



March 17, 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, 45 C.F.R Part 5, American Oversight makes the following request for records.

The outbreak of the novel coronavirus, SARS-CoV-2, and the disease it causes, COVID-19, has been declared a public health emergency at both the national and international levels.¹ Since late 2019, the virus has spread to dozens of countries, sickened tens of thousands of people, and resulted in thousands of deaths.² This is a rapidly evolving situation that is demanding coordinated attention and action across the federal government. Yet the Trump administration has so far failed to ensure timely availability of testing kits for healthcare providers,³ has prevented health experts from speaking about the growing crisis,⁴ and has removed information on the spread of the virus from public health resources.⁵ President

¹ *Coronavirus Disease 2019 (COVID-19) Situation Summary*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/coronavirus/2019-ncov/summary.html>.

² *Coronavirus Live Updates: W.H.O Says Covid-19 Has Higher Fatality Rate Than the Flu*, N.Y. TIMES, Mar. 4, 2020, https://www.nytimes.com/2020/03/04/world/coronavirus-news.html?action=click&pgtype=Article&state=default&module=style-coronavirus&variant=show®ion=TOP_BANNER&context=storyline_menu.

³ Alice Park, *Responding to Coronavirus Testing Problems, U.S. Government Expands Number of Labs That Can Run Tests* (Mar. 2, 2020, updated 1:50 PM EST), TIME, <https://time.com/5793605/coronavirus-testing-united-states/>.

⁴ Michael Shear & Maggie Haberman, *Pence Will Control All Coronavirus Messaging from Health Officials*, N.Y. TIMES, Feb. 27, 2020, <https://www.nytimes.com/2020/02/27/us/politics/us-coronavirus-pence.html>.

⁵ Brianna Ehley, *Trump's Team Shifts Tone from Preventing Coronavirus to Containing It*, POLITICO (Mar. 2, 2020, 7:52 PM), <https://www.politico.com/news/2020/03/02/trump-coronavirus-pence-119051>.



Trump has consistently downplayed the threat of the virus to public health, appearing to express concern and attention to the matter primarily with respect to any economic effects.⁶

American Oversight seeks records with the potential to shed light on how the administration is handling this public health emergency.

Requested Records

American Oversight requests that the Food and Drug Administration (FDA) process this request on an expedited basis and produce the following records as soon as practicable, and at least within twenty business days:

All email communications (including email messages, complete email chains, email attachments, calendar invitations) sent by (a) the FDA officials in Column A, to (b) external entities and individuals listed in Column B (including but not limited to at the email addresses provided) in the chart below.

Column A (FDA Officials)	Column B (External Entities and Individuals)
<ul style="list-style-type: none"> i. Stephen Hahn, Director ii. Amy Abernethy, Principal Deputy Commissioner iii. Keagan Lenihan, Chief of Staff iv. Martina Varnado, Director of the Office of the Executive Secretariat v. Anna Abram, Deputy Commissioner for Policy, Legislation, and International Affairs vi. Anand Shah, Deputy Commissioner for Medical and Scientific Affairs vii. Laura Caliguiri, Associate Commissioner for External Affairs 	<ul style="list-style-type: none"> i. American Clinical Laboratory Association (@acla.com) ii. National Independent Laboratory Association (@nila-usa.org) iii. Association of Public Health Laboratories (@aphl.org) iv. ARUP Laboratories (@aruplab.com) v. BioMérieux (@biomerieux.com) vi. BioReference Laboratories (@bioreference.com) vii. BGI Group (@bgi.com) viii. Co-Diagnostics, Inc. (@codiagnostics.com) ix. Genomica (@genomica.com) x. Laboratory Corporation of America (@labcorp.com) xi. Mayo Clinic Laboratories (@mayo.edu)

⁶ Alan Rappeport & Jim Tankersley, *As Stock Markets Plunge, Trump Calls for Economic Response to Coronavirus*, N.Y. TIMES, Mar. 9, 2020, <https://www.nytimes.com/2020/03/09/business/economy/trump-coronavirus-economic-fallout.html>.

viii.	Judith McMeekin, Acting Associate Commissioner for Regulatory Affairs	xii.	Meridian Biosciences (@meridianbioscience.com)
ix.	Lauren Roth, Acting Associate Commissioner for Policy	xiii.	OPKO Health (@opko.com)
x.	Lowell Schiller, Principal Associate Commissioner for Policy	xiv.	Oscar Health (hioscar.com)
xi.	Peter Marks, Director of the Center for Biologics Evaluation and Research	xv.	PharmaMar (@pharmamar.com)
xii.	Jeffrey E. Shuren, Director of the Center for Devices and Radiological Health	xvi.	Qiagen (@qiagen.com)
xiii.	Janet Woodcock, Director of the Center for Drug Evaluation and Research	xvii.	Quest Diagnostics (@QuestDiagnostics.com)
		xviii.	Roche (@roche.com)
		xix.	Sonic Healthcare USA (@sonichealthcare.com)
		xx.	Sonora Quest (@sonoraquest.com)
		xxi.	Thermo Fisher (@thermofisher.com)
		xxii.	University of Washington Virology Division (@u.washington.edu)
		xxiii.	University of Washington Department of Laboratory Medicine (@uw.edu)
		xxiv.	Clinical Molecular Microbiology Laboratory, UNC Medical Center (@unchealth.unc.edu)

In an effort to accommodate FDA and reduce the number of responsive records to be processed and produced, American Oversight has limited its request to emails sent by the identified officials. To be clear, however, American Oversight still requests that complete email chains be produced, displaying both the sent messages and the prior received messages in each email chain. This means, for example, that both an FDA official’s response to an email from an employee or representative of one of the external parties listed and the initial received message are responsive to this request and should be produced.

Please provide all responsive records from January 10, 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.”⁷ 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 whether and to what extent public health officials and other scientific experts are coordinating with private labs and test developers and taking action to ensure testing kits are available for use nationwide. 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.⁸ 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.⁹

American Oversight has also demonstrated its commitment to the public disclosure of documents and creation of editorial content through numerous substantive analyses posted to its website.¹⁰ Examples reflecting this commitment to the public disclosure of documents and the creation of editorial content include 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 posting records received as part of American Oversight’s “Audit the Wall”

⁷ 5 U.S.C. § 552(a)(4)(A)(iii).

⁸ See 5 U.S.C. § 552(a)(4)(A)(iii).

⁹ American Oversight currently has approximately 15,500 page likes on Facebook and 102,400 followers on Twitter. American Oversight, FACEBOOK, <https://www.facebook.com/weareoversight/> (last visited Mar. 12, 2020); American Oversight (@weareoversight), TWITTER, <https://twitter.com/weareoversight> (last visited Mar. 12, 2020).

¹⁰ News, AMERICAN OVERSIGHT, <https://www.americanoversight.org/blog>.

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>.

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 posting records regarding potential self-dealing at the Department of Housing & Urban Development and related analysis;¹³ posting records and analysis relating to the federal government's efforts to sell nuclear technology to Saudi Arabia;¹⁴ and posting records and analysis regarding the Department of Justice's decision in response to demands from Congress to direct a U.S. Attorney to undertake a wide-ranging review and make recommendations regarding criminal investigations relating to the President's political opponents and allegations of misconduct by the Department of Justice itself and the Federal Bureau of Investigation.¹⁵

Accordingly, American Oversight qualifies for a fee waiver.

Application for Expedited Processing

Pursuant to 5 U.S.C. § 552(a)(6)(E)(1) and 45 C.F.R. § 5.27(b), 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 received 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 steps the administration has undertaken to manage a public health emergency at both national and international levels. Because the virus has spread rapidly and has already killed several people in the United States,¹⁶ there is plainly an urgent need to inform the public about administration actions regarding decisions to test patients for the virus in the United

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 *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>.

¹⁴ *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>.

¹⁵ *Sessions' Letter Shows DOJ Acted on Trump's Authoritarian Demand to Investigate Clinton*, AMERICAN OVERSIGHT, <https://www.americanoversight.org/sessions-letter>.

¹⁶ *Coronavirus Live Updates*, *supra* note 1.

States, as cases have now appeared nationwide and the reach of the virus grows wider on a daily basis. The exceptionally widespread news reporting on testing for this virus demonstrates that the public urgently needs information about the federal government's efforts and policies concerning the subject matter of this request.¹⁷ Second, factual developments in the last few weeks have demonstrated a series of government failures to appropriately handle testing decisions, including failures in the rollout of coronavirus tests and overly restrictive testing protocols,¹⁸ as well as an effort by government officials to minimize press coverage and reduce public information¹⁹ about the testing of coronavirus cases. There is also widespread public concern that public health officials are being prevented from speaking about the coronavirus more broadly²⁰—information that is critical for educating the public on steps to contain the future spread of the virus and mitigate the outbreaks that have already occurred.

Moreover, I certify to be true and correct to the best of my knowledge and belief that there is an urgent need to inform the public about testing for coronavirus. American Oversight's request seeks information that can shed light on how and why testing decisions have been made—including whether and to what extent initial testing kits were contaminated, the rationale behind not using tests developed by the World Health Organization, the speed and approach for disseminating testing kits to healthcare providers, the criteria for giving a test to a patient, and how information is disseminated about any ongoing tests and presumptive positive cases in the United States. The public urgently needs the information to understand the extent of the growing health crisis and make decisions that promote public health and mitigate the spread of the disease.

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,²¹ 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.”²² American Oversight uses the information gathered, and its analysis of it, to educate the

¹⁷ *Id.*; Adam Taylor et al., *Live Updates: Italy to Close Schools as Coronavirus Death Toll Passes 100, L.A. County Declares Health Emergency as Cases Mount*, WASH. POST (Mar 4., 2020, 2:38 PM EST), <https://www.washingtonpost.com/world/2020/03/04/coronavirus-live-updates/>; Holly Yan & Kristina Sgueglia, *New York Now Has 6 Coronavirus Cases and City Officials Are Scrambling to Find Who Else Might Have It*, CNN HEALTH (Mar. 4, 2020 12:06 PM EST), <https://www.cnn.com/2020/03/04/health/new-york-coronavirus-cases/index.html>.

¹⁸ Park, *supra* note 3.

¹⁹ Ehley, *supra* note 5.

²⁰ Shear & Haberman, *supra* note 4.

²¹ 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).

²² *ACLU*, 321 F. Supp. 2d at 29 n.5 (quoting *EPIC*, 241 F. Supp. 2d at 11).

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.²³ As discussed previously, American Oversight has demonstrated its commitment to the public disclosure of documents and creation of editorial content.²⁴

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. We seek records of any kind, including electronic records, audiotapes, videotapes, and photographs, as well as

²³ American Oversight currently has approximately 15,500 page likes on Facebook and 102,100 followers on Twitter. American Oversight, FACEBOOK, <https://www.facebook.com/weareoversight/> (last visited Mar. 3, 2020); American Oversight (@weareoversight), TWITTER, <https://twitter.com/weareoversight> (last visited Mar. 3, 2020).

²⁴ 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>.

letters, emails, facsimiles, telephone messages, voice mail messages, and transcripts, notes, or minutes of any meetings, telephone conversations, or discussions.

- 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.²⁵ 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.²⁶
- 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,²⁷ 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.

²⁵ 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).

²⁶ See *Competitive Enter. Inst. v. Office of Sci. & Tech. Policy*, No. 14-cv-765, slip op. at 8 (D.D.C. Dec. 12, 2016).

²⁷ 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>.

- 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 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