



March 12, 2018

VIA ONLINE PORTAL

Sarah Kotler
Director, Division of Freedom of Information Office
Executive Secretariat Office of the Commissioner
Food and Drug Administration
12420 Parklawn Drive
Room 1020
Rockville, MD 20857

Re: Freedom of Information Act Request

Dear Ms. Kotler:

Pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, and the implementing regulations for the Food and Drug Administration (FDA), 21 C.F.R. Part 20, American Oversight makes the following request for records.

The nationwide epidemic of opioid abuse continues to worsen as the Centers for Disease Control and Prevention (CDC) have reported a continued increase in the dramatic number of U.S. opioid overdose deaths.¹ The President's Commission on Combating Drug Addiction and the Opioid Crisis ("the President's Opioid Commission") has recognized that opioid manufacturers, through their marketing and promotion of opioids, have contributed to the current crisis.² The President's Opioid Commission further identified the inadequate oversight of opioid drugs by the FDA as another contributor to the crisis.³

State and local governments have brought hundreds of lawsuits against opioid manufacturers alleging negligent distribution, misleading marketing and other wrongdoing.⁴ Opioid manufacturers

¹ CENTERS FOR DISEASE CONTROL AND PREVENTION, *Drug Overdose Deaths in the United States Continue to Increase in 2016*, Aug. 30, 2017, <https://www.cdc.gov/drugoverdose/epidemic/index.html>.

² THE PRESIDENT'S COMMISSION ON COMBATING DRUG ADDICTION AND THE OPIOID CRISIS, FINAL REPORT, Nov. 1, 2017, https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.

³ *Id.*

⁴ Erika Fry, *Big Pharma Is Getting Hit with a Huge Wave of Opioid Suits*, FORTUNE, Sep. 27, 2017, <http://fortune.com/2017/09/27/big-pharma-opioid-lawsuits/>; Alana Semuels, *Are Pharmaceutical Companies to Blame for the Opioid Epidemic?*, THE ATLANTIC, Jun. 2, 2017,



and distributors have reportedly responded to these government attempts to hold them accountable with political contributions and lobbying.⁵ And, FDA Commissioner Scott Gottlieb, who has received payments from opioid manufacturers and distributors,⁶ has previously publicly criticized law enforcement efforts to crack down of the industry's harmful practices.⁷

American Oversight seeks records to determine whether the opioid manufacturing and distribution industry is influencing federal policy related to this public health crisis.

Requested Records

American Oversight requests that the FDA produce the following within twenty business days:

All records reflecting communications (including but not limited to emails, email attachments, text messages, chat or Slack messages, telephone call logs, calendar invitations/entries, meeting notices, meeting agendas, informational material, draft legislation, talking points, any handwritten or electronic notes taken during any responsive communications, summaries of any responsive communications, or other materials) between (a) any FDA political appointee* or member of the Senior Executive Service (SES) and (b) any employee or representative of the following entities and their subsidiaries and affiliates:

1. McKesson Corporation;
2. Purdue Pharma L.P. (including any communications from, to or with J. David Haddox);
3. Endo Health Solutions Inc. and/or Endo Pharmaceuticals Inc.;
4. Cardinal Health, Inc.;
5. Johnson & Johnson and/or Janssen Pharmaceutica NV;
6. Mallinckrodt Pharmaceuticals;
7. AmerisourceBergen Drug Corporation;
8. Arnold & Porter Kaye Scholer LLP (including emails from any individual with an email address ending in @apks.com or @arnoldporter.com);
9. Quinn Emanuel Urquhart & Sullivan, LLP (including emails from any individual with an email address ending in @quinnemmanuel.com);

<https://www.theatlantic.com/business/archive/2017/06/lawsuit-pharmaceutical-companies-opioids/529020/>.

⁵ Julianna Goldman & Laura Strickler, *Drug Companies Flex Lobbying Muscle in Fight Against State Opioid Lawsuits*, CBS NEWS (Jan. 25, 2018, 7:45pm), <https://www.cbsnews.com/news/drug-companies-flex-lobbying-muscle-in-fight-against-state-opioid-lawsuits/>.

⁶ Lee Fang, *Donald Trump's Pick to Oversee Big Pharma Is Addicted to Opioid-Industry Cash*, THE INTERCEPT (Apr. 4, 2017, 2:15pm), <https://theintercept.com/2017/04/04/scott-gottlieb-opioid/>.

⁷ Scott Gottlieb, *The DEA's War on Pharmacies—and Pain Patients*, Am. Enter. Inst., March 23, 2012, <https://www.aei.org/publication/the-deas-war-on-pharmacies-and-pain-patients/>.

10. Williams & Connolly LLP (including emails from any individual with an email address ending in @wc.com); or
11. Covington & Burling LLP (including emails from any individual with an email address ending in @cov.com).

*“Political appointee” should be understood as any person who is a Presidential Appointee with Senate Confirmation (PAS), a Presidential Appointee (PA), a Non-career SES, any Schedule C employees, or any persons hired under Temporary Non-career SES Appointments, Limited Term SES Appointments, or Temporary Transitional Schedule C Appointments.

Please provide all responsive records from January 20, 2017, to the date the search is conducted.

In addition to the records requested above, American Oversight also requests records describing the processing of this request, including records sufficient to identify search terms used and locations and custodians searched and any tracking sheets used to track the processing of this request. If FDA 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.

American Oversight 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.**

Please search all records regarding agency business. **You may not exclude searches of files or emails in the personal custody of your 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.⁸ **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; American Oversight has a right to records contained in those files even if material has not yet been moved to official systems or if officials have, through negligence or willfulness, failed to meet their obligations.**⁹

⁸ See *Competitive Enter. Inst. v. Office of Sci. & Tech. Policy*, 827 F.3d 145, 149–50 (D.C. Cir. 2016); cf. *Judicial Watch, Inc. v. Kerry*, 844 F.3d 952, 955–56 (D.C. Cir. 2016).

⁹ See *Competitive Enter. Inst. v. Office of Sci. & Tech. Policy*, No. 14-cv-765, 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

In addition, please note that in conducting a “reasonable search” as required by law, you 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 FDA’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.**¹⁰ 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 FDA’s archiving tools would capture that email under Capstone. Accordingly, American Oversight insists that FDA 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. American Oversight is available to work with you 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.”¹¹ If it is your position that any portion of the requested records is exempt from disclosure, American Oversight 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 actually exempt under FOIA.”¹² 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.”¹³ Further, “the withholding agency must supply ‘a relatively detailed

[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).

¹⁰ Presidential Memorandum—Managing Government Records, 76 Fed. Reg. 75,423 (Nov. 28, 2011), <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), <https://www.archives.gov/files/records-mgmt/m-12-18.pdf>.

¹¹ FOIA Improvement Act of 2016 § 2 (Pub. L. No. 114-185).

¹² *Founding Church of Scientology v. Bell*, 603 F.2d 945, 949 (D.C. Cir. 1979).

¹³ *King v. U.S. Dep’t of Justice*, 830 F.2d 210, 223–24 (D.C. Cir. 1987) (emphasis in original).

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.”¹⁴

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.¹⁵ 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.

You should institute a preservation hold on information responsive to this request. American Oversight intends to pursue all legal avenues to enforce its right of access under FOIA, including litigation if necessary. Accordingly, FDA is on notice that litigation is reasonably foreseeable.

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, American Oversight welcomes an opportunity to discuss its request with you before you undertake your search or incur search or duplication costs. By working together at the outset, American Oversight and FDA can decrease the likelihood of costly and time-consuming litigation in the future.

Where possible, please provide responsive material in electronic format by email or in PDF or TIF format on a USB drive. Please send any responsive material being sent by mail to American Oversight, 1030 15th Street, NW, Suite B255, Washington, DC 20005. If it will accelerate release of responsive records to American Oversight, please also provide responsive material on a rolling basis.

Fee Waiver Request

In accordance with 5 U.S.C. § 552(a)(4)(A)(iii) and 21 C.F.R. § 20.46(e), American Oversight 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 to a better understanding of government operations by the general public in a significant way.¹⁶ Moreover, the request is primarily and fundamentally for non-commercial purposes.¹⁷

American Oversight requests a waiver of fees because disclosure of the requested information “[i]s in the public interest because it is likely to contribute significantly to public understanding of the

¹⁴ *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)).

¹⁵ *Mead Data Central*, 566 F.2d at 261.

¹⁶ 21 C.F.R. § 20.46(b).

¹⁷ 21 C.F.R. § 20.46(c).

operations or activities of the Government.”¹⁸ The disclosure of the information sought under this request will document and reveal the activities of the federal government, including whether an agency is communicating with, and being influenced by, opioid manufacturers and distributors in formulating policy to respond to a nationwide public health crisis. And, as described in more detail below, American Oversight’s website and social media accounts demonstrate its ability and intention to effectively convey information received to the public.

This request is primarily and fundamentally for non-commercial purposes.¹⁹ As a 501(c)(3) nonprofit, American Oversight does not have a commercial purpose and the release of the information requested is not in American Oversight’s financial interest. American Oversight’s mission is to promote transparency in government, to educate the public about government activities, and to ensure the accountability of government officials. American Oversight uses the information gathered, and its analysis of it, to educate the public through reports, press releases, or other media. American Oversight also makes materials it gathers available on its public website and promotes their availability on social media platforms, such as Facebook and Twitter.²⁰ American Oversight has demonstrated its commitment to the public disclosure of documents and creation of editorial content. For example, after receiving records regarding an ethics waiver received by a senior DOJ attorney,²¹ American Oversight promptly posted the records to its website and published an analysis of what the records reflected about DOJ’s process for ethics waivers.²² As another example, American Oversight has a project called “Audit the Wall,” where the organization is gathering and analyzing information and commenting on public releases of information related to the administration’s proposed construction of a barrier along the U.S.-Mexico border.²³

Accordingly, American Oversight qualifies for a fee waiver.

Conclusion

We share a common mission to promote transparency in government. American Oversight looks forward to working with FDA 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

¹⁸ 21 C.F.R. § 20.46(a)(1).

¹⁹ 21 C.F.R. § 20.46(c).

²⁰ American Oversight currently has approximately 11,800 page likes on Facebook and 40,900 followers on Twitter. American Oversight, FACEBOOK, <https://www.facebook.com/weareoversight/> (last visited Mar. 12, 2018); American Oversight (@weareoversight), TWITTER, <https://twitter.com/weareoversight> (last visited Mar. 12, 2018).

²¹ *DOJ Civil Division Response Noel Francisco Compliance*, AMERICAN OVERSIGHT, <https://www.americanoversight.org/document/doj-civil-division-response-noel-francisco-compliance>.

²² *Francisco & the Travel Ban: What We Learned from the DOJ Documents*, AMERICAN OVERSIGHT, <https://www.americanoversight.org/francisco-the-travel-ban-what-we-learned-from-the-doj-documents>.

²³ *Audit the Wall*, AMERICAN OVERSIGHT, www.auditthewall.org.

Dan McGrath at foia@americanoversight.org or 202-897-4213. Also, if American Oversight's request for a fee waiver is not granted in full, please contact us immediately upon making such a determination.

Sincerely,

A handwritten signature in blue ink, appearing to read "Austin R. Evers", with a long horizontal flourish extending to the left.

Austin R. Evers
Executive Director
American Oversight