

C A M P A I G N F O R

**ACCOUNTABILITY**

August 28, 2018

**By Fax: (800) 223-8164**

Daniel R. Levinson  
Inspector General  
U.S. Department of Health & Human Services  
PO Box 23489  
Washington, DC 20026

**By Email: [Elizabeth.Fischmann@hhs.gov](mailto:Elizabeth.Fischmann@hhs.gov)**

Elizabeth J. Fischmann  
Designated Agency Ethics Official  
U.S. Department of Health & Human Services  
200 Independence Ave., S.W., Room 700-E  
Washington, DC 20201

**Re: Request for Investigation of Secretary Alex Azar's Relationship with Eli Lilly**

Dear Mr. Levinson and Ms. Fischmann:

Campaign for Accountability (“CfA”) respectfully requests that you open an investigation into the Secretary of the Department of Health and Human Services (“HHS”), Alex Azar, and his relationship with the pharmaceutical manufacturer Eli Lilly and Company. Sec. Azar worked at Eli Lilly for more than a decade, and HHS recently proposed a new rule that would greatly benefit Sec. Azar’s former company. Sec. Azar has championed the issue since taking charge of the agency, while members of Congress from both parties have raised questions about Sec. Azar’s role lending further urgency to the need for an independent inquiry.

### **Background**

#### *Pharmacy Benefit Manager Rebates*

On December 28, 2016, the Office of Inspector General (“OIG”) released its annual notice soliciting proposals and recommendations for adding or modifying the safe harbor provisions of the federal anti-kickback statute.<sup>1</sup> On February 14, 2017, Eli Lilly submitted a comment in response to the OIG notice, urging OIG to “promulgate new or modified regulatory safe harbors and/or a Special Fraud Alert related to remuneration provided by manufacturers to

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<sup>1</sup> Solicitation of New Safe Harbors and Special Fraud Alerts, Office of Inspector General, Department of Health and Human Services, December 28, 2016, available at <https://www.regulations.gov/document?D=HHSIG-2017-0001-0001>.

pharmacy benefit managers (PBMs).”<sup>2</sup> Eli Lilly specifically encouraged OIG to address rebates for PBMs, among other issues.<sup>3</sup>

Drug manufacturers, like Eli Lilly, have long complained about the rebates they are forced to negotiate with PBMs.<sup>4</sup> These companies, like CVS and Express Scripts, operate as middle-men where they negotiate with manufacturers to establish lower drug prices for their clients, which include insurance companies and large employers.<sup>5</sup> These negotiations are opaque and complex, and the drug manufacturers often agree to provide rebates to clients served by the PBMs, which keep a portion of the rebate for themselves.<sup>6</sup> For several years, pharmaceutical manufacturers have blamed this structure and specifically PBMs for the high cost of prescription drugs.<sup>7</sup> As a result, drug manufacturers “started an industry war” by lobbying members of Congress and federal officials to limit the power of PBMs to negotiate rebates for their customers.<sup>8</sup>

On July 18, 2018, OIG submitted a proposed rule to the Office of Management and Budget (“OMB”) that essentially accedes to drug makers’ demands.<sup>9</sup> While the details of the proposal have not been released, the title of the proposed rule – “Removal Of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection.” – indicates that OIG plans to curb the rebates that manufacturers are allowed to offer PBMs.<sup>10</sup> OMB must review the proposal before the OIG can issue the final regulation.<sup>11</sup>

Eli Lilly, as one of the biggest drug manufacturers in the country, would greatly benefit from the new rule. Notably, between June 2007 and January 2017, Sec. Azar worked for Eli Lilly, serving most recently as the company’s president.<sup>12</sup> He left the drug manufacturer in 2017

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<sup>2</sup> Letter from Josh O’Harra, Assistant General Counsel for Eli Lilly, to Patrice Drew, Office of the Inspector General, February 14, 2017, available at <https://www.regulations.gov/document?D=HHSIG-2017-0001-0002>.

<sup>3</sup> *Id.*

<sup>4</sup> Katie Thomas, Meet the Rebate, the New Villain of High Drug Prices, *The New York Times*, July 27, 2018, available at <https://www.nytimes.com/2018/07/27/health/rebates-high-drug-prices-trump.html>.

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> Carolyn Y. Johnson, Pharma, Under Attack for Drug Prices, Started an Industry War, *The Washington Post*, January 2, 2018, available at [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](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).

<sup>8</sup> *Id.*

<sup>9</sup> Removal Of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection, RIN: 0936-AA08, Office of Management and Budget, July 18, 2018, available at <https://www.reginfo.gov/public/do/eoDetails?rrid=128288>.

<sup>10</sup> Trump Administration Proposes Altering Rule on Drug Rebates, *Reuters*, July 19, 2018, available at <https://www.reuters.com/article/us-usa-healthcare-kickbacks/trump-administration-proposes-altering-rule-on-drug-rebates-idUSKBN1K92ON>; Anna Edney, Trump Drug Plan Gains Momentum as Merck Lowers Prices, *Bloomberg*, July 18, 2018, available at <https://www.bloomberg.com/news/articles/2018-07-19/trump-administration-reviewing-proposal-to-curb-drug-rebates>.

<sup>11</sup> *Id.*

<sup>12</sup> Robert Pear, He Raised Drug Prices at Eli Lilly. Can He Lower Them for the U.S.?, *The New York Times*, November 26, 2017, available at <https://www.nytimes.com/2017/11/26/us/politics/alex-azar-senate-confirmation-hearing-hhs.html>; <https://www.linkedin.com/in/azaralex/>.

to start a consulting firm, Seraphim Strategies.<sup>13</sup> On January 24, 2018, Sec. Azar was confirmed by the Senate to lead HHS.<sup>14</sup> Sec. Azar had also worked at HHS before moving to Eli Lilly, serving as general counsel and Deputy Secretary in the George W. Bush Administration.<sup>15</sup>

During his time at Eli Lilly, Sec. Azar championed the pharmaceutical industry's goal of limiting the ability of PBMs to negotiate rebates. On November 3, 2016, for instance, while president of Eli Lilly, Sec. Azar delivered a speech at the Manhattan Institute suggesting HHS should reform the safe harbor provisions of the anti-kickback statutes to allow drug manufacturers to bypass PBMs and negotiate unique schemes with insurance companies.<sup>16</sup>

On November 14, 2016, *RheumNow*, a publication for rheumatologists, published on its YouTube channel an interview with then Eli Lilly president Azar, where he criticized PBM rebates.<sup>17</sup> Sec. Azar argued that the rebates negotiated with PBMs should be passed on to consumers, rather than accrue to the PBMs.<sup>18</sup>

Since joining the administration, Sec. Azar has continued to blame PBM rebates for the high cost of drug prices. In May 2018, HHS released "American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs."<sup>19</sup> The blueprint, which included an introductory message from Sec. Azar, specifically criticized PBM rebates for causing drug prices to remain high stating, "Because health plans, pharmacy benefit managers (PBMs), and wholesalers receive higher rebates and fees when list prices increase, there is little incentive to control list prices."<sup>20</sup>

Sec. Azar has continued to promote the administration's blueprint through speeches and briefings. At a White House press briefing on May 11, 2018, Sec. Azar called eliminating PBM rebates a cornerstone of the administration's plan to lower drug prices, stating:

The other big area we have to look at is the entire system of rebates that we have with pharmacy benefit managers. We are calling into question, today, the entire structure of using rebates as the method of negotiating discounts in the pharmacy channel.<sup>21</sup>

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<sup>13</sup> <https://www.linkedin.com/in/azaralex/>.

<sup>14</sup> Adam Cancryn, *Trump's New Health Chief Takes Over Battered Agency*, *Politico*, January 24, 2018, available at <https://www.politico.com/story/2018/01/24/alex-azar-secretary-health-confirmed-trump-nominee-365471>.

<sup>15</sup> <https://www.linkedin.com/in/azaralex/>.

<sup>16</sup> Pear, *The New York Times*, Nov. 26, 2017; *Prescription For Value - Keeping Innovation Affordable For Patients*, *Manhattan Institute*, November 3, 2016, available at <https://www.manhattan-institute.org/html/prescription-value-keeping-innovation-affordable-patients-9342.html>.

<sup>17</sup> <https://www.youtube.com/watch?v=HU52aAIVj54>.

<sup>18</sup> *Id.*

<sup>19</sup> *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, Department of Health and Human Services, May 2018, available at <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>.

<sup>20</sup> *Id.* at 17.

<sup>21</sup> *Press Briefing by Press Secretary Sarah Sanders and HHS Secretary Alex Azar*, *The White House*, May 11, 2018, available at <https://www.whitehouse.gov/briefings-statements/press-briefing-press-secretary-sarah-sanders-hhs-secretary-alex-azar-051118/>.

Three days later, Sec. Azar delivered a speech at HHS headquarters repeating his criticisms of PBM rebates almost verbatim.<sup>22</sup> He also claimed that HHS has the power to eliminate PBM rebates through the regulatory process. “It is easily within our power to forbid remuneration from pharmaceutical companies—to eliminate rebates, align interests, and end the corrupt bargain that keeps driving list prices skyward.”<sup>23</sup>

Sec. Azar continued to push this line of reasoning to members of Congress. At a Senate hearing in June, Sec. Azar responded to a question from Sen. Rand Paul (R-KY) by claiming HHS has the authority to eliminate the rebate system.<sup>24</sup> He said, “The genesis of the rebate system is the rebate safe harbor and I don’t believe that anything in that gets in our way,” continuing, “I believe that by regulation we could get at it.”<sup>25</sup>

Now it appears Sec. Azar has taken action to eliminate the rebates. After HHS submitted its proposed rule to OMB on July 18, 2018, Sec. Azar continued to promote the agency’s position that eliminating PBM rebates is good for consumers and within the agency’s power. On August 20, 2018, Sec. Azar said during a conference call with reporters that the agency has the power to eliminate PBM rebates in order to lower drug prices for consumers.<sup>26</sup>

### *Fixed Price as an Alternative*

While repeatedly criticizing the PBM rebate system, Sec. Azar has supported an alternative model of fixed price agreements. The Trump administration’s blueprint for lower drug prices, which was authored by HHS, asserts that fixed price is a preferable alternative to PBM rebates.<sup>27</sup> Following the release of the blueprint, at the May 11, 2018 White House press briefing, Sec. Azar said that companies and PBMs should negotiate a fixed price for drugs rather than using rebates.<sup>28</sup> A few days later, in his speech at HHS headquarters, Sec. Azar explained:

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<sup>22</sup> Alex M. Azar II, Remarks on Drug Pricing Blueprint, Department of Health and Human Services, May 14 2018, available at <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html>.

<sup>23</sup> *Id.*

<sup>24</sup> The Cost of Prescription Drugs: Examining the President’s Blueprint ‘American Patients First’ to Lower Drug Prices, U.S. Senate Committee on Health, Education, Labor, & Pensions, June 12, 2018, available at <https://www.c-span.org/video/?446791-1/secretary-azar-testifies-prescription-drug-pricing-plan&start=5220>; <https://www.help.senate.gov/hearings/the-cost-of-prescription-drugs-examining-the-presidents-blueprint-american-patients-first-to-lower-drug-prices>.

<sup>25</sup> *Id.*

<sup>26</sup> Yasmeen Abutaleb, U.S. Health Secretary Says Agency Can Eliminate Drug Rebates, *Reuters*, August 20, 2018, available at <https://www.reuters.com/article/us-usa-drugpricing-azar/u-s-health-secretary-says-agency-can-eliminate-drug-rebates-idUSKCN1L512H>.

<sup>27</sup> American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, Department of Health and Human Services, May 2018, available at <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>.

<sup>28</sup> Press Briefing by Press Secretary Sarah Sanders and HHS Secretary Alex Azar, *The White House*, May 11, 2018, available at <https://www.whitehouse.gov/briefings-statements/press-briefing-press-secretary-sarah-sanders-hhs-secretary-alex-azar-051118/>.

We believe that the entire system of pharmacy benefit managers negotiating rebates needs to be re-examined. Right now, we're asking a pretty straightforward question: What if, instead of the current system where drug companies get paid rebates and middlemen take a cut, we just had fixed-price discounts?<sup>29</sup>

Sec. Azar also told senators during the hearing in June that fixed price is a better model for consumers than rebates.<sup>30</sup>

Unsurprisingly, Eli Lilly is also a champion of the fixed price model. In its February 2017 comment on the proposed HHS rule regarding safe harbors, Eli Lilly argued that “Expressly permitting only a fixed fee would eliminate the incentive for PBMs to prefer high-list priced products and would safeguard the integrity to the FMV calculation.”<sup>31</sup> Eli Lilly also submitted suggested edits to the existing safe harbor regulations, arguing that the current regulations should be changed from *allowing* PBMs to charge a fixed price to their customers to *requiring* PBMs to charge a fixed price.<sup>32</sup>

Eli Lilly has promoted the fixed price alternative in other venues as well. On June 14, 2018, Eli Lilly's CEO told *CNBC* that the current system of rebates and fees needs to change, and that the Trump administration's blueprint represents a positive alternative.<sup>33</sup> One month later, on July 16, 2018, Eli Lilly's trade association, PhRMA, submitted a 130-page response to the blueprint, in which the industry detailed its support for a fixed price model in lieu of the rebate system.<sup>34</sup>

### Sec. Azar's Conflicts of Interest

The recent decision by HHS to propose new safe harbor provisions that deliver benefits to Eli Lilly and other drug manufacturers suggests Sec. Azar's actions regarding the rebates may violate ethics regulations. On April 12, 2018, Sec. Azar signed his Certification of Ethics Agreement Compliance in which he stated that he had not received any waivers pursuant to

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<sup>29</sup> Alex M. Azar II, Remarks on Drug Pricing Blueprint, Department of Health and Human Services, May 14 2018, available at <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html>.

<sup>30</sup> The Cost of Prescription Drugs: Examining the President's Blueprint 'American Patients First' to Lower Drug Prices, U.S. Senate Committee on Health, Education, Labor, & Pensions, June 12, 2018, available at <https://www.c-span.org/video/?446791-1/secretary-azar-testifies-prescription-drug-pricing-plan&start=5220>; <https://www.help.senate.gov/hearings/the-cost-of-prescription-drugs-examining-the-presidents-blueprint-american-patients-first-to-lower-drug-prices>.

<sup>31</sup> Letter from Josh O'Harra, Assistant General Counsel for Eli Lilly, to Patrice Drew, Office of the Inspector General, February 14, 2017, available at <https://www.regulations.gov/document?D=HHSIG-2017-0001-0002>.

<sup>32</sup> *Id.*

<sup>33</sup> Kellie Ell, Eli Lilly CEO: 'It's Time for a Change' in the Drug Pricing System, *CNBC*, June 14, 2018, available at <https://www.cbc.com/2018/06/14/eli-lilly-ceo-its-time-for-a-change-in-the-drug-pricing-system.html>.

<sup>34</sup> Comments of the Pharmaceutical Research and Manufactures of America, PhRMA, July 16, 2018, available at [https://www.phrma.org/public-communication/rfi-comments-on-hhs-blueprint-to-lower-drug-prices-and-reduce-out-of-pocket-costs?\\_ga=2.83060182.1921767344.1535138407-1673328843.1535138407](https://www.phrma.org/public-communication/rfi-comments-on-hhs-blueprint-to-lower-drug-prices-and-reduce-out-of-pocket-costs?_ga=2.83060182.1921767344.1535138407-1673328843.1535138407).

President Trump's Executive Order 13770 exempting him from various conflict of interest laws and regulations.<sup>35</sup> The executive order requires executive branch officials to pledge, in part:

I will not for a period of 2 years from the date of my appointment participate in any particular matter involving specific parties that is directly and substantially related to my former employer or former clients, including regulations and contracts.<sup>36</sup>

The executive order clarifies that:

“Particular matter involving specific parties” shall have the same meaning as set forth in section 2641.201(h) of title 5, Code of Federal Regulations, except that it shall also include any meeting or other communication relating to the performance of one's official duties with a former employer or former client, unless the communication applies to a particular matter of general applicability and participation in the meeting or other event is open to all interested parties.

The Code of Federal Regulations and the laws on which they are based generally define “particular matter” in relation to former government employees.<sup>37</sup> The president's executive order, however, specifically extends the definition beyond the statutory definition to include communications between a current government employee and his or her former employer about any matter. By signing this ethics agreement, Sec. Azar agreed to forgo any contact with his former employer unless it involved a meeting with a wide variety of parties.

If Sec. Azar contacted Eli Lilly or worked with the company's representatives on the proposed safe harbor rule, he may have violated the terms of Executive Order 13770. The executive order directs each agency's designated ethics official to administer the executive order and directs the Attorney General to investigate any violations.<sup>38</sup> CfA, therefore, requests that you open an investigation into Sec. Azar's conduct pursuant to Executive Order 13770 4(a)(2)).

### *Congressional Scrutiny*

CfA is not alone in questioning Sec. Azar's conduct concerning this particular rule. On August 17, 2018, Sen. Elizabeth Warren (D-MA) and Sen. Tina Smith (D-MN) sent a letter to Sec. Azar questioning his motivations for criticizing PBM rebates, writing:

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

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<sup>35</sup> Alex Michael Azar II, *Certification of Ethics Agreement Compliance*, *Office of Government Ethics*, April 12, 2018, available at [https://extapps2.oge.gov/201/Presiden.nsf/PAS+Index/E5121F1B97BCBE0485258273002C1E18/\\$FILE/Azar,%20Alex%20EA%20Certification%201%20of%201.pdf](https://extapps2.oge.gov/201/Presiden.nsf/PAS+Index/E5121F1B97BCBE0485258273002C1E18/$FILE/Azar,%20Alex%20EA%20Certification%201%20of%201.pdf).

<sup>36</sup> Executive Order 13770 § 1(6), available at <https://www.whitehouse.gov/presidential-actions/executive-order-ethics-commitments-executive-branch-appointees/>.

<sup>37</sup> 18 U.S. Code § 207(i)(3); 5 C.F.R. § 2641.201(h)(2).

<sup>38</sup> Executive Order 13770 § 4(a)(2); § 5(c).

Americans mad at” these same middlemen in order to deflect blame from themselves. 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.<sup>39</sup>

Senators Warren and Smith also pressed Sec. Azar to turn over any communications between him or his staff and the pharmaceutical industry.<sup>40</sup> It is unclear if Sec. Azar has responded to the letter.

Additionally, Sen. Orrin Hatch (R-UT) and Rep. Greg Walden (R-OR) sent a letter OMB expressing concern about the safe harbor rule’s effect on consumers. They urged OMB Director Mulvaney to subject the rule to a robust economic analysis to ensure “that any eventual change is in the best interest of patients, the federal programs that provide care for them, and the taxpayers who support them.”<sup>41</sup>

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<sup>39</sup> Letter from Sen. Elizabeth Warren (D-MA) and Sen. Tina Smith (D-MN) to Sec. Alex Azar, August 17, 2018, available at <https://www.warren.senate.gov/imo/media/doc/2018-08-17%20Letter%20to%20Azar%20from%20Senators%20Warren%20and%20Smith.pdf>.

<sup>40</sup> *Id.*

<sup>41</sup> Letter from Sen. Orrin Hatch (R-UT) and Rep. Greg Walden (R-OR) to Mick Mulvaney, Director of the Office of Management and Budget, August 9, 2018, available at <https://www.finance.senate.gov/imo/media/doc/8.9.2018%20OGH%20and%20Walden%20to%20Director%20Mulyaney%20Letter.pdf>.

### **Conclusion**

The intensity of both Sec. Azar's and Eli Lilly's support for the proposed safe harbor provision calls into question Sec. Azar's motivation for seeking to implement the proposed rule. While Sec. Azar claims the rule is in the best interests of consumers, the public deserves to know whether he is actually supporting the rule to benefit his former employer. The rule in question would unequivocally provide a substantial benefit to Eli Lilly, and the company has directly lobbied HHS to implement the rule. Members of Congress, however, question whether the rule would provide any real benefit to the general public. Therefore, CfA respectfully requests that you investigate Sec. Azar's relationship with his former employer, Eli Lilly, to determine whether the relationship played any undue role the Department's recent decision to propose new safe harbor provisions.

Sincerely,

A handwritten signature in blue ink, appearing to read "Dan E Stevens", with a long horizontal flourish extending to the right.

Daniel E. Stevens  
Executive Director