

C A M P A I G N F O R

ACCOUNTABILITY

August 30, 2018

By email: FOIARequest@hhs.gov

Michael Marquis
Freedom of Information Act Officer
Department of Health and Human Services
Hubert H. Humphrey Building, Room 729H
200 Independence Avenue SW
Washington, DC 20201

Re: Freedom of Information Request

Dear Mr. Marquis:

Campaign for Accountability (“CfA”) makes this request for records pursuant to the Freedom of Information Act (“FOIA”), 5 U.S.C. § 552 et seq., and Department of Health and Human Services (“HHS”) implementing regulations, 45 C.F.R. Part 5.

Specifically, CfA requests that HHS produce the following within 20 business days:

- All communications exchanged between any employee or representative of the Office of the Secretary, including but not limited to, Sec. Alex Azar, and any employee or representative of Eli Lilly and Company, including, but not limited, any of the following lobbyists that work for the company:¹
 - Catherine Hinckley
 - Harrison Cook
 - Anjulen Anderson
 - David Talbot
 - Jesse Sevcik
 - Jesse Price
 - Eric Steiner
 - Jennifer Romans
 - Paul Burkhead
 - Joseph Kelly
 - Sonya Sotak Elling
 - Sara Kyle
 - Robert Wood
 - Dave Boyer
 - Brent Del Monte

¹ Client Name Search: Eli Lilly, 2018 First and Second Quarters, Lobbying Disclosure Act Database, Secretary of the Senate, Office of Public Records, *accessed* August 29, 2018.

- Robb Walton
- John Stone
- Matthew Hoffman
- Phil Cox
- Larissa Martin
- C. Stewart Verdery
- Andrew Howell
- Kimberly Ellis
- Rich Thomas
- Ashley Hoy
- John Mulligan
- Kate Mills
- T.A. Hawks
- Raissa Downs
- Jennifer Young
- Michelle Easton
- Elizabeth Murray
- Charlotte Ivancic
- Pamela Smith
- Robert A. Russell
- Kyle Simmons
- Stephanie Silverman
- Natascha Cumberlidge
- Michael Spira
- Tyler Roberts
- Claire Badger
- Melissa Bonicelli

Please provide all responsive records from January 24, 2018, to the date the search is conducted.

By way of background, on July 18, 2018, HHS submitted a proposed rule to the Office of Management and Budget (“OMB”) that would curb the rebates that pharmacy benefit managers (“PBMs”) negotiate with drug companies.² Eli Lilly, where Sec. Azar worked for a decade until January 2017, submitted comments to HHS urging the agency to tackle PBM rebates.³ Sec. Azar has supported the drug industry’s calls to limit PBM rebates – both while he was the president of Eli Lilly and more recently as the Secretary of HHS.⁴

² 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>.

³ 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>; 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/>.

⁴ 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->

On August 28, 2018 CfA called on HHS officials to investigate Sec. Azar's relationship with Eli Lilly and determine whether his support for the proposed rule violated President Trump's Executive Order prohibiting government employees from contacting their former employers about official government business for two years.⁵ In response to CfA's complaint, HHS officials told the healthcare publication *STAT*:

Secretary Azar fully disclosed his former employment with Eli Lilly to the Senate, the U.S. Office of Government Ethics, and the HHS Ethics Office prior to his appointment at HHS. He has been completely transparent and agreed to recuse as required by the Ethics Pledge. Under the guidance of the HHS Ethics Office, he has instituted a robust screening arrangement to help ensure that, as required by the Ethics Pledge, he does not participate in any particular matters where his former employer is a party to the matter, or a party representative.⁶

What HHS officials failed to address, however, is whether Sec. Azar communicated with employees or representatives of Eli Lilly about the proposed rule to rein in PBM rebates. CfA, therefore, seeks the requested records to determine whether and to what extent Sec. Azar communicated with representatives of his former employer about the proposed policy change.

In addition to the records requested above, please provide records reflecting the processing of this request, including any tracking sheets; records sufficient to identify search terms used, and locations and custodians searched. If your agency uses FOIA questionnaires or certifications completed by individual custodians or components to determine whether they possess responsive materials or to describe how they conducted searches, we also request any such records prepared in connection with the processing of this request.

CfA seeks all responsive records regardless of format, medium, or physical characteristics. In conducting your search, please understand the terms "record," "document," and "information" in their broadest sense, to include any written, typed, recorded, graphic, printed, or audio material of any kind. We seek records of any kind, including electronic records, audiotapes, videotapes, and photographs, as well as letters, emails, facsimiles, telephone messages, voice mail messages and transcripts, notes, or minutes of any meetings, telephone conversations or discussions. Our request includes any attachments to these records. No category of material should be omitted from search, collection, and production.

[keeping-innovation-affordable-patients-9342.html](https://www.whitehouse.gov/briefings-statements/press-briefing-press-secretary-sarah-sanders-hhs-secretary-alex-azar-051118/); 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/>.

⁵ Letter from Daniel Stevens, Executive Director of Campaign for Accountability, to Daniel R. Levinson, Inspector General of HHS, and Elizabeth J. Fischman, Designated Agency Ethics Official of HHS, August 28, 2018, available at <https://campaignforaccountability.org/watchdog-calls-for-investigation-into-hhs-secretary-azars-relationship-with-former-employer-eli-lilly-following-proposed-rule-change/>.

⁶ Ed Silverman, *Watchdog Asks Ethics Officials to Probe Azar Over Industry Ties and Views on Rebates*, *STAT*, August 28, 2018, available at <https://www.statnews.com/pharmalot/2018/08/28/watchdog-ethics-azar-rebates/>.

Please search all records regarding agency business. Please do not exclude searches of files or emails in the personal custody of agency officials, such as personal email accounts. Records of official business conducted using unofficial systems or stored outside of official files is subject to the Federal Records Act and FOIA.⁷ It is not adequate to rely on policies and procedures that require officials to move such information to official systems within a certain period of time; CfA has a right to access those files even if they have not yet been moved to official systems or if officials have, through negligence or willfulness, failed to meet their obligations.⁸

In addition, please note that in conducting a “reasonable search” as required by law, HHS must employ the most up-to-date technologies and tools available, in addition to searches by individual custodians likely to have responsive information. Recent technology may have rendered HHS’s prior FOIA practices unreasonable. In light of the government-wide requirements to manage information electronically by the end of 2016, it is no longer reasonable to rely exclusively on custodian-driven searches.⁹ Furthermore, agencies that have adopted the National Archives and Records Agency (NARA) Capstone program, or similar policies, now maintain emails in a form that is reasonably likely to be more complete than individual custodians’ files. For example, a custodian may have deleted a responsive email from his or her email program, but HHS’s archiving tools would capture that email under Capstone. Accordingly, CfA insists that HHS use the most up-to-date technologies to search for responsive information and take steps to ensure that the most complete repositories of information are searched. CfA is available to work with HHS to craft appropriate search terms. However, custodian searches are still required; agencies may not have direct access to files stored in .PST files, outside of network drives, in paper format, or in personal email accounts.

Under the FOIA Improvement Act of 2016, agencies must adopt a presumption of disclosure, withholding information “only if . . . disclosure would harm an interest protected by an exemption” or “disclosure is prohibited by law.”¹⁰ If it is your position that any portion of the requested records is exempt from disclosure, CfA requests that you provide an index of those documents as required under *Vaughn v. Rosen*, 484 F.2d 820 (D.C. Cir. 1973), *cert. denied*, 415 U.S. 977 (1974). As you are aware, a *Vaughn* index must describe each document claimed as exempt with sufficient specificity “to permit a reasoned judgment as to whether the material is

⁷ See *Competitive Enterprise Institute v. Office of Science & Tech. Policy*, 827 F.3d 145, 149—150 (D.C. Cir. 2016); cf. *Judicial Watch, Inc. v. Kerry*, 844 F.3d 952, 955—956 (D.C. Cir. 2016).

⁸ See *Competitive Enterprise Institute v. Office of Science & Tech. Policy*, ___, slip op. at 8 (D.D.C. Dec. 12, 2016) (“The Government argues that because the agency had a policy requiring [the official] to forward all of his emails from his [personal] account to his business email, the [personal] account only contains duplicate agency records at best. Therefore, the Government claims that any hypothetical deletion of the [personal account] emails would still leave a copy of those records intact in [the official’s] work email. However, policies are rarely followed to perfection by anyone. At this stage of the case, the Court cannot assume that each and every work-related email in the [personal] account was duplicated in [the official’s] work email account.” (citations omitted)).

⁹ Presidential Memorandum – Managing Government Records, 76 Fed. Reg. 75,423 (Nov. 28, 2011), available at <https://obamawhitehouse.archives.gov/the-press-office/2011/11/28/presidential-memorandum-managing-government-records>; Office of Mgmt. & Budget, Exec. Office of the President, Memorandum for the Heads of Executive Departments & Independent Agencies, “Managing Government Records Directive,” M-12-18 (Aug. 24, 2012), available at <https://www.archives.gov/files/records-mgmt/m-12-18.pdf>.

¹⁰ *FOIA Improvement Act of 2016* § 2 (Pub. L. No. 114–185).

actually exempt under FOIA.”¹¹ Moreover, the *Vaughn* index “must describe *each* document or portion thereof withheld, and for *each* withholding it must discuss the consequences of disclosing the sought-after information.”¹² Further, “the withholding agency must supply ‘a relatively detailed justification, specifically identifying the reasons why a particular exemption is relevant and correlating those claims with the particular part of a withheld document to which they apply.’”¹³

In the event some portions of the requested records are properly exempt from disclosure, please disclose any reasonably segregable non-exempt portions of the requested records. If it is your position that a document contains non-exempt segments, but that those non-exempt segments are so dispersed throughout the document as to make segregation impossible, please state what portion of the document is non-exempt, and how the material is dispersed throughout the document.¹⁴ Claims of nonsegregability must be made with the same degree of detail as required for claims of exemptions in a *Vaughn* index. If a request is denied in whole, please state specifically that it is not reasonable to segregate portions of the record for release.

To ensure that this request is properly construed, that searches are conducted in an adequate but efficient manner, and that extraneous costs are not incurred, CfA welcomes an opportunity to discuss its request with HHS before you undertake your search or incur search or duplication costs. By working together at the outset, CfA and HHS can decrease the likelihood of costly and time-consuming litigation in the future.

Where possible, please provide responsive material in electronic format via email at dstevens@campaignforaccountability.org. Alternatively, our mailing address is Campaign for Accountability, 611 Pennsylvania Avenue SE, #337, Washington DC 20003. If it will accelerate the release, please also provide responsive material on rolling basis.

Fee Waiver Request

In accordance with 5 U.S.C. § 552(a)(4)(A)(iii) and 45 C.F.R. § 5.54, CfA requests a waiver of fees associated with processing this request for records. The subject of this request concerns the operations of the federal government, and the disclosures will likely contribute significantly to a better understanding of relevant government procedures by the general public. Moreover, the request is primarily and fundamentally for non-commercial purposes. 5 U.S.C. § 552(a)(4)(A)(iii).¹⁵

CfA requests a waiver of fees because disclosure of the requested information is in the public interest because it is “likely to contribute significantly to public understanding of the operations or activities of the government.”¹⁶ The disclosure of the information sought under this request

¹¹ *Founding Church of Scientology v. Bell*, 603 F.2d 945, 949 (D.C. Cir. 1979).

¹² *King v. U.S. Dep’t of Justice*, 830 F.2d 210, 223—24 (D.C. Cir. 1987) (emphasis in original).

¹³ *Id.* at 224 (citing *Mead Data Central, Inc. v. U.S. Dep’t of the Air Force*, 566 F.2d 242, 251 (D.C. Cir. 1977)).

¹⁴ *Mead Data Central*, 566 F.2d at 261.

¹⁵ *See, e.g., McClellan Ecological Seepage Situation v. Carlucci*, 835 F.2d 1282, 1285 (9th Cir. 1987).

¹⁶ 45 C.F.R. § 5.54(a).

will document and reveal the operations of the federal government, including how officials conduct the public's business.

As noted above, Sec. Azar joined HHS after working for Eli Lilly – one of the largest pharmaceutical companies in the country – which stands to benefit from the proposed rule. The records CfA seeks will help the public understand whether Sec. Azar worked with his former employer on shepherd a favored policy provision through HHS.

This request is primarily and fundamentally for non-commercial purposes. As a 501(c)(3) organization, CfA does not have a commercial purpose and the release of the information requested is not in CfA's financial interest. CfA is committed to protecting the public's right to be aware of the activities of government officials and to ensuring the integrity of those officials. CfA uses a combination of research, litigation, and advocacy to advance its mission. CfA will analyze the information responsive to this request, and will share its analysis with the public, either through memoranda, reports, or press releases. In addition, CfA will disseminate any documents it acquires from this request to the public through its website, www.campaignforaccountability.org.

Accordingly, CfA qualifies for a fee waiver.

News Media Fee Waiver Request

CfA also asks that it not be charged search or review fees for this request because CfA qualifies as a "representative of the news media" pursuant to the FOIA and HHS regulation 45 C.F.R. § 5.53. In *Nat'l Sec. Archive v. U.S. Dep't of Defense*, 880 F.2d 1381, 1386 (D.C. Cir. 1989), the Court of Appeals for the District of Columbia Circuit found the National Security Archive was a representative of the news media under the FOIA, relying on the FOIA's legislative history, which indicates the phrase "representative of the news media" is to be interpreted broadly; "[i]t is critical that the phrase 'representative of the news media' be broadly interpreted if the act is to work as expected . . . In fact, *any person or organization which regularly publishes or disseminates information to the public . . . should qualify for waivers as a 'representative of the news media.'*" 132 Cong. Rec. S14298 (daily ed. Sept. 30, 1986) (emphasis added), cited in *id.* CfA meets this test.

CfA routinely and systematically "gathers information of potential interest to a segment of the public, uses its editorial skills to turn raw materials into a distinct work, and distributes that work to an audience."¹⁷ It does so by regularly posting documents it receives through open records laws, including the FOIA, to its website,¹⁸ analyzing those documents, and publishing reports,

¹⁷ 45 C.F.R. § 5.3; 5 U.S.C. § 552(a)(4)(A)(ii)(III).

¹⁸ Letter from Daniel Stevens, Executive Director, Campaign for Accountability, to Thomas B. Pahl, Acting Director, Bureau of Consumer Protection, Federal Trade Commission (July 19, 2017), *available at* <https://campaignforaccountability.org/work/ftc-solar-complaint/>; Letter from Katie O'Connor, Legal Counsel, Campaign for Accountability, to Margaret Moore, Travis County District Attorney (Sept. 26, 2017), *available at* <https://www.documentcloud.org/public/search/projectid:35338-CfA-Letter-to-Travis-County-DA-9-26-17>.

letters, and further requests based those documents.¹⁹ Based on its publication activities, CfA qualifies as a “representative of the news media” under the FOIA and agency regulations.

Conclusion

CfA looks forward to working with HHS on this request. If you do not understand any part of this request, have any questions, or foresee any problems in fully releasing the requested records, please contact me at 202-780-5750. Further, if CfA’s request for a fee waiver is not granted in full, please contact me immediately upon making such a determination.

Thank you for your assistance.

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

¹⁹ Campaign for Accountability, [Utah Commission for the Stewardship of Public Lands](https://campaignforaccountability.org/work/utah-commission-stewardship-public-lands/), Sept. 7, 2017, available at <https://campaignforaccountability.org/work/utah-commission-stewardship-public-lands/>; Campaign for Accountability, [Documenting Discrimination](https://campaignforaccountability.org/work/documenting-discrimination/), July 2016, available at <https://campaignforaccountability.org/work/documenting-discrimination/>; CfA Complaints Against the Heidi Group, Sept. 26, 2017, available at <https://campaignforaccountability.org/work/cfa-complaints-against-the-heidi-group/>.