-B-Phase-1-Report_Phys-and-Hosp.pdf)

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

**“Increasing the integrity of the Medicaid Drug Rebate Program, so that manufacturers pay their fair share in rebates by [...] remov[ing] ambiguity regarding how drugs should be reported under the program”**

Drug manufacturers misclassifying drugs as generics rather than brand-name under the Medicaid Drug Rebate Program can result in lower rebates from manufacturers to Medicaid. The White House proposes to remedy this problem through clarifying definitions of what drugs qualify for rebates of different levels. This could have a positive, albeit extremely limited impact on Medicaid spending on prescription drugs.

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. HHS OIG issued a report<sup>20</sup> 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<sup>21</sup> \$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.

### **Counterproductive Measures and Omissions**

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<sup>20</sup> <https://oig.hhs.gov/oei/reports/oei-03-17-00100.pdf>

<sup>21</sup> <https://www.medicaid.gov/medicaid/financing-and-reimbursement/state-expenditure-reporting/expenditure-reports/index.html>

The worst part of the White House Blueprint are in its omissions. Before exploring some of those omissions, this paper will highlight one negative proposal included in the administration's budget and expected to continue to be pursued by the administration.

**“Proposing in the President’s FY2019 Budget to call for new Medicaid demonstration authority for up to five states to test drug coverage and financing reforms that build on private sector best practices. Participating states would determine their own drug formularies, coupled with an appeals process to protect beneficiaries access to non-covered drugs based on medical need, and negotiate drug prices directly with manufacturers.”**

The White House budget proposes<sup>22</sup> to allow up to five states not to participate in the Medicaid Drug Rebate Program, and instead to negotiate prices with manufacturers and make use of a closed formulary. One of its stated aims in conducting such a demonstration is to allow for the exploration of outcomes-based purchasing arrangements. But this proposal is unlikely to produce substantial savings – indeed, it could increase Medicaid prescription drug spending – and threatens access to medicines for people that rely on Medicaid.

Through statutory rebates and negotiations, Medicaid achieves far better prices than Medicare Part D. HHS OIG found<sup>23</sup> that in 2012, rebates accounted for 47% of Medicaid expenditures, but only 15% of Part D expenditures. A Public Citizen study<sup>24</sup> found that on average a brand-name drug costs for Medicaid 55% of what the same drug costs for Medicare Part D.

Currently through the Medicaid Drug Rebate Program, manufacturers must provide a basic rebate of at least 23.1% off of AMP or greater to meet the best price offered in the private sector. Additionally, Medicaid receives an inflation-based rebate if the price of a drug rises faster than general inflation. In addition to these mandatory rebates, Medicaid programs may negotiate additional rebates with use of a formulary that prefers one treatment over another and through use of prior authorization requirements.

The Center for Budget and Policy Priorities notes<sup>25</sup> that while it is unlikely that negotiations conducted through the Trump administration's proposed demonstration project would achieve substantially more in savings than what programs currently receive (and perhaps significantly less), it could prevent some Medicaid beneficiaries from getting the medications they need. Prof. Edwin Park at Georgetown University argued the same<sup>26</sup>, and that if the proposed demonstration

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<sup>22</sup> <https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf>

<sup>23</sup> <https://oig.hhs.gov/oei/reports/oei-03-13-00650.pdf>

<sup>24</sup> <https://www.citizen.org/sites/default/files/2269a.pdf>

<sup>25</sup> <https://www.cbpp.org/research/health/health-proposals-in-presidents-budget-would-reduce-health-insurance-coverage-and>

<sup>26</sup> <https://ccf.georgetown.edu/2018/04/02/trump-administration-medicare-drug-rebate-proposal-raises-serious-concerns-for-beneficiaries-unlikely-to-reduce-costs/>

were to result in any substantial savings, it would be a result of states restricting access to needed medicines.

Further, the so-called outcomes-based purchasing arrangements that the administration states that it seeks to advance would be highly unlikely to generate much, if any, savings. Prior analysis from Public Citizen<sup>27</sup> found that international examples of outcomes-based purchasing arrangements have shown minimal savings to health programs; such arrangements are difficult to establish and create significant administrative burdens, including considerable costs of additional costs of hospital consultants' and pharmacists' time. Experts at Memorial Sloan Kettering highlight<sup>28</sup> there are a number of ways outcomes-based contracts could be gamed, such as setting a price far too high in the first place, choosing an inappropriate outcome upon which to base payments.

As the drug industry advocates for outcomes-based arrangements, it argues to poke holes in rules<sup>29</sup> that prohibit communications about uses of drugs that have not been approved by the FDA and anti-kickback laws, as well as exemptions to the Medicaid 'best-price rule' – all long-time targets of prescription drug corporations.

### **Trump's Blueprint proposals fail to leverage government negotiating power to get lower prices for seniors**

While he was on the campaign trail, then-candidate Trump backed<sup>30</sup> allowing the government to negotiate Medicare Part D drug prices directly with pharmaceutical companies. He reiterated support<sup>31</sup> 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<sup>32</sup> inherent in Medicare Part D; Part D spent \$99.5 billion<sup>33</sup> on prescription drug benefits in 2016, compared to an estimated \$1.1 trillion in global<sup>34</sup> prescription drug spending in 2016. If through government negotiations, the government realized the same prices on brand name drugs as Medicaid or the

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<sup>27</sup> [https://www.citizen.org/sites/default/files/trump-pharma-outcomes-based-arrangements\\_0.pdf](https://www.citizen.org/sites/default/files/trump-pharma-outcomes-based-arrangements_0.pdf)

<sup>28</sup> <https://www.statnews.com/2017/08/31/475000-price-tag-new-cancer-drug-crazy-meh/>

<sup>29</sup> [https://www.citizen.org/sites/default/files/trump-pharma-outcomes-based-arrangements\\_0.pdf](https://www.citizen.org/sites/default/files/trump-pharma-outcomes-based-arrangements_0.pdf)

<sup>30</sup> <https://www.politico.com/story/2016/01/trump-backs-medicare-negotiating-drug-prices-218215>

<sup>31</sup> [https://www.washingtonpost.com/news/wonk/wp/2017/01/11/trump-on-drug-prices-pharma-companies-are-getting-away-with-murder/?utm\\_term=.666e8c7c52da](https://www.washingtonpost.com/news/wonk/wp/2017/01/11/trump-on-drug-prices-pharma-companies-are-getting-away-with-murder/?utm_term=.666e8c7c52da)

<sup>32</sup> <https://www.citizen.org/sites/default/files/2269a.pdf>

<sup>33</sup> <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/downloads/tr2017.pdf>

<sup>34</sup> <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/global-outlook-for-medicines-through-2021.pdf>

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.

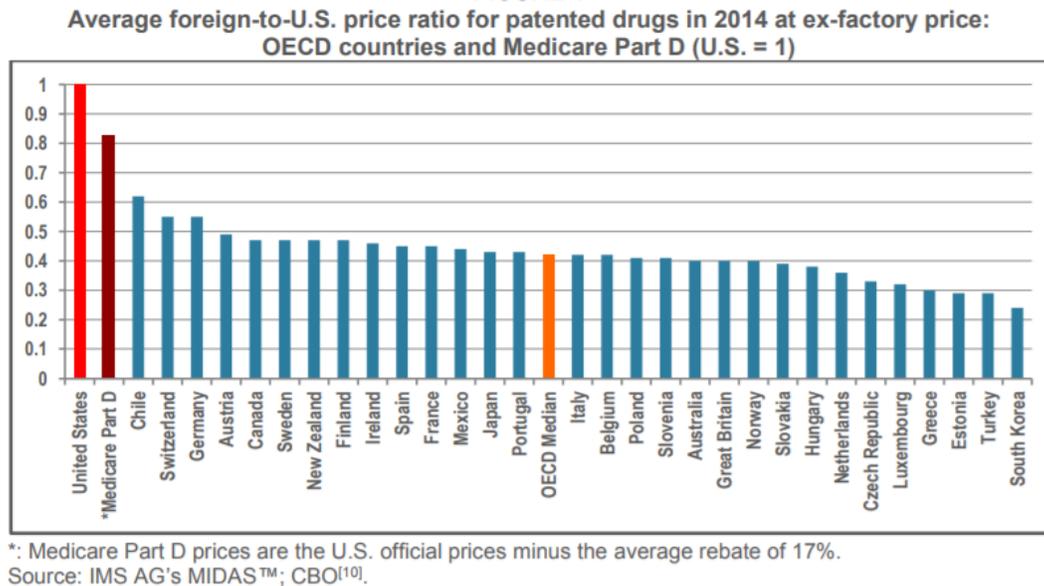


Figure retrieved from: Gagnon MA, Wolfe S. *Mirror, mirror on the wall: Medicare Part D pays needlessly high brand-name drug prices compared with other OECD countries and with U.S. government programs.* Available at <https://www.citizen.org/sites/default/files/2269a.pdf>

### Trump's Blueprint proposals fail to put an end to price spikes

While the Trump administration proposed to put in place an inflation limit for Medicare Part B prescription drug reimbursements, it has failed to propose any solution that would provide consumers across our health care system relief from sharp year-over-year price spikes just below 10%<sup>35</sup> that have become commonplace for prescription drug corporations across the industry.

The Blueprint should have embraced Sens. Brown and Gillibrand's and Rep. Pocan's *Stop Price Gouging Act* (S. 1369, H.R. 2974)<sup>36</sup>, 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<sup>37</sup> 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

<sup>35</sup> <https://www.fiercepharma.com/pharma/drug-price-hikes-a-few-bad-actors-or-widespread-pharma>

<sup>36</sup> <https://www.govtrack.us/congress/bills/115/s1369>

<sup>37</sup> <https://www.healthaffairs.org/doi/10.1377/hblog20170512.060041/full/>

returns.” Further, the experts believe this measure could slow price increases and compress gross-to-net spreads to the benefit of patients.

### **Trump’s Blueprint 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, from fraudulent reimbursement schemes<sup>38</sup> to efforts to inappropriately extend monopolies through patent evergreening<sup>39</sup> and Risk Evaluation and Mitigation Strategy (REMS) abuse<sup>40</sup>. 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<sup>41</sup> 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

While Public Citizen appreciates the attention the administration has given to the issue of REMS abuse, including through publishing a list of drugs, the samples of which generic manufacturers have not been able to obtain, further action is required. The *CREATES Act* (S. 974, H.R. 2212)<sup>42</sup> 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.

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<sup>38</sup> <https://www.citizen.org/our-work/health-and-safety/pharmaceutical-industry-penalties>

<sup>39</sup> [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3061567](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3061567)

<sup>40</sup> <http://www.neim.org/doi/pdf/10.1056/NEJMp1400488>

<sup>41</sup> <http://www.i-mak.org/wp-content/uploads/2017/09/I-MAKFINALFDASubmission17Sep2017.pdf>

<sup>42</sup> <https://www.congress.gov/bill/115th-congress/senate-bill/974/text>

### 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<sup>43</sup> 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.

On May 3, Public Citizen and the Baltimore City Health Department requested<sup>44</sup> that the Trump administration exercise this authority to end rationing of the opioid overdose reversal drug naloxone and ensure easy-to-administer formulations of the drug are affordable for cities and communities around the country. We again urge you to move forward with granting this request.

### **Pointing Fingers Instead of Solving Problems**

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

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<sup>43</sup> <https://kaiserhealthnews.files.wordpress.com/2017/04/yale-journal-of-law-technology-2016-brennan.pdf>

<sup>44</sup> <https://www.citizen.org/sites/default/files/naloxone-product-government-use-request.pdf>

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 the not the first time the administration has put forth this flawed narrative<sup>45</sup>, 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<sup>46</sup>. The U.S. Department of Health & Human Services found<sup>47</sup> that pharmaceutical corporations set prices not because of R&D spending, but to maximize profits.

Similarly, the bipartisan investigation<sup>48</sup> 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<sup>49</sup> 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<sup>50</sup> than they do on research and development. And even by their own measures, pharma’s corporate profits exceed what they spend on R&D<sup>51</sup> – 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.

Thank you for taking our comments into consideration.

For further information, contact:

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<sup>45</sup> [https://www.citizen.org/system/files/case\\_documents/trump-drug-pricing-eo-trade-and-monopolies-memo.pdf](https://www.citizen.org/system/files/case_documents/trump-drug-pricing-eo-trade-and-monopolies-memo.pdf)

<sup>46</sup> <https://www.bmj.com/content/360/bmj.k1088>

<sup>47</sup> <http://apps.who.int/medicinedocs/documents/s23128en/s23128en.pdf>

<sup>48</sup>

[https://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20\(Full%20Report\).pdf](https://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20(Full%20Report).pdf)

<sup>49</sup> <http://healthaffairs.org/blog/2017/03/07/rd-costs-for-pharmaceutical-companies-do-not-explain-elevated-us-drug-prices/>

<sup>50</sup> <https://www.vox.com/2015/2/11/8018691/big-pharma-research-advertising>

<sup>51</sup> <https://www.citizen.org/sites/default/files/pharma-profits-and-r-and-d-report.pdf>

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