



September 9, 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: Expedited 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 expedited request for records.

In recent weeks, both the media and members of Congress have raised questions regarding the potential politicization of the U.S. Food & Drug Administration (FDA), including in the context of the FDA's decision to grant emergency use authorization to convalescent plasma for the treatment of coronavirus, statements and actions pertaining to the development and approval of a coronavirus vaccines, and the hiring and/or firing of certain officials and consultants.¹

¹ See, e.g., News Release, Warren, Markey Request All Communications Between FDA and White House on Potentially Politicized Convalescent Plasma Emergency Use Authorization, Elizabeth Warren, Aug. 25, 2020, <https://www.warren.senate.gov/oversight/letters/warren-markey-request-all-communications-between-fda-and-white-house-on-potentially-politicized-convalescent-plasma-emergency-use-authorization>; *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-fda/2020/08/29/e39a75ec-e935-11ea-bc79-834454439a44_story.html; Sheila Kaplan & Katie Thomas, *Two P.R. Experts at F.D.A. Have Been Ousted After Blood Plasma Fiasco*, N.Y. Times (Aug. 28, 2020), <https://www.nytimes.com/2020/08/28/health/blood-plasma-fda.html>; John Pacenti, *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*



American Oversight seeks records with the potential to shed light on any politicization of the FDA's activities, particularly in the context of the coronavirus response.

Requested Records

American Oversight seeks expedited review of this request for the reasons identified below and requests that FDA produce the following records as soon as practicable, and at least within twenty business days:

All email communications (including emails, email attachments, complete email chains, calendar invitations, and calendar invitation attachments) sent by (a) former Assistant Commissioner for External Affairs **Emily Miller**,² former Associate Commissioner for External Affairs **John E. Wagner**, or Senior Advisor **David Gortler**, to (b) any email address ending in **.com**, **.net**, **.org**, **.us**, **.mail**, or **.edu**, containing (c) any of the **key terms** listed below (including as part of email addresses).

End of 2020 — Without Acknowledging the Scientific Uncertainty, Stat, Aug. 27, 2020, <https://www.statnews.com/2020/08/27/trump-pledge-vaccine-end-2020/>.

² According to public reporting, Ms. Miller was removed from her position as Assistant Commissioner for External Affairs but has remained an employee of FDA. Dan Diamond & Sarah Owerhohle, *Hahn, HHS in 'Tit for Tat' Feud over Covid-19 Messaging*, Politico (Sept. 2, 2020, 9:36 PM), <https://www.politico.com/news/2020/09/02/stephen-hahn-fda-hhs-coronavirus-feud-408136>. American Oversight seeks responsive records both from Ms. Miller's tenure in her original position, and in any position she has held since then.

Key Terms

1. POTUS
2. Trump
3. VPOTUS
4. Pence
5. Kushner
6. Azar
7. AMA
8. Hahn
9. Redfield
10. R3
11. Fauci
12. Moncef
13. Slaoui
14. Perna
15. Hepburn
16. Atlas
17. EUA
18. "Emergency Use"
19. Vaccine
20. Vaccines
21. Vaccine(s)
22. Vaccination
23. Moderna
24. Oxford
25. AstraZeneca
26. Pfizer
27. Gilead
28. Remdesivir
29. Mayo
30. "Convalescent Plasma"
31. "Convalescent Serum"
32. CCP
33. "Warp Speed"
34. OWS
35. Countermeasures
36. RNC
37. GOP
38. OAN
39. OANN
40. Sinclair
41. "Fox News"
42. Breitbart
43. "Daily Caller"

In an effort to accommodate your agency and reduce the number of potentially responsive records, American Oversight agrees that the search for responsive email communications may be limited to emails sent by the specified officials. Despite this search accommodation, American Oversight still requests that complete email chains be produced, displaying both sent and received messages. For example, if Assistant Commissioner Miller sent a response to an incoming message from an external email address containing one of the key terms above, both the original email and her response should be included.

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

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.”³ 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 potential politicization of the FDA.⁴ 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.⁵ 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.⁶

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.⁷ Examples reflecting this commitment to the public disclosure of documents and the creation of editorial content include the posting of records related to

³ 5 U.S.C. § 552(a)(4)(A)(iii).

⁴ 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/>.

⁵ See 5 U.S.C. § 552(a)(4)(A)(iii).

⁶ 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).

⁷ See *generally News*, American Oversight, <https://www.americanoversight.org/blog>.

the Trump Administration’s contacts with Ukraine and analyses of those contacts;⁸ posting records and editorial content about the federal government’s response to the Coronavirus pandemic;⁹ 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;¹⁰ 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;¹¹ and posting records and analysis of federal officials’ use of taxpayer dollars to charter private aircraft or use government planes for unofficial business.¹²

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

⁸ *Trump Administration’s Contacts with Ukraine*, American Oversight, <https://www.americanoversight.org/investigation/the-trump-administrations-contacts-with-ukraine>.

⁹ 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>.

¹⁰ 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>.

¹¹ *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>.

¹² 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>.

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 the activities of an FDA political appointee who was at the center of recent uproar over the FDA's decision to grant emergency use authorization to convalescent plasma despite limited data on its effectiveness for the treatment of COVID-19.¹³ Indeed, shortly after these events transpired, this official was removed from their position, as were other FDA officials and consultants, in what reports describe as a "tit for tat" battle between FDA and HHS leadership.¹⁴ Most concerning, these events have raised questions among the public regarding whether the FDA's scientific integrity can be trusted or if it will succumb to political pressure.¹⁵ In the midst of a pandemic that has already killed more than 185,000 people in the United States,¹⁶ there is plainly an urgent need to inform the public about the current state of affairs within FDA and, in particular, the activities of its political appointees. The exceptionally widespread news reporting on the 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.¹⁷

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,¹⁸ 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."¹⁹ 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

¹³ Facher, *supra* note 1.

¹⁴ Dan Diamond & Sarah Oweremohle, *Hahn, HHS in 'Tit for Tat' Feud over Covid-19 Messaging*, Politico (Sept. 2, 2020, 9:36 PM), <https://www.politico.com/news/2020/09/02/stephen-hahn-fda-hhs-coronavirus-feud-408136>.

¹⁵ See *supra* notes 1 & 5.

¹⁶ *Coronavirus in the U.S.: Latest Map and Case Count*, N.Y. Times (Sept. 2, 2020, 12:09 PM), <https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html>.

¹⁷ See *supra* notes 1 & 5.

¹⁸ 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).

¹⁹ *ACLU*, 321 F. Supp. 2d at 29 n.5 (quoting *EPIC*, 241 F. Supp. 2d at 11).

media platforms, such as Facebook and Twitter.²⁰ As discussed previously, American Oversight has demonstrated its commitment to the public disclosure of documents and creation of editorial content,²¹ including specifically with respect to documents related to the coronavirus.²²

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

²⁰ See *supra* note 8.

²¹ 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>.

²² *'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>.

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.²³ 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.²⁴
- 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,²⁵ 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.

²³ 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).

²⁴ See *Competitive Enter. Inst. v. Office of Sci. & Tech. Policy*, No. 14-cv-765, slip op. at 8 (D.D.C. Dec. 12, 2016).

²⁵ 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 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