



September 1, 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 Officer:

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.

The novel virus, SARS-CoV-2, has spread across the globe, sickened millions of people, and resulted in hundreds of thousands of deaths.¹ Earlier this year, a former top official in the U.S. Department of Health and Human Services (HHS) alleged that the White House was “politicizing science,”² and public reports indicated that the Office of Special Counsel (OSC) had received thirty-one whistleblower complaints related to the coronavirus and the federal response to the coronavirus as of May 4, 2020.³ Since then, numerous media reports have come out raising further questions about politicization of the federal government’s response to the coronavirus, including but not limited to the approval of potential coronavirus vaccines.⁴

¹ *Coronavirus Map: Tracking the Global Outbreak*, N.Y. Times (Aug. 31, 2020, 8:07 AM), <https://www.nytimes.com/interactive/2020/world/coronavirus-maps.html>.

² Nicholas Florke, *An Ousted Vaccine Agency Director Offers an Explosive, Direct Allegation: Trump Is Politicizing Science*, Stat, April 22, 2020, <https://www.statnews.com/2020/04/22/rick-bright-allegations-politicize-science/>.

³ Nick Swellenbach, *Watchdog Examining Dozens of Federal Coronavirus Whistleblower Cases*, Proj. on Gov’t Oversight, May 4, 2020, <https://www.pogo.org/investigation/2020/05/watchdog-examining-dozens-of-federal-coronavirus-whistleblower-cases/>.

⁴ See, e.g., *FDA Commissioner Says Willing to Fast-Track COVID-19 Vaccine: FT*, Reuters (Aug. 30, 2020, 7:35 AM) <https://www.reuters.com/article/us-health-coronavirus-usa-hahn-idUSKBN25Q0G7>; McGinley et al., *Inside Trump’s Pressure Campaign on Federal Scientists Over a Covid-19 Treatment*, Wash. Post (Aug. 30, 2020, 8:00 AM), <https://www.washingtonpost.com/health/convalescent-plasma-treatment-covid19->



American Oversight seeks records with the potential to shed light on improper, inappropriate, or illegal government actions taken in response to the coronavirus pandemic.

Requested Records

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

All questions, complaints, or concerns regarding actual or perceived politicization, improper influence, or White House influence or interference in agency actions or decision-making in the context of the federal government's response to the coronavirus pandemic submitted to any of the following offices or officers:

- a. Office of Ethics and Integrity, including via the email address FDAEthics_Advice@fda.hhs.gov
- b. Center for Biologics Evaluation & Research, including via the email address CBEREthics@fda.hhs.gov
- c. Center for Drug Evaluation & Research (CDER) Ethics Liaison, including via the email address CDER-Ethics-Liaison@fda.hhs.gov
- d. Center for Devices & Radiological Health (CDRH) Ethics Liaison, including via the email address CDRHEthics@fda.hhs.gov
- e. Office of Regulatory Affairs (ORA) Ethics Liaison, including via the email address ORAEthics@fda.hhs.gov

[fda/2020/08/29/e39a75ec-e935-11ea-bc79-834454439a44_story.html](https://www.fda.gov/2020/08/29/e39a75ec-e935-11ea-bc79-834454439a44_story.html); John Pacentl, *COVID Vaccine Trial in Country Paused Due to 'Political Pressure,' Doctor Says*, Palm Beach Post (Aug. 27, 2020, 6:38 PM), <https://www.palmbeachpost.com/story/news/2020/08/27/coronavirus-vaccine-trial-palm-beach-county-paused/5642163002/>; Lev Facher, *Trump Pledges a Covid-19 Vaccine by End of 2020 — Without Acknowledging the Scientific Uncertainty*, Stat, Aug. 27, 2020, <https://www.statnews.com/2020/08/27/trump-pledge-vaccine-end-2020/>; Nick Valencia et al., *CDC Was Pressured 'From the Top Down' to Change Coronavirus Testing Guidance, Official Says*, CNN (Aug. 27, 2020, 12:30 AM), <https://www.cnn.com/2020/08/26/politics/cdc-coronavirus-testing-guidance/index.html>; Sheryl Gay Stolberg, *Top U.S. Officials Told C.D.C. to Soften Coronavirus Testing Guidelines*, N.Y. Times, Aug. 26, 2020, <https://www.nytimes.com/2020/08/26/us/politics/coronavirus-testing-trump-cdc.html>; Valerie Strauss, *Democratic Lawmakers Probing Whether CDC Guidelines on Reopening Schools Were Influenced by Political Pressure*, Wash. Post (July 27, 2020, 3:36 PM), <https://www.washingtonpost.com/education/2020/07/28/democratic-lawmakers-probing-whether-cdc-guidelines-reopening-schools-were-influenced-by-political-pressure/>; Adam Cancryn, *Hundreds of Health Groups Petition Against Trump*, Politico (July 7, 2020, 5:00 AM), <https://www.politico.com/news/2020/07/07/hundreds-health-groups-petition-trump-350154>.

- f. Office of the Commissioner (OC)/Office of Operations (OO) Ethics Liaison, including via the email address OC_OOethics@fda.hhs.gov

Please provide responsive records from January 1, 2020, through the date of the search.

American Oversight understands that the privacy interests of FDA employees may warrant the application of redactions under FOIA Exemption 6, particularly for the identity of career officials. The requested documents also likely contain significant segregable information that is properly subject to disclosure.

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 the federal government's response to the coronavirus. Records with the potential to shed light on this matter would contribute significantly to public understanding of operations of the federal government, including potentially improper, inappropriate, or illegal actions taken by federal agencies, consultants, or contractors in responding to the coronavirus pandemic.⁶ 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.⁷ 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

⁵ 5 U.S.C. § 552(a)(4)(A)(iii).

⁶ See, e.g., Ed Silverman, *Poll: Most Americans Believe the Covid-19 Vaccine Approval Process Is Driven by Politics, Not Science*, Stat, Aug. 31, 2020, <https://www.statnews.com/pharmalot/2020/08/31/most-americans-believe-the-covid-19-vaccine-approval-process-is-driven-by-politics-not-science/>; Lev Facher, *Trump Has Launched an All-Out Attack on the FDA. Will Its Scientific Integrity Survive?*, Stat, Aug. 27, 2020, <https://www.statnews.com/2020/08/27/trump-has-launched-an-all-out-attack-on-the-fda-will-its-scientific-integrity-survive/>.

⁷ See 5 U.S.C. § 552(a)(4)(A)(iii).

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.⁸

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.⁹ 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;¹⁰ posting records and editorial content about the federal government’s response to the Coronavirus pandemic;¹¹ 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 analyses of what those records reveal;¹² 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;¹³ and posting records and

⁸ American Oversight currently has approximately 15,600 page likes on Facebook and 104,700 followers on Twitter. American Oversight, Facebook, <https://www.facebook.com/weareoversight/> (last visited Aug. 31, 2020); American Oversight (@weareoversight), Twitter, <https://twitter.com/weareoversight> (last visited Aug. 31, 2020).

⁹ See generally *News*, American Oversight, <https://www.americanoversight.org/blog>.

¹⁰ *Trump Administration’s Contacts with Ukraine*, American Oversight, <https://www.americanoversight.org/investigation/the-trump-administrations-contacts-with-ukraine>.

¹¹ 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>.

¹² 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>.

¹³ *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>.

analysis of federal officials' use of taxpayer dollars to charter private aircraft or use government planes for unofficial business.¹⁴

Accordingly, American Oversight qualifies for a fee waiver.

Application for Expedited Processing

Pursuant to 5 U.S.C. § 552(a)(6)(E)(1), American Oversight requests that your agency expedite the processing of this request.

I certify to be true and correct to the best of my knowledge and belief that the information requested is urgently needed in order to inform the public concerning actual or alleged government activity, and American Oversight is primarily engaged in disseminating the information it receives from public records requests to the public.

Recent reporting demonstrates that there is clearly an urgent need to inform the public regarding the matters that are the subject of American Oversight's FOIA request. First, American Oversight has requested records with the potential to shed light on potentially improper actions undertaken as part of the federal government's response to the ongoing, and nearly unprecedented, coronavirus pandemic. Because the virus has spread rapidly and killed more than 182,000 people in the United States,¹⁵ there is plainly an urgent need to inform the public about the actions that the government has taken to mitigate the spread, assist in treating the ongoing cases, and aid those affected by the pandemic's economic impacts, and the bases for such actions.¹⁶ It is particularly urgent that potential malfeasance, waste, and other improper conduct be exposed so that it can be addressed before citizens are harmed by it.¹⁷ The exceptionally widespread news reporting on the

¹⁴ 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>.

¹⁵ *Coronavirus in the U.S.: Latest Map and Case Count*, N.Y. Times (Aug. 31, 2020, 8:07 AM), <https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html>.

¹⁶ See, e.g., Silverman, *supra* note 6; Facher, *supra* note 6.

¹⁷ See, e.g., Jeremy Diamond et al., *Fauci Says He Was in Surgery When Task Force Discussed CDC Testing Guidelines*, CNN (Aug. 27, 2020, 1:08 AM), <https://www.cnn.com/2020/08/26/politics/fauci-coronavirus-cdc-testing/index.html> (“I am concerned about the interpretation of these recommendations and worried it will give people the incorrect assumption that asymptomatic spread is not of great concern. In fact it is,” said Fauci, director of the National Institute of Allergy and Infectious Diseases.”); Tom Frieden et al., *We Ran the CDC. No President Ever Politicized Its Science the Way Trump Has*, Wash. Post (July 14, 2020, 6:00 AM), <https://www.washingtonpost.com/outlook/2020/07/14/cdc-directors-trump-politics/> (“We’re seeing the terrible effect of undermining the CDC play out in our population.

federal government's handling of the response to the virus, including whether and to what extent testing guidelines and therapeutic and vaccines approval decisions are affected by political interests, demonstrates that the public urgently needs information concerning the subject matter of this request.¹⁸

I further certify that American Oversight is primarily engaged in disseminating information to the public. 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. Similar to other organizations that have been found to satisfy the criteria necessary to qualify for expedition,¹⁹ American Oversight "gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw material into a distinct work, and distributes that work to an audience."²⁰ American Oversight uses the information gathered, and its analysis of it, to educate the public through reports, press releases, and 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.²¹ As discussed previously, American Oversight has demonstrated its commitment to the public disclosure of documents and

Willful disregard for public health guidelines is, unsurprisingly, leading to a sharp rise in infections and deaths.").

¹⁸ See, e.g., Reuters, *supra* note 4; McGinley, *supra* note 4; Pacentl, *supra* note 4; Facher, *supra* note 4; Stolberg, *supra* note 4; Strauss, *supra* note 4; Diamond et al., *supra* note 17.

¹⁹ See *ACLU v. U.S. Dep't of Justice*, 321 F. Supp. 2d 24, 30–31 (D.D.C. 2004); *EPIC v. Dep't of Defense*, 241 F. Supp. 2d 5, 15 (D.D.C. 2003).

²⁰ *ACLU*, 321 F. Supp. 2d at 29 n.5 (quoting *EPIC*, 241 F. Supp. 2d at 11).

²¹ See *supra* note 8.

creation of editorial content,²² including specifically with respect to documents related to the coronavirus.²³

Accordingly, American Oversight's request satisfies the criteria for expedition.

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.
- 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.
- 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

²² See generally *News*, American Oversight, <https://www.americanoversight.org/blog>; see, e.g., *DOJ Civil Division Response Noel Francisco Compliance*, 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>; *Audit the Wall*, American Oversight, <https://www.americanoversight.org/investigation/audit-the-wall>; *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>; *Documents Reveal Ben Carson Jr.'s Attempts to Use His Influence at HUD to Help His Business*, American Oversight, <https://www.americanoversight.org/documents-reveal-ben-carson-jr-s-attempts-to-use-his-influence-at-hud-to-help-his-business>; *Investigating the Trump Administration's Efforts to Sell Nuclear Technology to Saudi Arabia*, American Oversight, <https://www.americanoversight.org/investigating-the-trump-administrations-efforts-to-sell-nuclear-technology-to-saudi-arabia>; *Sessions' Letter Shows DOJ Acted On Trump's Authoritarian Demand to Investigate Clinton*, American Oversight, <https://www.americanoversight.org/sessions-letter>.

²³ *'We Are Flying Blind': Health Officials' Late February Emails Show Rising Coronavirus Concerns*, American Oversight, <https://www.americanoversight.org/we-are-flying-blind-health-officials-late-february-emails-show-rising-coronavirus-concerns>.

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.²⁴ 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.²⁵
- 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,²⁶ 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.
- 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

²⁴ 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).

²⁵ See *Competitive Enter. Inst. v. Office of Sci. & Tech. Policy*, No. 14-cv-765, slip op. at 8 (D.D.C. Dec. 12, 2016).

²⁶ 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>.

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 H. 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