

United States Senate

WASHINGTON, DC 20510

October 25, 2018

The Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20001

Dear Secretary Azar:

We are writing regarding the Trump Administration's conspicuous failure to reduce drug prices and to ask – for the second time – that you address ongoing questions about the truthfulness of the explanations you provided for this failure in your testimony before the U.S. Senate.

We wrote to you in August to request additional information about claims you made in your June 2018 Senate testimony before the Senate HELP and Finance Committees. In this testimony, as an explanation for President Trump's broken promise of "massive" drug price cuts, you repeatedly blamed pharmacy benefit managers (PBMs) and drug distributors for the fact that drug manufacturers have refused to meaningfully reduce their prices. But information we obtained from these drug industry actors and released in August 2018 did not support the allegations you made in your testimony.¹

Our offices sent you a letter on August 17, 2018 that contained a series of questions asking you to explain the discrepancies between what you told the Senate and what we learned from pharmacy benefit managers and drug distributors. It also asked for additional details about the "massive," voluntary drug price reductions promised by President Trump; whether specific companies had indicated they wished to pursue these price reductions; and the basis for your testimony asserting that pharmacy benefit managers and distributors were preventing these companies from reducing their prices.²

Your response, which we received on September 13, 2018, is inadequate, and raises even more questions about whether you provided truthful testimony to the Senate in June. Specifically, your response provides no factual basis for your June 2018 testimony before the Senate; in fact, your response appears to be – with no explanation – a significant departure from

¹ Letter from Senator Elizabeth Warren to HHS Secretary Alexander Azar, August 17, 2018, <https://www.warren.senate.gov/oversight/letters/warren-smith-raise-questions-about-accuracy-of-secretary-azars-testimony-blaming-pbms-for-high-drug-prices>

² Letter from Senator Elizabeth Warren to HHS Secretary Alexander Azar, August 17, 2018, <https://www.warren.senate.gov/oversight/letters/warren-smith-raise-questions-about-accuracy-of-secretary-azars-testimony-blaming-pbms-for-high-drug-prices>

that testimony, in which you blamed PBMs and drug distributors for the failure of the pharmaceutical industry to voluntarily reduce prices. It fails to answer our questions about your interactions with the pharmaceutical industry, and why and how you provided the Senate with misleading testimony. We therefore ask that you provide full and complete answers to the questions in our letter.

Your complete, accurate, and timely answers to our questions are particularly important given the ongoing failure of the President's plan to reduce drug prices. A new analysis released earlier this month by the Associated Press found that, even as President Trump made his promises about imminent and voluntary drug industry price cuts, "it's been business as usual for drug manufacturers, with far more price hikes than cuts."³ In fact, the analysis found that "over the first seven months of [2018], there were 96 price hikes for every cut," and that "the median price increase was 5.2% in June and July of 2018," more than twice the average inflation rate for 2018.

This is not surprising given that your administration has failed to take the aggressive steps necessary to fully address the problem of high drug prices. Last week, you heralded HHS's new policy requiring drug manufacturers to include list prices in their drug advertisements as "historic."⁴ You went further to explain that by publicly shaming companies, you are creating "new incentives for drug companies to start lowering their list prices, rather than raising them."⁵ This policy will help further educate consumers about high drug prices, but alone, it is far from sufficient and will not come close to addressing the problem of high drug prices. Doing so will require more far-reaching policies. As one analyst noted, "the fact that drugs are expensive isn't news to most Americans. Actually bringing down prices would likely require much more complicated policy interventions,"⁶— interventions that so far, you have been unwilling or unable to take.

The American public deserves answers about why President Trump – despite his big promises on drug pricing – has accomplished nothing. And they deserve to know why you have not been forthcoming about the reasons for this failure.

Introduction

Earlier this year, when President Trump unveiled his drug pricing proposals, he promised the public that they would see rapid reductions in drug prices. He said, "some of the big drug companies in ... two weeks ... because of what we did — they're going to announce voluntary

³ Associated Press, "AP investigation: Drug prices going up despite Trump promise," Linda A. Johnson and Nicky Forster, September 24, 2018, <https://apnews.com/b28338b7c91c4174ad5fad682138520d>.

⁴ HHS Secretary Alex M. Azar II, Remarks on Drug Pricing to the National Academy of Medicine, October 15, 2018, <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-to-the-national-academy-of-medicine.html>.

⁵ CMS, CMS Proposes to Require Manufacturers to Disclose Drug Prices in Television Ads, October 15, 2018, <https://www.cms.gov/newsroom/press-releases/cms-proposes-require-manufacturers-disclose-drug-prices-television-ads>.

⁶ Max Nissen, Bloomberg Opinion Analysis, Trump's Drug-Ad Price Shaming Won't Fix the Problem, October 15, 2018, https://www.washingtonpost.com/business/trumps-drug-ad-price-shaming-wont-fix-the-problem/2018/10/15/265a47c4-d0c7-11e8-a4db-184311d27129_story.html?utm_term=.d701be7b92b8.

massive drops in prices.”⁷ But by June 2018, when you testified before the Senate, it was clear that President Trump was unable to keep his promises. There were no drug price drops of significance – and there have been virtually none since. In fact, none out of the ten largest drug manufacturers – to whom we wrote before the hearing, asking about whether they had reduced prices in response to the President’s blueprint – said that they had lowered prices and none gave any indication that they planned to do so. Indeed, one manufacturer noted that they planned price increases for later in the year.⁸ At this hearing, Senator Warren asked you to explain why drug prices remained high despite President Trump’s assurances.⁹ In response, you indicated that pharmacy benefit managers and drug distributors – not drug manufacturers – were to blame.

You said:

We’ve had several drug companies come in who ... want to execute substantial material reductions in their drug prices. They’re finding hurdles from pharmacy benefit managers and distributors ... where they might say if you decrease your list price, I will take you off formulary compared to your competitor.¹⁰

You repeated these allegations several times in the hearing, challenging Congress and PBM customers to investigate this matter.¹¹ You also repeated them, nearly verbatim, at a Senate Finance Committee hearing two weeks later.¹²

The allegations that you made and repeated while testifying before the U.S. Senate are disturbing and serious. If these allegations were true, it would mean that PBMs and drug distributors – who tout themselves as key players in negotiating lower drug prices and making the market for drugs more efficient – are acting against their customers’ interests, and it would

⁷ Politico, “Trump’s Drug Price Comments Appear to Catch Industry Off Guard,” Brianna Ehley, May 30, 2018, <https://www.politico.com/story/2018/05/30/trump-drug-prices-613931>.

⁸ Letter from Senator Elizabeth Warren to HHS Secretary Azar, June 11, 2018, <https://www.warren.senate.gov/oversight/letters/warren-and-smith-press-hhs-secretary-azar-on-broken-promises-in-trump-drug-pricing-proposal-prior-to-appearance-before-congress>

⁹ Sen. Elizabeth Warren, “The Cost of Prescription Drugs: Examining the President’s Blueprint ‘American Patients First’ to Lower Drug Prices,” Committee on Health, Education, Labor, and Pensions, June 12, 2018, <https://www.c-span.org/video/?446791-1/secretary-azar-testifies-prescription-drug-pricing-plan>.

¹⁰ HHS Secretary Alex Azar, “The Cost of Prescription Drugs: Examining the President’s Blueprint ‘American Patients First’ to Lower Drug Prices,” Committee on Health, Education, Labor, and Pensions, June 12, 2018, <https://www.c-span.org/video/?446791-1/secretary-azar-testifies-prescription-drug-pricing-plan>.

¹¹ For example, you said that, “There are actually several drug companies that are looking at substantial and material decreases of drug prices. ... They’re working right now with the pharmacy benefit managers and distributors. ... What they’re trying to do is work to ensure they’re not discriminated against for lowering their prices. You should focus ... on the PBMs and distributors who might say to these [drug companies] do not decrease your price,” and that “[E]mployers and payer customers of PBMs ... should be asking their PBMs right now, have you received any commitments of lower list prices and what have you done ... and are you pushing back on drug companies saying you would prefer higher list drug prices?” HHS Secretary Alex Azar, “The Cost of Prescription Drugs: Examining the President’s Blueprint ‘American Patients First’ to Lower Drug Prices,” Committee on Health, Education, Labor, and Pensions, June 12, 2018, <https://www.c-span.org/video/?446791-1/secretary-azar-testifies-prescription-drug-pricing-plan>.

¹² HHS Secretary Alex Azar, “Prescription Drug Affordability and Innovation: Addressing Challenges in Today’s Market, Committee on Finance,” June 26, 2018, <https://www.c-span.org/video/?447466-1/hhs-secretary-alex-azar-pressed-migrant-family-reunification-efforts>

directly contradict the public statements that PBMs have made about their actions and their interest in securing lower list prices from drug companies.¹³ But if your allegations were false, they raise questions about your own truthfulness and whether you misled the Senate – either purposefully, or because you did not have complete or accurate information at your disposal.

To address the questions raised by your testimony, we wrote to the six largest pharmacy benefit managers and the three largest drug distributors on June 29, 2018, asking them to respond to your allegations.¹⁴ Every PBM we wrote to indicated that your allegations were false. These responses raised questions about the accuracy of two aspects of your testimony: (1) your claim that drug manufacturers want to and are attempting to enact voluntary price reductions; and (2) your claim that PBMs are putting up barriers to and preventing these voluntary price reductions.

CVS Health and Express Scripts are the largest PBMs in the country. In response to our questions, both indicated that no drug manufacturer had promised meaningful price reductions – and that they had not “discouraged or ‘pushed back’ against any drug maker efforts to lower list prices,” “neither stated nor implied that we would prefer that drug companies not reduce their prices,” and that they had not “stated or implied that we would remove products from a formulary for lower drug prices.”¹⁵ Other PBMs and drug distributors provided similar answers.¹⁶

Inadequate Response to Our Questions

To address the concerns about your testimony, we sent you a letter on August 17, 2018 that included 20 questions. We asked you to provide the specific facts that would support your June 2018 testimony that drug manufacturers were willing to “execute substantial material reductions in their drug prices”; we asked you for specific information about your allegations

¹³ STAT News, “Why Do We Need Drug Rebates Anyway? A Top Lawmaker Wants to Know,” Ike Swetlitz, October 17, 2017, <https://www.statnews.com/2017/10/17/drug-rebates-pricing-senate/>; Washington Post, “In May, Trump predicted the pharmaceutical industry would cut prices in two weeks. It hasn’t happened yet,” Carolyn Y. Johnson, June 26, 2018, <https://www.washingtonpost.com/news/wonk/wp/2018/06/25/in-may-trump-predicted-the-pharmaceutical-industry-would-start-cutting-prices-in-two-weeks-its-been-three/>; Politico Pulse, “Azar Faces Senate Finance on drug prices,” Dan Diamond, June 26, 2018, <https://www.politico.com/newsletters/politico-pulse/2018/06/26/azar-faces-senate-finance-on-drug-prices-263911>; “Just Cut the Price” advertisement, Pharmaceutical Care Management Association, June 25, 2018, <https://www.pcmnet.org/americas-pharmacy-benefit-managers-pbms-agree-with-the-administration-and-patients/>.

¹⁴ The letters were sent to the PBMs Express Scripts, CVS Health, MedImpact, OptumRx, Humana, and Prime Therapeutics, and to the drug distributors CardinalHealth, McKesson, and AmerisourceBergen.

¹⁵ Letter from Jonah C. Houts, Vice President, Express Scripts, to Senators Elizabeth Warren and Tina Smith, July 11, 2018, <https://thehill.com/policy/healthcare/402346-groups-that-manage-drug-benefits-for-insurers-say-theyve-received-no>

¹⁶ Letter from John M. Prince, Chief Executive Officer, OptumRx, to Senators Elizabeth Warren and Tina Smith, July 13, 2018; Letter from James DuCharme, President and Chief Executive Officer, Prime Therapeutics, to Senators Elizabeth Warren and Tina Smith, July 13, 2018; Letter from Greg Watanabe, President and Chief Operating Officer, MedImpact Healthcare Systems, to Senators Elizabeth Warren and Tina Smith, July 12, 2018; Letter from Douglas Stoss, Vice President, Humana, Inc., to Senators Elizabeth Warren and Tina Smith, July 13, 2018; Letter from Sean Callinicos, Senior Vice President, Global Government Relations and Public Policy, Cardinal Health to Sens. Warren and Smith, July 23, 2018; Letter from Nick Loporcaro, President, McKesson to Sens. Warren and Smith, July 25, 2018; Letter from John Chou, Executive Vice President and Chief Legal and Business Officer, AmeriSourceBergen to Sens. Warren and Smith, July 20, 2018.

that PBMS and drug distributors were preventing manufacturers from enacting any price reductions; we asked about any contacts with the pharmaceutical industry that would explain the unusual coincidence that your testimony was also consistent with the drug industry's efforts to "get Americans mad at" PBMs and drug distributors; and we provided you with the opportunity to explain and clarify your testimony.¹⁷

You replied to our questions about your testimony on September 13, 2018.¹⁸ While we appreciate your efforts, your answers were wholly insufficient, and at times contradictory to the claims you made during the hearings.

Your responses repeatedly failed to provide a factual basis for the claims you made about drug manufacturers and pharmacy benefit managers. For example, we asked you to provide simple and specific details about the companies that wanted "to execute substantial material reductions in their drug prices." You failed to provide any such information. Instead, you claimed that "Staff at the Department of Health and Human Services have had conversations with a number of stakeholders," and that, "several manufacturers ... have indicated that hurdles remain in enacting material reductions in list prices." Again, this is exactly the opposite of what our investigation uncovered.

Similarly, in your June 2018 testimony, when asked why drug manufacturers had not made any voluntary price reductions, you placed the blame squarely on the back of pharmacy benefit managers and drug distributors. We asked for the factual basis for that claim. You failed to provide any such information in your response – instead walking us through a hypothetical example of how arrangements that pharmacy benefit managers have with payers could be affected by a lowered list price, based on a "typical contract." You also asserted that "We have been informed by manufacturers seeking to lower their list price" that pharmacy benefit managers would insist on the fulfillment of existing contractual obligations and "at least in part due to these contractual provisions, most manufacturers did not lower their list price."¹⁹ Again, our own investigation into this assertion found no evidence that manufacturers had taken meaningful steps to engage PBMs in a discussion around lowering list prices.

At other points in your response and in your public statements regarding the drug pricing blueprint, you appear to have revised the position you expressed during the hearing that pharmacy benefit managers are to blame for drug companies' failure to reduce their list prices. In your letter, you now claim that "all parties – the entire system – bear blame." Speaking to

¹⁷ Washington Post, "Pharma, under attack for drug prices, started an industry war," Carolyn Y. Johnson, Jan. 2, 2018, https://www.washingtonpost.com/business/economy/pharma-under-attack-for-drug-prices-started-an-industry-war/2017/12/29/800a3de8-e5bc-11e7-a65d-1ac0fd7f097e_story.html.

¹⁸ Letter from the Honorable Alex M. Azar II, to Sen. Elizabeth Warren (Sep. 13, 2018); Letter from the Honorable Alex M. Azar II, to Sen. Tina Smith (Sep. 13, 2018)

¹⁹ HHS Secretary Alex Azar, "Prescription Drug Affordability and Innovation: Addressing Challenges in Today's Market, Committee on Finance," June 26, 2018, <https://www.c-span.org/video/?447466-1/hhs-secretary-alex-azar-pressed-migrant-family-reunification-efforts>

Bloomberg on September 12th, you further walked back your statements, saying: “I am not blaming pharmacy benefit managers for the position we are in around drug pricing.”²⁰

The vast majority of our other questions – including questions about how and why you provided testimony that appeared to be inaccurate – were ignored entirely.

Summary

In your June testimony before the Senate HELP and Finance Committees, you made very serious allegations about the extent to which PBMs and drug distributors were preventing drug manufacturers from reducing prices and claimed that these middlemen were to blame for President Trump’s failed promise of lower drug prices.

Our investigation revealed that that testimony was not factually correct, and you have now provided us with new information that appears to reflect a different understanding of the pharmaceutical market.

But we have important questions about why you provided inaccurate testimony in the first place. We therefore ask that you provide answers to the following questions no later than November 7, 2018.

1. Your letter to us indicates that you now believe that “all parties – the entire system – bear blame” for high drug prices, while your previous testimony indicates that you were primarily focused on the role of pharmacy benefit managers and drug distributors. What information have you obtained that has caused you to modify your views and your emphasis on what entities are responsible for high drug prices?
2. Our initial letter asked whether drug manufacturers – per your June testimony – have indicated to you that they “want to execute substantial material reductions in their drug prices.” Your response confirmed that HHS “staff have had conversations with a number of stakeholders” – including drug manufacturers – “in our effort to provide pricing relief to Americans,” but failed to provide specific answers to our questions. We therefore reiterate our request that you provide this information, including:
 - a. Which specific companies have come to you and indicated that they want to cut drug prices?
 - b. When and with what drug manufacturers did these meetings take place? Were they before or after President Trump promised “massive” price reductions? Were they before or after you testified before the Senate HELP and Finance Committees in June 2018?
 - c. What specific price reductions have been discussed with these drug manufacturers? On what drugs, and what magnitude of price reductions?
 - d. What was the outcome of these discussions?

²⁰ Bloomberg, “Trump Eyeing ‘Disruptive’ Changes to Drug Pricing, Health Secretary Says,” Cynthia Koons and Anna Edney, September 12, 2018, <https://www.bloomberg.com/news/articles/2018-09-12/trump-eyes-disruptive-changes-to-drug-pricing-hhs-chief-says>

- e. Why have these discussions failed to result in substantial and meaningful price reductions?
3. Our August 17, 2018 letter asked you for the basis of your testimony that the manufacturers are “finding hurdles from pharmacy benefit managers and distributors.” You failed to provide a detailed answer to this question, instead providing a theoretical and vague example of how a certain type of multi-year contractual agreement between PBMs and payers could provide incentives for PBMS to prefer higher list prices. In order for us to understand this dynamic in detail, we ask that you provide information on the following:
 - a. What specific hurdles are pharmacy benefit managers putting in place to prevent drug manufacturers from reducing their prices? And how widespread are these practices?
 - b. How did you learn of these PBM hurdles? Please provide a list of all discussions on this matter by you or your staff with pharmaceutical company or other industry officials.
 - c. Have you discussed these hurdles with representatives from PBMs or their trade association?
 - i. If so, please list all such discussions.
 - ii. What was the nature and outcome of such discussions?
 - d. What specific hurdles are drug distributors putting in place to prevent drug manufacturers from reducing prices? And how widespread are these practices?
 - e. How did you learn of these drug distributor hurdles? Please provide a list of all discussions of this matter by you or your staff with pharmaceutical company or other industry officials.
 - f. Have you discussed these hurdles with representatives from drug distribution companies or their trade group?
 - i. If so, please list all such discussions.
 - ii. What was the nature and outcome of such discussions?
4. Our initial letter noted the extensive drug industry ties of you and many of your key staff, and noted that “[i]t may be an unusual coincidence that the allegations you made regarding the PBMs and drug distributors were highly consistent with the pharmaceutical industry’s “efforts to diffuse and deflect the focus on their role” and “slow down a discussion of pricing.”²¹ But we also raised concerns that you may have “coordinated with the pharmaceutical industry to concoct a scenario in which the drug company failure to reduce prices is blamed on industry middlemen rather than attributed to the drug companies themselves.” You ignored our questions on this matter. We therefore again ask that you provide us the information we requested on whether you or your staff had any discussions with pharmaceutical industry officials or representatives regarding “the


²¹ Washington Post, Carolyn Y. Johnson, Pharma, under attack for drug prices, started an industry war, Jan. 2, 2018, https://www.washingtonpost.com/business/economy/pharma-under-attack-for-drug-prices-started-an-industry-war/2017/12/29/800a3de8-e5bc-11e7-a65d-1ac0fd7f097e_story.html?utm_term=.20624a9c3d2c.

pharmaceutical industry's efforts to 'get Americans mad at' drug industry middlemen,"²² including:


- a. If you have had these discussions, what was the nature of these discussions?
- b. Please provide any and all email or other communications between you or your staff and pharmaceutical industry officials or representatives regarding the behavior of PBMs and drug distributors.

Thank you for your attention to this matter. Please contact Brian Cohen of Sen. Warren's staff and Beth Wikler of Sen. Smith's staff should you have any questions.

Sincerely,



Elizabeth Warren
United States Senator



Tina Smith
United States Senator

cc: Sen. Lamar Alexander, HELP Committee Chairman
Sen. Orrin Hatch, Finance Committee Chairman
Sen. Patty Murray, HELP Committee Ranking Member
Sen. Ron Wyden, Finance Committee Ranking Member

²² Washington Post, "Pharma, under attack for drug prices, started an industry war," Carolyn Y. Johnson, Jan. 2, 2018, https://www.washingtonpost.com/business/economy/pharma-under-attack-for-drug-prices-started-an-industry-war/2017/12/29/800a3de8-e5bc-11e7-a65d-1ac0fd7f097e_story.html.