

United States Senate

WASHINGTON, DC 20510

August 17, 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 your June 2018 Senate testimony in which you blamed pharmacy benefit managers and drug distributors for the fact that drug manufacturers have refused to meaningfully reduce their prices, despite President Trump's promises that manufacturers would voluntarily enact "massive" price cuts. New information we have obtained from these drug industry actors does not support the allegations you made in your testimony and raises questions about the accuracy of your statements. We request that you provide additional information to clarify this matter.

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, "We're going to have some of the big drug companies in in two weeks and they're going to announce — because of what we did — they're going to announce voluntary massive drops in prices ... there will be a major drop in the cost of prescription drugs."¹

But President Trump has not been able to keep his promise. There have been no drug price drops of significance. Instead, drug companies have – at best – announced token actions that are nothing more than public relations stunts. Some companies have announced so-called price reductions that actually make little difference to patients – like when Merck announced a 60% price drop on the Hepatitis C drug Zepatier – a drug "that had no U.S. revenues in the first quarter" of 2018.² Others have pledged to temporarily freeze future price increases – meaning that drug prices remain just as high as when President Trump made his promises, and can be raised again whenever companies decide public attention has faded. One drug lobbyist described

¹ 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>.

² Politico, "How drug companies are beating Trump at his own game," Sarah Karlin-Smith, Sarah Owerhohle, and Andrew Restuccia, Aug. 2, 2018, <https://www.politico.com/story/2018/08/03/trump-drug-prices-companies-721145>.

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these as “nothing-burger steps.”³ Another profanely described them as “sh*t [that] is meaningless to satisfy Trump.”⁴

The President’s drug pricing promises do not appear to be making the slightest bit of difference in the skyrocketing cost of prescription drugs still burdening American families. On June 11, 2018, our offices sent you a letter asking a series of questions about these failed promises and asking you to come to a hearing before the Senate Committee on Health, Education, Labor, and Pensions prepared to answer them. At this hearing, Senator Warren raised these questions again, asking you to explain why drug prices remained high despite President Trump’s assurances of massive price reductions.⁵ 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.⁶

You repeated these allegations several times in the hearing, challenging Congress and pharmacy benefit manager (PBM) customers to investigate this matter.⁷ You also repeated them, nearly verbatim, at a Senate Finance Committee hearing two weeks later, claiming that “w[e] have had many major drug companies with major products who want to make substantial and material price decreases. and the reaction ... [from pharmacy benefit managers and drug distributors] has been if you were to decrease your price you

³ Politico, How drug companies are beating Trump at his own game, Sarah Karlin-Smith, Sarah Owerhohle, and Andrew Restuccia, Aug. 2, 2018, <https://www.politico.com/story/2018/08/03/trump-drug-prices-companies-721145>.

⁴ Politico, How drug companies are beating Trump at his own game, Sarah Karlin-Smith, Sarah Owerhohle, and Andrew Restuccia, Aug. 2, 2018, <https://www.politico.com/story/2018/08/03/trump-drug-prices-companies-721145>.

⁵ 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>.

⁶ 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>.

⁷ 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>.

will actually be harmed in terms of formulary status, and patient access, versus your competitor who has a higher price.”⁸

The allegations that you made and repeated while testifying before the U.S. Congress are disturbing and serious. If these allegations are 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 directly contradict the public statements that PBMs have made about their actions and their interest in securing lower list prices from drug companies.⁹

But if your allegations are false, you owe the HELP Committee and the Finance Committee an explanation for why you misled these committees about the reasons for President Trump’s failure to meet his promises to reduce drug prices.

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.¹⁰ Together, these nine entities account for approximately 90% of the PBM and pharmaceutical distribution market.¹¹ We asked them directly and clearly about whether they were engaged in the activities you described.

Responses from PBMs

Each of the six PBMs provided specific responses to our request. These responses raise 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, CVS indicated that “we have had very limited discussions with drug companies

⁸ 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>;

⁹ 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/>.

¹⁰ The letters were sent to Express Scripts, CVS Health, MedImpact, OptumRx, Humana, and Prime Therapeutics

¹¹ Statista, “Market share of the top 5 pharmacy benefit managers in the U.S. prescription market in 2016,” <https://www.statista.com/statistics/239976/us-prescription-market-share-of-top-pharmacy-benefit-managers/>; MDM, “2017 Top Pharmaceutical Distributors,” Adam J. Fein, <https://www.mdm.com/2017-top-pharmaceuticals-distributors/>;

related to the Administration's drug pricing initiative."¹² In fact, the company only identified one case where they had received a commitment to reduce prices from a drug manufacturer – and that was when Pfizer, on July 12, 2018, reversed a price *increase* that they had announced on July 1, 2018.¹³

When asked if the allegations you made about PBMs – that they had “pushed back” against price reductions, or stated or implied that that drug companies would lose formulary placement or otherwise be harmed if they reduced prices, CVS gave unequivocal answers: “No,” to each and every question.¹⁴

Express Scripts responded to our questions on July 11, 2018.¹⁵ In response to our questions, the company indicated that “we have explored ways for a brand drug maker to introduce products with lower list prices,” but that “we have not received any commitment of lower list prices from drug manufacturers.”¹⁶ In addition, in contrast to the allegations you made in your testimony, Express Scripts indicated that “we have not discouraged or ‘pushed back’ against any drug maker efforts to lower list prices,” that “we have neither stated nor implied that we would prefer that drug companies not reduce their prices,” and that “we have not stated or implied that we would remove products from a formulary for lower drug prices. In fact, the opposite is true. Lower net price products receive favorable formulary consideration ... Our reaction to drug makers has consistently been that we welcome lower list prices and lower list prices would not harm formulary status or patient access.”¹⁷

The other four PBMs provided similar answers. Optum indicated that “[c]omments made at recent Committee hearings in the U.S. Senate have sparked a discussion over whether pharmacy benefit managers are standing in the way of drug companies lowering their list prices. This is simply not the case with OptumRx. ... We have not discouraged them from lowering their prices, nor have we excluded drugs with lower list prices from the formulary.”¹⁸ Prime Therapeutics informed us that “we have not received any suggestions or approaches from drug companies for lower list prices.”¹⁹ In fact, the company indicated that they had received only one drug company phone call “that is even tangentially related to the Trump Administration drug pricing initiative,” and that that came “from a drug company which was conducting very preliminary market research to understand the supply chain implications of any change in their

¹² Letter from Melissa A. Schulman, Senior Vice President, CVSHealth, to Sens. Warren and Smith, July 17, 2018.

¹³ Letter from Melissa A. Schulman, Senior Vice President, CVSHealth, to Sens. Warren and Smith, July 17, 2018.

¹⁴ Letter from Melissa A. Schulman, Senior Vice President, CVSHealth, to Sens. Warren and Smith, July 17, 2018.

¹⁵ Letter from Jonah C. Houts, Vice President, Express Scripts, to Senators Elizabeth Warren and Tina Smith, July 11, 2018.

¹⁶ Letter from Jonah C. Houts, Vice President, Express Scripts, to Senators Elizabeth Warren and Tina Smith, July 11, 2018.

¹⁷ Letter from Jonah C. Houts, Vice President, Express Scripts, to Senators Elizabeth Warren and Tina Smith, July 11, 2018.

¹⁸ Letter from John M. Prince, Chief Executive Officer, OptumRx, to Senators Elizabeth Warren and Tina Smith, July 13, 2018.

¹⁹ Letter from James DuCharne, President and Chief Executive Officer, Prime Therapeutics, to Senators Elizabeth Warren and Tina Smith, July 13, 2018.

pricing strategy.”²⁰ Prime Therapeutics flatly denied allegations that they had stated or implied that price reductions would harm drug manufacturers, and indicated that “we would welcome offers to reduce list prices.”²¹

MedImpact told us that the PBM “has not received any commitment of lower list prices from any drug manufacturer,” and that “MedImpact has not stated nor implied that if any drug manufacturer were to decrease their price that they would ‘actually be harmed in terms of formulary status, and patient access, versus [their] competitor who has a higher price.’”²² And Humana indicated that the company had not “received any commitments of lower list prices from drug manufacturers,” had not stated or implied that they preferred that drug companies not reduce prices, and had not stated or implied that they would remove products from a formulary in response to a drug company offer of lower prices.²³

Responses from Drug Distributors

In your testimony before the Senate HELP and Finance Committees, you made allegations about drug distributors that were similar to those you made about PBMs. We also asked the three largest drug distributors about these allegations. These three companies declined to provide the same level of specificity as the PBMs – but the limited information they did provide also raised questions about the accuracy of the allegations that you made about whether they were responsible for the drug companies’ failure to enact the price cuts promised by President Trump. Each company indicated that they had little or no control over how manufacturers set or changed list prices, but that they would be supportive of efforts to reduce prices.

Cardinal Health indicated that “[w]e are supportive of efforts to reduce the cost of prescription drugs to patients...Prescription pharmaceutical manufacturers set the [listed Wholesale Acquisition Cost] for their products. Pharmaceutical wholesale distributors do not play a role in that process.”²⁴ McKesson indicated that “manufacturers change the list prices of their products without involvement from, or influence by, wholesalers.”²⁵ And AmeriSource-Bergen informed us that “[p]harmaceutical wholesale distributors do not set the prices of the branded pharmaceuticals we purchase from manufacturers, and we do not influence, or have any

²⁰ Letter from James DuCharne, President and Chief Executive Officer, Prime Therapeutics, to Senators Elizabeth Warren and Tina Smith, July 13, 2018.

²¹ Letter from James DuCharne, President and Chief Executive Officer, Prime Therapeutics, to Senators Elizabeth Warren and Tina Smith, July 13, 2018.

²² Letter from Greg Watanabe, President and Chief Operating Officer, MedImpact Healthcare Systems, to Senators Elizabeth Warren and Tina Smith, July 12, 2018.

²³ Letter from Douglas Stoss, Vice President, Humana, Inc., to Senators Elizabeth Warren and Tina Smith, July 13, 2018.

²⁴ Letter from Sean Callinicos, Senior Vice President, Global Government Relations and Public Policy, Cardinal Health to Sens. Warren and Smith, July 23, 2018.

²⁵ Letter from Nick Loporčaro, President, McKesson to Sens. Warren and Smith, July 25, 2018.

ability to influence, how branded pharmaceutical prices are set.we negotiate fees for the services we provide our manufacturer partners agnostic of their product pricing.”²⁶

Summary

In your testimony before the Senate HELP and Finance Committees, you made very serious allegations about whether PBMs and drug distributors were preventing drug manufacturers from reducing prices and whether these middlemen were to blame for President Trump’s failed promise of lower drug prices. You indicated that (1) “we’ve had many major drug companies with major products who want to make substantial and material price decreases.” And you indicated that (2), the manufacturers are “finding hurdles from pharmacy benefit managers and distributors” that were preventing them from enacting voluntary price cuts. In order to understand these allegations, we asked a series of detailed questions of the PBMs and drug distributors that control the vast majority of these markets.

These companies all responded in writing to our request for information; in doing so, they subjected themselves to potential criminal penalties if they made “any materially false, fictitious, or fraudulent statement or representation” to Congress.²⁷ And the information they provided raises serious questions about both of the allegations you made in your testimony, and about whether you were providing accurate and complete information when you indicated that PBMs and drug distributors – rather than drug manufacturers – were responsible for the drug manufacturers’ refusal to reduce drug prices, and about President Trump’s continued inability to deliver price cuts he promised. In fact, the information the PBMs and drug distributors provided in response to our questions directly contradicts the allegations you made about their behavior.

This is a very important distinction, and the accuracy of your testimony is a serious matter. Congress cannot appropriately fix the problem of high drug prices unless we have correct information about what is causing them and who is responsible. We are troubled by public reports indicating that the pharmaceutical industry is trying to shift the blame for their actions and “get Americans mad at” PBMs and drug distributors in order to deflect blame from drug manufacturers and prevent Congress or the Administration from enacting tougher drug pricing policies.²⁸ We would be even more disturbed if you or other Administration officials were engaging in similar behavior.

In a letter we sent you prior to your HELP Committee testimony, we raised a number of concerns about pharmaceutical industry influence on this plan. 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

²⁶ Letter from John Chou, Executive Vice President and Chief Legal and Business Officer, AmeriSourceBergen to Sens. Warren and Smith, July 20, 2018.

²⁷ 18 U.S.C. § 1001

²⁸ 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

elsewhere in the Administration were also former drug industry lobbyists or executives.²⁹ When your drug pricing plan was released, analysts described it as being “very, very positive to pharma”³⁰ – and, to date this continues to be true.

To be clear, PBMs and drug distributors play a role in the drug pricing chain, and to the extent their actions result in higher prices, this role should be addressed. But we also believe that we should have accurate facts about drug prices and which industry sectors are responsible for high prices.

It 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 “get Americans mad at” these same middlemen in order to deflect blame from themselves.³¹ But if it is not a mere coincidence – if you 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, it would raise very serious questions about your commitment to enhancing and protecting the health and well-being of all Americans as the Secretary of Health and Human Services.

To address these issues, we ask that you provide answers to the following question no later than August 31, 2018.

1. Have drug manufacturers indicated to you that they “want to execute substantial material reductions in their drug prices”?
 - a. If so, which specific companies have come to you and indicated that they want to do so?
 - b. If so, when 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?
 - c. What specific price reductions have been discussed? On what drugs, and what magnitude of price reductions?
 - d. What was the outcome of these discussions?
2. What was the basis for your testimony that the manufacturers are “finding hurdles from pharmacy benefit managers and distributors”?
 - a. What specific hurdles are pharmacy benefit managers putting in place to prevent drug manufacturers from reducing their prices?
 - 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.

²⁹ Politico, “Former Drug Industry Lobbyist Helps Steer Trump Drug Plan”, David Pittman, May 27, 2018, <https://www.politico.com/story/2018/05/27/trump-drug-plan-lobbyist-joe-grogan-609170>.

³⁰ New York Times, “Trump Promises Lower Drug Prices, but Drops Populist Solutions,” Robert Pear, May 11, 2018, <https://www.nytimes.com/2018/05/11/us/politics/trump-prescription-drugs-plan.html>.

³¹ 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.

- 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?
 - 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?
3. Have you or your staff had any discussions with pharmaceutical industry officials or representatives regarding “the pharmaceutical industry’s efforts to ‘get Americans mad at’ drug industry middlemen”?³²
- a. If so, 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.
4. Do you wish to clarify or otherwise modify your June 2018 testimony before the Senate HELP and Senate Finance Committees?

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

³² 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.