United States Senate
WASHINGTON, DC 20510

June 11, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Azar:

Last month, you joined President Trump when he released his new drug pricing proposals. During the campaign, President Trump made a series of bold promises about reducing drug prices. He accused drug companies of "getting away with murder,"[1] promised that he could save "$300 billion a year" by negotiating for lower drug prices,[2] and said that "When it comes time to negotiate the cost of drugs, we are going to negotiate like crazy."[3]

But the drug pricing proposal released by the President last month broke those promises.[4] It did not include any meaningful new authority to negotiate for lower drug prices; it proposed a set of policies that reportedly were shepherded through the Administration by a former drug industry lobbyist; and it contained several proposals that could *increase* drug costs for many seniors.

Tomorrow, you will be testifying before the Health, Education, Labor, and Pensions (HELP) Committee. In advance of that hearing, we have carefully analyzed the President's proposals. We are gravely concerned that the American public has been misled by the President – that his plan breaks his campaign promises, and would do little to reduce out-of-pocket drug costs for American families.

The remainder of this letter describes our concerns about the content and development of the President's plan, containing new analysis and information on how it may increase drug costs for millions of American seniors. This letter also contains a series of questions about the plan and its impact. We ask that you come to the hearing tomorrow prepared to answer those questions.

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[1] *Washington Post*, "Trump on drug prices: Pharma Companies Are 'Getting Away With Murder,'" January 11, 2017, www.washingtonpost.com/news/wonk/wp/2017/01/11/trump-on-drug-prices-pharma-companies-are-getting-away-with-murder/.

[2] *Associated Press*, "Donald Trump Says Medicare Should Negotiate Drug Prices," January 26, 2016, www.statnews.com/2016/01/26/trump-negotiate-drug-prices/.

[3] *Wall Street Journal*, "Trump Vows to Take on 'Powerful Drug Companies, Drive Down Prices," February 4, 2016, blogs.wsj.com/washwire/2016/02/04/trump-vows-to-take-on-powerful-drug-companies-drive-down-prices/.

[4] U.S. Department of Health and Human Services, "American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," May 2018, (https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.)

We have four main concerns with the plan outlined in the blueprint:

- **The plan would "significantly increase out-of-pocket costs for some of the sickest people on Medicare."**[5] In particular, the proposed shift of drug coverage for seniors from Medicare Part B to Medicare Part D would (1) leave millions of seniors with no apparent source of insurance for these drugs; (2) increase co-pays and out-of-pocket costs for the drugs; and (3) provide seniors with no protection from runaway drug prices. These costs would be exacerbated by Administration proposals to impose new out-of-pocket costs on seniors in the Part D program.

- **President Trump's promises that voluntary price reductions are a solution to the drug pricing problem are proven failures.** Drug companies have pledged to hold down costs in the past, particularly at times of heightened scrutiny of their pricing practices, but these pledges have failed to restrain growth in drug prices. There is no indication that voluntary price reductions will prove a meaningful solution to the current problem of skyrocketing prices. Last month, we sent letters to the ten largest drug companies asking if they had made any price reductions in response to the President's speech.[6] Not one indicated that they had reduced prices in response or planned to do so – and one of the few companies that gave us a clear answer indicated that "we do have some planned price increases later this year."[7]

- **The plan does nothing to reduce runaway drug company profits and drug company CEO pay.** You indicated that you had little patience for criticism that the drug pricing plan would cut into pharmaceutical company profits – but analysts largely concluded that the plan would *not* impact profits. Indeed, current trends in drug company profits and CEO pay appear to remain untouched by the Administration's proposals.

- **The plan was reportedly developed by former drug industry lobbyists, with little input from patients and seniors with high drug costs.** You were a drug industry executive before joining the Administration. The individual "who has sweeping authority over drug pricing, entitlement programs and other aspects of federal health policy at the Office of Management and Budget" and who convened the first meetings of the administration's drug pricing working group was a former industry lobbyist, and several other key staff at HHS and elsewhere in the Administration were former drug industry lobbyists or executives — raising obvious questions about who influenced the plan and who it is designed to benefit.[8]

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[5] New York Times, Trump Plan to Lower Drug Prices Could Increase Costs for Some Patients, June 2, 2018, www.nytimes.com/2018/06/02/us/politics/medicare-drug-costs.html.)

[6] Letter from Senators Elizabeth Warren and Tina Smith to Pfizer, Novartis, Hoffman-LaRoche, Merck, Sanofi, Johnson & Johnson, Gilead, GlaxoSmithKline, Abbvie, and Amgen, May 30, 2018.

[7] Letter from Thomas N. Kendris, President, Novartis, to Sens. Warren and Smith, June 8, 2018.

[8] *Politico*, "Former Drug Industry Lobbyist Helps Steer Trump Drug Plan", May 27, 2018, https://www.politico.com/story/2018/05/27/trump-drug-plan-lobbyist-joe-grogan-609170.

The remainder of this letter describes our concerns in more detail and contains questions about the proposal.

Shifting Drugs from Medicare Part B to Medicare Part D Would Increase Prices for Millions of Medicare Enrollees

The President has broken one of his central campaign promises, that "When it comes time to negotiate the cost of drugs, we are going to negotiate like crazy."[9] His new drug plan contains no new negotiating authority for the federal government, even in cases where the government pays billions of dollars for prescription drugs. Instead, he has proposed a weak substitute, shifting an unspecified set of drugs from Medicare Part B –the portion of the Medicare program that pays for drugs dispensed at a doctor's office – to Medicare Part D, which is the part of the Medicare program that pays for outpatient drugs.[10]

Under Medicare Part B, the government reimburses providers using a fixed pricing formula for each drug. Under Part D, private plans offering the prescription drug benefit can negotiate with drug manufacturers for lower prices. You have indicated that, "the President has called on us to merge Medicare Part B into Part D, where negotiation has been so successful on so many drugs. This is how we follow through on his promise to do smart bidding and tough negotiating for our seniors."[11]

In 2005, when you were a high-ranking official at HHS, the Bush Administration rejected the idea of shifting drugs from Part B to Part D, saying that "such a change would not be desirable for most categories of Part B drugs" and raising concerns around the financial implications for many Medicare beneficiaries.[12] Little appears to have changed. We have identified at least five significant problems with this proposal, which could result in price increases for millions of Americans – particularly those that already have the highest drug costs. These problems are:

a. Millions of Americans Do Not Have Medicare Part D Drug Coverage

Nationwide, there are 59.2 million Americans enrolled in the Medicare Part B program – but only 43.9 million enrolled in the Part D program – meaning that there are over 15 million Americans at risk of having no coverage at all for drugs that are switched into Part D coverage. In Massachusetts, there are approximately 300,000 seniors and people with disabilities at risk of losing drug coverage under the President's plan; in Minnesota, there are almost 230,000 at risk.[13]

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[9] *Wall Street Journal*, "Trump Vows to Take on 'Powerful Drug Companies, Drive Down Prices," February 4, 2016, blogs.wsj.com/washwire/2016/02/04/trump-vows-to-take-on-powerful-drug-companies-drive-down-prices/.

[10] HHS Secretary Alex M. Azar II, Remarks on Drug Pricing Blueprint, May 14, 2018, (https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html)

[11] HHS Secretary Alex M. Azar II, Remarks on Drug Pricing Blueprint, May 14, 2018, (https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html)

[12] HHS, Report to Congress Transitioning Medicare Part B Covered Drugs to Part D, 2005, (https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/RtC_PtbtoPtD_2005_4.pdf.)

[13] In Massachusetts, as of January 2018, there were 1.29 million enrollees in traditional Medicare, and 991,000 with Medicare prescription drug coverage. In Minnesota, there were 980,000 enrollees in traditional Medicare, and

The President's blueprint acknowledges that "27% of beneficiaries [. . .] do not have Medicare prescription drug coverage," but the proposal contains no details on how the Administration plans to address this issue.[14]

b. Medicare Part D Co-pays Are Higher than Medicare Part B Co-pays

For many drugs, co-pays under Medicare Part D will be significantly higher than co-pays for those same drugs under Part B – driving costs up rather than down for seniors and people with disabilities. Under the Medicare law, seniors pay 20% of the cost of drugs in the Part B program. But under Part D, there are few limits on co-payment and coinsurance amounts. Drug plans have the ability to charge beneficiaries more – and they often do, especially for the most expensive drugs, such as cancer drugs.

According to a recent analysis by the Kaiser Family Foundation, Medicare beneficiaries are forced to pay as much as 40% of the total cost of drugs that insurance companies place on non-preferred formulary tiers – double the Part B coinsurance amount of 20%.[15] This same analysis found that more than four in ten Part D enrollees paid more than 33% coinsurance rates for the most expensive drugs.[16] These seniors would likely pay much more than the 20% Part B coinsurance rate if their drugs are instead switched to Part D.

c. Supplemental Coverage Reduces Part B Co-pays – But Is Not Available for Medicare Part D

Nearly 12 million Medicare beneficiaries currently enroll in Medigap supplemental plans, many of which are designed to eliminate or significantly reduce drug and other co-pays.[17] These plans serve to substantially reduce out-of-pocket costs for even the most expensive drugs – but they are not available to cover Part D drugs. If drugs are switched from Medicare Part B to Part D, seniors and people with disabilities who currently reduce drug co-pays through Medigap supplemental coverage may end up paying substantially higher costs.

d. Not All Drugs Are Covered Under Part D

753,000 with Medicare prescription drug coverage. CMS, Medicare Enrollment Dashboard, 2018, (https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/Medicare-Enrollment/Enrollment%20Dashboard.html.)

[14] U.S. Department of Health and Human Services, "American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," May 2018, p. 30, https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.

[15] Henry J. Kaiser Family Foundation, Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost-Sharing, May 17, 2018, https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/.

[16] Henry J. Kaiser Family Foundation, Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost-Sharing, May 17, 2018, https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing//

[17] AHIP, Trends in Medigap Enrollment and Coverage Options, 2015, https://www.ahip.org/wp-content/uploads/2017/05/Medigap_Report_5.1.17.pdf

Drug coverage under Part B is simple and quick. Once a drug is approved, it becomes available as a benefit. There are no restrictions or complicated formulas or "specialty tiers" that limit availability or increase co-pays. In contrast, Part D drugs are subject to numerous limitations. Plans can require special authorization, limit co-pays, or choose not to cover some drugs at all – meaning that "Medicare patients could face new limits or control on their use of prescription drugs – techniques widely used in commercial health plans."[18]

e. The Part D Program Has Failed to Rein In Runaway Drug Costs

You have described the plans that run Part D as able to "do smart bidding and tough negotiating for our seniors."[19] But the plans' actual record of reducing drug costs is atrocious. Last week, the HHS Office of Inspector General (OIG) released a new analysis of Part D drug costs between 2011 and 2015. It found that –despite a drop in the total number of Part D prescriptions filled over this period, reimbursement costs (including manufacturer rebates) for these drugs increased by a total of 62%. The OIG concluded that "Part D unit costs for brand-name drugs rose nearly 6 times faster than inflation from 2011 to 2015."[20] As a result of Part D plans' inability to rein in runaway price increases, drug costs increased rapidly for seniors. According to the OIG, "the percentage of beneficiaries responsible for out-of-pocket costs of at least $2,000 per year for brand-name drugs nearly doubled" during the period studied.[21]

The net result of these differences in benefits is that millions of seniors and people with disabilities are likely to pay higher prices for their drugs under President Trump's plan. An analysis by Avalere Health concluded that "in 2016, average out-of-pocket costs were about 33% higher for Part D-covered new cancer therapies … than for those covered in Part B." –an $800 difference.[22] The report concluded that "if new cancer therapies, or any high-cost drug therapies are switched from Part B to Part D, many Medicare patients would pay more out-of-pocket."[23]

Another change proposed by the Administration, to "exclude manufacturer discounts from the calculation of beneficiary out-of-pocket costs in the Medicare Part D coverage gap" – would make this even worse, forcing many seniors to spend more out-of-pocket prior to hitting the Medicare Part D catastrophic benefit.[24] Under current law, when seniors are in the Medicare

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[18] *New York Times*, "Trump Plan to Lower Drug Prices Could Increase Costs for Some Patients," June 2, 2018, www.nytimes.com/2018/06/02/us/politics/medicare-drug-costs.html.

[19] HHS Secretary Alex M. Azar II, Remarks on Drug Pricing Blueprint, May 14, 2018, https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html

[20] HHS Office of Inspector General, Data Brief: Increases in Reimbursements for Brand-Name Drugs in Part D,June 2018, https://oig.hhs.gov/oei/reports/oei-03-15-00080.asp.

[21] HHS Office of Inspector General, Data Brief: Increases in Reimbursements for Brand-Name Drugs in Part D,June 2018, https://oig.hhs.gov/oei/reports/oei-03-15-00080.asp.

[22] Avalere, "Avalere Analysis Highlights Complexities of Transitioning Medicare Part B Drugs into Part D," May 21, 2018, http://avalere.com/expertise/life-sciences/insights/avalere-analysis-highlights-complexities-of-transitioning-medicare-part-b-d.

[23] Avalere, "Avalere Analysis Highlights Complexities of Transitioning Medicare Part B Drugs into Part D," May 21, 2018, http://avalere.com/expertise/life-sciences/insights/avalere-analysis-highlights-complexities-of-transitioning-medicare-part-b-d.

[24] Budget of the U.S. Government for Fiscal year 2019, at 127, https://www.whitehouse.gov/wp-content/uploads/2018/02/budget-fy2019.pdf.

Part D donut hole, drug manufacturers provide discounts on their drugs. But the Administration has proposed modifications to the Part D true out of pocket cost, or "TROOP" calculation, that would force seniors to spend more out-of-pocket before they qualify for the Part D catastrophic benefit. This proposal in the Administration's budget could be partially mitigated by another administration proposal to cap overall Part D expenses for seniors, but could still cost seniors billions of dollars in higher out-of-pocket costs.

The blueprint released by the Administration on May 11 did not include sufficient detail to analyze how Medicare beneficiaries would be financially affected by these proposals. We therefore ask that you provide answers to the following questions.

1. What drugs is the Administration proposing to switch from Part B coverage to Part D coverage?

2. What evidence does the Administration have that this switch will result in lower prices for seniors?

3. To what extent do Medicare Part D plans effectively negotiate lower drug prices?
    a. For all brand-name drugs, what is the average percentage manufacturer rebate and discount obtained by Medicare Part D plans? For this same group of drugs, please list changes in the average net price and the percentage change in average net price increases over the past five years.
    b. For the 100 highest selling brand-name drugs by dollar sales, what is the average percentage manufacturer rebate and discount obtained by Medicare Part D plans? For this same group of drugs, please list changes in the average net price and the percentage change in average net price increases over the past five years.
    c. For all specialty drugs, what is the average percentage manufacturer rebate and discount obtained by Medicare Part D plans? For this same group of drugs, please list changes in the average net price and the percentage change in average net price increases over the past five years.
    d. For all cancer drugs, what is the average percentage manufacturer rebate and discount obtained by Medicare Part D plans? For this same group of drugs, please list changes in the average net price and the percentage change in average net price increases over the past five years.

4. If drugs are switched from Medicare Part B to Medicare Part D, how will the Administration address increased drug costs for the millions of beneficiaries who do not have Part D drug coverage?

5. If drugs are switched from Medicare Part B to Medicare Part D, how will the Administration address increased drug costs for the millions of beneficiaries who will no longer be able to use their Part B supplemental drug coverage to cover the cost of these drugs?

6. All approved drugs are available under Medicare Part B, but drug plans can impose formularies and other coverage restrictions under Medicare Part D. How will you

ensure that seniors do not lose access to the drugs they need if drugs are switched from Part B to Part D?

7. Under Medicare Part B, seniors pay a 20% coinsurance rate, but under Part D, coinsurance can be as high as 40% – and the most expensive specialty drugs have the highest co-pays. How will you ensure that seniors are protected from these high costs if drugs are switched from Part B to Part D?

8. For the average senior, how much will the changes to the TROOP calculation increase drug spending under Medicare Part B? How many seniors will pay higher costs as a result of the changes to the TROOP calculation?

9. Please provide copies of all internal CMS Actuary estimates of the cost of modifying the TROOP calculations, including estimates that indicate the distributional effects of these changes.

President Trump's Promises That the Drug Industry Will Voluntarily Reduce Prices Are Proven Failures

Statements from both you and President Trump indicate that you believe that the pharmaceutical industry will voluntarily reduce prices in response to your proposals. Last week, President Trump stated that "We're going to have some of the big drug companies in two weeks and they're going to announce — because of what we did — they're going to announce voluntary massive drops in prices, so that's great ...For the first time ever in this country, there will be a major drop in the cost of prescription drugs."[25] White House Press Secretary Sarah Sanders indicated, "We do expect some specific policy pieces to come out on that soon."[26] And you stated, "I expect the President will be interested in hearing which companies lowered their prices and took other actions to support the changes we want to make."[27]

These kinds of voluntary pledges are not new. In March 1993, soon after President Clinton took office, and as discussions began about President Clinton's health care reform proposals, "the pharmaceutical industry ... formally offered to limit average price increases to the general inflation rate. ... Under the voluntary plan, each company's pricing would be checked by outside accountants and submitted for review to the Secretary of Health and Human Services and the General Accounting Office of Congress. If a company exceeded the price limit, it would have to make up the excess by lowering prices the next year."[28]

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[25] *Politico*, "Trump's Drug Price Comments Appear to Catch Industry Off Guard," May 30, 2018, https://www.politico.com/story/2018/05/30/trump-drug-prices-613931.

[26] *Politico*, "Trump's Drug Price Comments Appear to Catch Industry Off Guard," May 30, 2018, https://www.politico.com/story/2018/05/30/trump-drug-prices-613931.

[27] HHS Secretary Alex M. Azar II, Remarks on Drug Pricing Blueprint, May 14, 2018, https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html.

[28] *New York Times*, "Drug Makers Propose Self Control on Prices," March 16, 1993, www.nytimes.com/1993/03/16/business/drug-makers-propose-self-control-on-prices.html.

But these promises by the drug industry have a demonstrated record of failure. Since the 1990s, "the amount of money people spend on prescription drugs has nearly doubled."[29] Prescription drug prices have skyrocketed by more than 130% since the 1993 pledge, growing far faster than the inflation rate.[30]

Relying on drug companies to take the lead in reducing drug prices is a poor excuse for a meaningful proposal to tackle the nation's drug pricing problem. Following your statement that "the President will be interested in hearing which companies lowered their prices" in response to his speech, we wrote to the CEOs of the ten largest pharmaceutical companies to ask if they had made any immediate price reductions in response to your speech or planned to take other actions to reduce prices for seniors and other patients.[31] None of these companies have indicated that they had made price reductions in response to the President's announcement or planned to do so. Instead, nearly all replied with a series of non-committal responses. They told us that they "seek to align pricing to value to reduce costs,"[32] that they are "dedicated to working with policymakers to enhance the private marketplace,"[33] and that they "are committed to ensuring our products are accessible and affordable for patients,"[34] and, in a variety of other ways, refused to make any commitments about pricing. There was one exception. Novartis, the only company to give us a clear answer, indicated that "we do have some planned price increases later this year."[35]

We ask that you provide answers to the following questions on the drug industry's voluntary efforts to reduce prices:

1. What did President Trump mean when he stated that "We're going to have some of the big drug companies in in two weeks and they're going to announce ... voluntary massive drops in prices"? When will this announcement be made?

2. What individuals in the Administration have met with drug manufacturers to discuss voluntary proposals? What has been the nature of these discussions?

3. What specific commitments on pricing have you obtained from drug manufacturers?

4. What is the nature of these voluntary proposals? Will these voluntary agreements reduce prices on drugs that cost the most or contribute the most to overall spending?

5. How will the Administration ensure that drug manufacturers do not break any of the voluntary pledges they may make to reduce drug prices or price increases?

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[29] U.S. Government Accountability Office, "Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals," https://www.gao.gov/products/GAO-18-40.

[30] Bureau of Labor Statistics, Prescription Drugs in U.S. City Average, Urban Wage Earners and Clerical Workers, Not Seasonally Adjusted, Series ID CWUR0000SEMF01, 1993-2018.

[31] Letter from Senators Elizabeth Warren and Tina Smith to Pfizer, Novartis, Hoffman-LaRoche, Merck, Sanofi, Johnson & Johnson, Gilead, GlaxoSmithKline, Abbvie, and Amgen, May 30, 2018.

[32] Letter from Robert A. Bradway, Amgen, to Sens. Warren and Smith, June 8, 2018.

[33] Letter from William Schuyler, GSK, to Sens. Warren and Smith, June 7, 2018.

[34] Letter from Kenneth C. Frazier, Merck, to Sens. Warren and Smith, June 8, 2018

[35] Letter from Thomas N. Kendris, President, Novartis, to Sens. Warren and Smith, June 8, 2018.

President Trump's Plan Does Nothing to Reduce Runaway Drug Company Profits and CEO Pay

As drug prices have climbed for patients and the health system as a whole, pharmaceutical companies have raked in massive profits and rapidly increased compensation for top executives. Pharmaceutical CEOs dominate the list of the most highly compensated CEOs in the country.[36] Drug companies have enjoyed an average profit margin of 17.1% over roughly the past decade – more than double the profit margin of the 500 largest companies across all industries.[37]

The pharmaceutical industry also profited handsomely from the Republican tax bill signed into law later in 2017. Rather than using revenue from these tax cuts to lower prices for consumers, drug companies plowed billions into stock buybacks to boost share prices. Not coincidentally, most of the compensation of pharmaceutical industry CEOs comes in the form of stocks and stock options. CEOs were, in effect, giving themselves a pay raise, rather than reducing prices for consumers.[38]

You and the President indicated that the Administration's drug pricing plan represented a new era in getting tough on the industry. Following the President's drug pricing speech, you remarked that "I've been a drug company executive – I know the tired talking points: the idea that if one penny disappears from pharma profit margins, American innovation will grind to a halt."[39] You indicated that you were "not interested in hearing those talking points anymore, and neither is the President."[40]

However, the drug pricing blueprint does not live up to the promises that you and the President made. On the day President Trump announced his proposal, drug company stocks "soared"[41] –a reaction to the details of the plan, which largely stick to PhRMA-approved policies and fail to contain key proposals like government price negotiation or allowing seniors to import

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[36] *International Business Times*, "Healthcare and Pharma CEOs Paid More Than Top Execs in Any Other Industry, Analysis Finds," Elizabeth Whitman, May 25, 2016, http://www.ibtimes.com/healthcare-pharma-ceos-paid-more-top-execs-any-other-industry-analysis-finds-2374013.

[37] U.S. Government Accountability Office, "Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals," https://www.gao.gov/products/GAO-18-40.

[38] *Axios*, "Pharma's $50 Billion Tax Windfall for Investors," Bob Herman, February 22, 2018. https://www.axios.com/pharma-share-buyback-tax-reform-40a30b93-6149-4c67-bd65-cd05ee814215.html. See also: The Motley Fool, Which Big Pharma CEOs Least Deserved Their Big Pay Increases? https://www.fool.com/investing/2018/04/04/which-big-pharma-ceos-least-deserved-their-recent.aspx

[39] HHS Secretary Alex Azar, Remarks on Drug Pricing Blueprint, May 14, 2018, https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html.

[40] HHS Secretary Alex Azar, Remarks on Drug Pricing Blueprint, May 14, 2018, https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html.

[41] STAT, "Trump Promised to Bring Pharma to Justice. His Speech Sent Drug Stocks Soaring," May 11, 2018, ttps://www.statnews.com/2018/05/11/trump-drug-pricing-speech-stocks/.

less expensive drugs from other countries that obtain lower prices. Overall, analysts described the plan as being "very, very positive to pharma."[42]

You claimed that "stock analysts, who are really quite smart individuals generally, totally missed the boat here" and urged them to "do a bit more reading and looking, listening and understanding" in order to grasp how tough the plan was on the drug industry.[43]

We ask that you provide answers to the following questions regarding the impact of the Administration's drug pricing plan on drug company profits and the compensation of pharmaceutical company executives:

1. What do you believe stock analysts got wrong in their assessment of the President's drug pricing proposal? Did the administration expect stock prices to decline following the President's announcement on May 11?

2. What impact do you anticipate the implementation of the President's drug pricing proposal will have on pharmaceutical company profits? What evidence did you rely on in making this assessment?

3. Do you think it's fair that drug companies rake in such high profits given much of the research underpinning their products and new drug development generally is funded by taxpayers?

4. Do you believe that drug company CEO compensation is too high? What policies is the Administration considering, if any, to lower CEO pay at drug companies?

PhRMA's Influence on the Drug Pricing Plan

We are also concerned about the pharmaceutical industry's influence on the drug proposal. For months prior to releasing his proposal, President Trump had tough words for the drug industry, and promised to take on the PhRMA and its lobbyists.

When discussing the blueprint, you and the President also promised that you would press ahead with aggressive action to lower drug prices, even if the drug industry mobilized its lobbying apparatus to oppose your efforts. The President stated that "No industry spends more money on lobbying than the pharmaceutical health products industry. Last year, these companies spent nearly $280 million on lobbyists. That's more than tobacco, oil, and defense contractors combined."[44] You underscored the President's point in your remarks a few days later, stating "I'm sure that pharmaceutical manufacturers took note on Friday when the

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[42] *New York Times*, "Trump Promises Lower Drug Prices, but Drops Populist Solutions," May 11, 2018, https://www.nytimes.com/2018/05/11/us/politics/trump-prescription-drugs-plan.html.

[43] *Politico*, "Azar to Drug Plan Critics: Bring on the Fight," Dan Diamond, May 17, 2018, https://www.politico.com/story/2018/05/17/alex-azar-drug-plan-lower-price-critics-596966.

[44] Remarks by President Trump on Lowering Drug Prices, May 11, 2018, https://www.whitehouse.gov/briefings-statements/remarks-president-trump-lowering-drug-prices/.

President pointed out that they are one of the most aggressive industries when it comes to lobbying."[45]

Despite this strong rhetoric, assessments of the drug pricing plan note that it "spares"[46] the pharma industry and "won't do much to change the status quo."[47] We are concerned that one reason why the plan is so friendly to the big drug manufacturers is the strong influence of PhRMA and its former lobbyists and employees in the Trump Administration. Prior to joining the Trump Administration, you were a top executive at Eli Lilly for a decade. You now claim that this experience gives you independence and insight into the industry.

But you are not the only former drug industry lobbyist or executive in the Administration. We are particularly concerned about the role of Joe Grogan, "who has sweeping authority over drug pricing, entitlement programs and other aspects of federal health policy at the Office of Management and Budget," and who worked as a lobbyist at Gilead Sciences — the company responsible for jacking up prices on the hepatitis C drug Sovaldi — for almost six years prior to joining the Administration.[48]

Politico reported that Mr. Grogan "convened the first meeting on the administration's drug pricing policies in mid-April 2017 with a half dozen senior Health and Human Services officials, then led at least a dozen follow-up meetings through June to develop the plan,"[49] and that "in his position at OMB, Grogan would shape or have a say over efforts to lower the price Medicare pays for drugs or to modify its prescription drug benefit. He'd also play some part in FDA initiatives to increase competition among different classes of medicines."[50]

In addition to Mr. Grogan, other industry lobbyists or executives working closely on the drug plan "include Dan Best, a former CVS vice president who is now heading up drug pricing efforts at HHS and Lance Leggitt ... [the] deputy director of the White House Domestic Policy Council, who represented drug companies while overseeing health care lobbying at Baker Donelson. John O'Brien, a staffer in [your] immediate office who is primarily supporting HHS' Medicare initiatives, worked for PhRMA earlier in his career."[51]

We ask that you provide answers to the following questions on the development of the Administration's drug plan.

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[45] HHS Secretary Alex Azar, Remarks on Drug Pricing Blueprint," May 14, 2018, https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html.

[46] Time, "President Trump's Plan to Lower Drug Prices Spares Pharma Industry," Matthew Perone and Jill Colvin, May 12, 2018, http://time.com/5275168/trump-plan-lower-drug-prices/.

[47] Bloomberg, "Trump's 'Sweeping' Drug-Price Plan Comes Up Short," Max Nisen, May 11, 2018, https://www.bloomberg.com/view/articles/2018-05-11/trump-drug-price-plan-comes-up-short.

[48] *Politico*, "Former Drug Industry Lobbyist Helps Steer Trump Drug Plan," May 27, 2018, https://www.politico.com/story/2018/05/27/trump-drug-plan-lobbyist-joe-grogan-609170.

[49] *Politico*, "Former Drug Industry Lobbyist Helps Steer Trump Drug Plan," May 27, 2018, https://www.politico.com/story/2018/05/27/trump-drug-plan-lobbyist-joe-grogan-609170

[50] *Politico*, "Former Drug Industry Lobbyist Helps Steer Trump Drug Plan," May 27, 2018, https://www.politico.com/story/2018/05/27/trump-drug-plan-lobbyist-joe-grogan-609170.

[51] *Politico*, "Former Drug Industry Lobbyist Helps Steer Trump Drug Plan," May 27, 2018, https://www.politico.com/story/2018/05/27/trump-drug-plan-lobbyist-joe-grogan-609170.

1. Which individuals at HHS or elsewhere in the Administration were responsible for developing and approving the final list of proposals included in the Administration's drug pricing plan?
2. Did Mr. Grogan play a role, and if so, what was this role? Similarly, what were the specific roles and responsibilities of Mr. Best, Mr. Leggitt, and Mr. O'Brien? Did any other administration staff that formerly worked for or lobbied for drug manufacturers play a role in the development of the drug plan? If so, please describe their roles.
3. How many meetings have you and your staff held with drug manufacturers during the development of the drug proposal? How many meetings have you had with organizations representing seniors and other consumers?
4. What actions have you taken to prevent HHS staff from taking actions that may benefit their former employers or companies that they lobbied for or represented before joining the Administration?

Conclusion

During his campaign, President Trump made a series of bold promises about reducing drug prices. But the drug pricing proposal released by the President last month broke those promises. The plan –which reportedly was written or heavily influenced by former drug industry employees or lobbyists who now work for the Administration –does not go far enough to help Americans with high drug costs. In fact, changes proposed by the Administration could significantly increase costs for many Medicare enrollees. The voluntary price reductions promised by the President have been shown to be proven failures. And the plan does nothing to reduce runaway drug company profits and drug company CEO pay.

We ask that you come to tomorrow's HELP Committee hearing prepared to address our questions and concerns with the Trump Administration's drug pricing plan. If you have any questions about this letter, please contact Brian Cohen in the office of Senator Elizabeth Warren or Beth Wikler in the office of Senator Tina Smith.

Sincerely,

Elizabeth Warren
United States Senator

Tina Smith
United States Senator