



October 21, 2020

VIA ONLINE PORTAL

Sarah Kotler
Freedom of Information Officer
Food and Drug Administration
5630 Fishers Lane, Room 1035
Rockville, MD. 20857
Via Online Portal

Re: Freedom of Information Act Request

Dear FOIA Officers:

Pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, and the implementing regulations of your agency, American Oversight makes the following request for records.

On September 13, 2020, Albert Bourla, the CEO of Pfizer, said there is a “good chance” the company will know if its COVID-19 vaccine is effective by end of October, but the extent to which Americans will be able to receive the vaccine before 2021 is dependent on federal regulators.¹ While the company has frequently touted the end of October deadline,² it recently stated the vaccine will not be ready until mid-to-late November.³ Pfizer is one of the leading contenders in the vaccine race, and has reportedly been in communication with the White House objecting to more stringent standards for the emergency authorization of the vaccine.⁴

¹ Melissa Quinn, *Pfizer CEO Says Company Will Know if Vaccine Works by End of October*, CBS News (Sept. 14, 2020, 7:04 AM), <https://www.cbsnews.com/news/covid-vaccine-effectiveness-october-pfizer/>.

² Joe Palca, *Pfizer Seems to Lead Coronavirus Vaccine Development Race. How Did It Get Ahead?*, NPR (Oct. 15, 2020, 4:06 PM), <https://www.npr.org/2020/10/15/924150224/pfizer-seems-to-lead-coronavirus-vaccine-development-race-how-did-it-get-ahead>.

³ Richard Harris, *Pfizer COVID-19 Vaccine Won't Be Ready By Election Day*, NPR (Oct. 16, 2020, 12:15 PM), <https://www.npr.org/sections/coronavirus-live-updates/2020/10/16/924502362/pfizer-covid-19-vaccine-wont-be-ready-by-election-day>.

⁴ Adam Cancryn, *White House Cited Drug Companies' Objections in Overruling FDA's Vaccine Standards*, Politico (Oct. 5, 2020, 7:58 PM), <https://www.politico.com/news/2020/10/05/white-house-fda-vaccine-standards-426605>.



American Oversight seeks records with the potential to shed light on whether and to what extent Pfizer was coordinating with the White House and top agency officials regarding its plan for seeking authorization for its vaccine, including the timeline for doing so and standards that would apply.

Requested Records

American Oversight requests that your agency produce the following records within twenty business days:

All records reflecting communications (including emails, email attachments, text messages, messages on messaging platforms (such as Slack, GChat or Google Hangouts, Lync, Skype, or WhatsApp), telephone call logs, calendar invitations, calendar entries, meeting notices, meeting agendas, informational material, draft legislation, talking points, any handwritten or electronic notes taken during any oral communications, summaries of any oral communications, or other materials) between (a) the Food and Drug Administration (FDA) officials specified below and (b) any representatives or employees of Pfizer, including Albert Bourla, John Young, Kathrin Jansen, Mikael Dolsten, Nanette Cocero, William Gruber, Luis Jodar, Nicholas Kitchin, John Kraemer, Donna Boyce, Ed Harnaga, Rosalie Go, Ann Protasiewicz, Guatam Gupta, Raul Isturiz, and anyone communicating with an email ending in @pfizer.com.

Specified Officials

- a. Stephen Hahn, Commissioner of Food and Drugs
- b. Amy Abernathy, Principal Deputy Commissioner
- c. Anand Shah, Deputy Commissioner for Medical and Scientific Affairs
- d. Keagan Lenihan, Chief of Staff
- e. Peter Marks, Director of the Center for Biologics Evaluation and Research
- f. Janet Woodcock, Director of the Center for Drug Evaluation and Research

Please provide all responsive records from August 1, 2020, through the date the search is conducted.

Fee Waiver Request

In accordance with 5 U.S.C. § 552(a)(4)(A)(iii) and your agency's 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 a better understanding of relevant government procedures by the general public in a significant way. 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 operations or activities of the government.”⁵ The public has a significant interest in communications top health officials are having with companies working to produce a COVID-19 vaccine. Records with the potential to shed light on this issue would contribute significantly to public understanding of operations of the federal government, including any discussions between top health officials and vaccine manufacturers regarding the timeline and standards for granting emergency authorization or approval of a vaccine. American Oversight is committed to transparency and makes the responses agencies provide to FOIA requests publicly available, and the public’s understanding of the government’s activities would be enhanced through American Oversight’s analysis and publication of these records.

This request is primarily and fundamentally for non-commercial purposes.⁶ 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.⁷

American Oversight has also demonstrated its commitment to the public disclosure of documents and creation of editorial content through regular substantive analyses posted to its website.⁸ Examples reflecting this commitment to the public disclosure of documents and the creation of editorial content include the posting of records related to the Trump Administration’s contacts with Ukraine and analyses of those contacts;⁹ posting records and editorial content about the federal government’s response to the Coronavirus pandemic;¹⁰ posting records received as part of American Oversight’s “Audit the Wall” project to gather and analyze information related to the administration’s proposed construction of a barrier along the U.S.-Mexico border, and

⁵ 5 U.S.C. § 552(a)(4)(A)(iii).

⁶ *See id.*

⁷ American Oversight currently has approximately 15,600 page likes on Facebook and 105,400 followers on Twitter. American Oversight, Facebook, <https://www.facebook.com/weareoversight/> (last visited Oct. 14, 2020); American Oversight (@weareoversight), Twitter, <https://twitter.com/weareoversight> (last visited Oct. 14, 2020).

⁸ *See generally* News, American Oversight, <https://www.americanoversight.org/blog>.

⁹ *Trump Administration’s Contacts with Ukraine*, American Oversight, <https://www.americanoversight.org/investigation/the-trump-administrations-contacts-with-ukraine>.

¹⁰ *See generally* *The Trump Administration’s Response to Coronavirus*, American Oversight, <https://www.americanoversight.org/investigation/the-trump-administrations-response-to-coronavirus>; *see, e.g., CDC Calendars from 2018 and 2019: Pandemic-Related Briefings and Meetings*, American Oversight, <https://www.americanoversight.org/cdc-calendars-from-2018-and-2019-pandemic-related-briefings-and-meetings>.

analyses of what those records reveal;¹¹ the posting of records related to an ethics waiver received by a senior Department of Justice attorney and an analysis of what those records demonstrated regarding the Department's process for issuing such waivers;¹² and posting records and analysis of federal officials' use of taxpayer dollars to charter private aircraft or use government planes for unofficial business.¹³

Accordingly, American Oversight qualifies for a fee waiver.

Guidance Regarding the Search & Processing of Requested Records

In connection with its request for records, American Oversight provides the following guidance regarding the scope of the records sought and the search and processing of records:

- Please search all locations and systems likely to have responsive records, regardless of format, medium, or physical characteristics. For instance, if the request seeks “communications,” please search all locations likely to contain communications, including relevant hard-copy files, correspondence files, appropriate locations on hard drives and shared drives, emails, text messages or other direct messaging systems (such as iMessage, WhatsApp, Signal, or Twitter direct messages), voicemail messages, instant messaging systems such as Lync or ICQ, and shared messages systems such as Slack.
- 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.

¹¹ See generally *Audit the Wall*, American Oversight, <https://www.americanoversight.org/investigation/audit-the-wall>; see, e.g., *Border Wall Investigation Report: No Plans, No Funding, No Timeline, No Wall*, American Oversight, <https://www.americanoversight.org/border-wall-investigation-report-no-plans-no-funding-no-timeline-no-wall>.

¹² *DOJ Records Relating to Solicitor General Noel Francisco's Recusal*, American Oversight, <https://www.americanoversight.org/document/doj-civil-division-response-noel-francisco-compliance>; *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>.

¹³ See generally *Swamp Airlines: Chartered Jets at Taxpayer Expense*, American Oversight, <https://www.americanoversight.org/investigation/swamp-airlines-private-jets-taxpayer-expense>; see, e.g., *New Information on Pompeo's 2017 Trips to His Home State*, American Oversight, <https://www.americanoversight.org/new-information-on-pompeos-2017-trips-to-his-home-state>.

- Our request for records includes any attachments to those records or other materials enclosed with those records when they were previously transmitted. To the extent that an email is responsive to our request, our request includes all prior messages sent or received in that email chain, as well as any attachments to the email.
- Please search all relevant records or systems containing records regarding agency business. Do not exclude records regarding agency business contained in files, email accounts, or devices in the personal custody of your officials, such as personal email accounts or text messages. Records of official business conducted using unofficial systems or stored outside of official files are subject to the Federal Records Act and FOIA.¹⁴ 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, by intent or through negligence, failed to meet their obligations.¹⁵
- Please use all tools available to your agency to conduct a complete and efficient search for potentially responsive records. Agencies are subject to government-wide requirements to manage agency information electronically,¹⁶ and many agencies have adopted the National Archives and Records Administration (NARA) Capstone program, or similar policies. These systems provide options for searching emails and other electronic records in a manner that is reasonably likely to be more complete than just searching individual custodian files. For example, a custodian may have deleted a responsive email from his or her email program, but your agency’s archiving tools may capture that email under Capstone. At the same time, custodian searches are still necessary; agencies may not have direct access to files stored in .PST files, outside of network drives, in paper format, or in personal email accounts.
- 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 a request is denied in whole, please state specifically why it is not reasonable to segregate portions of the record for release.

¹⁴ 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).

¹⁵ See *Competitive Enter. Inst. v. Office of Sci. & Tech. Policy*, No. 14-cv-765, slip op. at 8 (D.D.C. Dec. 12, 2016).

¹⁶ 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>.

- Please take appropriate steps to ensure that records responsive to this request are not deleted by the agency before the completion of processing for this request. If records potentially responsive to this request are likely to be located on systems where they are subject to potential deletion, including on a scheduled basis, please take steps to prevent that deletion, including, as appropriate, by instituting a litigation hold on those records.

Conclusion

If you have any questions regarding how to construe this request for records or believe that further discussions regarding search and processing would facilitate a more efficient production of records of interest to American Oversight, please do not hesitate to contact American Oversight to discuss this request. 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 your agency can decrease the likelihood of costly and time-consuming litigation in the future.

Where possible, please provide responsive material in an electronic format by email. Alternatively, please provide responsive material in native format or in PDF 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.

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, please contact Christine Monahan at foia@americanoversight.org or (202) 869-5244. 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,



Austin R. Evers
Executive Director
American Oversight