



February 27, 2019

VIA ONLINE PORTAL

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

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 of the Food and Drug Administration (FDA), 21 C.F.R. Part 20, American Oversight makes the following request for records. In particular, American Oversight seeks records that will inform the American public of how senior government officials are spending their time and resources.

Requested Records

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

1. All calendars or calendar entries for Scott Gottlieb, including any calendars maintained on his behalf (e.g., by an administrative assistant). American Oversight requests that Mr. Gottlieb's calendars be produced in a format that includes all invitees, any notes, and all attachments.
2. All calendars or calendar entries for Paul Howard, including any calendars maintained on his behalf (e.g., by an administrative assistant). For Mr. Howard's calendars, American Oversight does not need the records to be produced in a format that includes all invitees, notes, and attachments. Rather, American Oversight seeks only a format that includes dates, times, and meeting titles, such as the "Daily" format used by Microsoft Outlook or a similar format.

Please provide all responsive records from the date each custodian joined FDA through the date the search is conducted.



Please do not limit your search to Outlook calendars. We request the production of any document—paper or electronic, whether on government-issued or personal devices—used to track or coordinate how these individuals allocate their time on agency business.

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 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.

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 are subject to the Federal Records Act and FOIA.¹ **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.**²

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

¹ 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).

² 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 [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)).

custodians likely to have responsive information. Recent technology may have rendered your agency'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.**³ Furthermore, agencies that have adopted the National Archives and Records Administration (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 your agency's archiving tools would capture that email under Capstone. Accordingly, American Oversight insists that your agency 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."⁴ 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."⁵ 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."⁶ 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.'"⁷

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

³ 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>.

⁴ FOIA Improvement Act of 2016 § 2 (Pub. L. No. 114-185).

⁵ *Founding Church of Scientology v. Bell*, 603 F.2d 945, 949 (D.C. Cir. 1979).

⁶ *King v. U.S. Dep't of Justice*, 830 F.2d 210, 223-24 (D.C. Cir. 1987) (emphases in original).

⁷ *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)).

document.⁸ 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, you are 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 hopes to 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 your agency's implementing regulations, 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 public understanding of those operations. Moreover, the request is primarily and fundamentally for non-commercial purposes.

American Oversight 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."⁹ The disclosure of the information sought under this request will document and reveal the activities of the federal government, including how high-ranking agency personnel are using their official time, with whom they are meeting to discuss official agency business, and whether and to what extent external interests are influencing administration policy decisions. For example, in one prior case, American Oversight successfully obtained Education Secretary DeVos's calendar entries, which revealed DeVos's frequent absences from office, staffing choices, and the influence of charter schools and for-profit colleges on the Education Department.¹⁰ In this case, the requested calendar entries would "contribute

⁸ *Mead Data Central*, 566 F.2d at 261.

⁹ 5 U.S.C. § 552a(4)(A)(iii).

¹⁰ See *Influence & Access at the Department of Education*, AMERICAN OVERSIGHT, <https://www.americanoversight.org/investigation/influence-access-at-the-department-of-education>; <https://www.americanoversight.org/unexcused-absences-devos>; *Unexcused Absences: DeVos*

significant to public understanding of the operations and activities” of officials leading your agency.¹¹ And, as described in more detail below, American Oversight’s website and social media accounts demonstrate its ability and intention to effectively convey information to the public.

This request is primarily and fundamentally for non-commercial purposes.¹² 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.¹³ 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,¹⁴ 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.¹⁵ 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.¹⁶

Accordingly, American Oversight qualifies for a fee waiver.

Calendars Show Frequent Days Off, AMERICAN OVERSIGHT, *Betsy DeVos’s School Schedule Shows Focus on Religious and Non Traditional Schools*, N.Y. TIMES, Oct. 27, 2017, <https://www.nytimes.com/2017/10/27/us/politics/betsy-devos-work-schedule-education.html>; *What Betsy DeVos’s Schedule Tells Us About Her Agenda*, CNN (Oct. 29, 2017 12:22 PM), <http://www.cnn.com/2017/10/28/politics/devos-schedules-education/index.html>.

¹¹ 5 U.S.C. § 552a(4)(A)(iii).

¹² *Id.*

¹³ American Oversight currently has approximately 12,200 page likes on Facebook and approximately 50,700 followers on Twitter. American Oversight, FACEBOOK, <https://www.facebook.com/weareoversight/> (last visited Feb. 26, 2019); American Oversight (@weareoversight), TWITTER, <https://twitter.com/weareoversight> (last visited Feb. 26, 2019).

¹⁴ *DOJ Records Related to Solicitor General Noel Francisco’s Recusal*, AMERICAN OVERSIGHT, <https://www.americanoversight.org/document/doj-civil-division-response-noel-francisco-compliance>.

¹⁵ *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>.

¹⁶ *Audit the Wall*, AMERICAN OVERSIGHT, <https://www.americanoversight.org/investigation/audit-the-wall>.

Conclusion

We share a common mission to promote transparency in government. American Oversight looks forward to working with your agency 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 Katherine Anthony at foia@americanoversight.org or (202) 897-3918. 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 that reads "Austin R. Evers". The signature is fluid and cursive, with a long horizontal stroke extending to the left.

Austin R. Evers
Executive Director
American Oversight