



May 6, 2020

VIA EMAIL

Michael Marquis
FOIA Officer
Department of Health and Human Services
Hubert H. Humphrey Building, Room 729H
200 Independence Avenue SW
Washington, DC 20201
FOIARequest@hhs.gov

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, 45 U.S.C. Part 5, American Oversight and Lower Drug Prices Now make 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 millions of people, and resulted in more than 229,000 deaths worldwide.² Of particular concern to the public is whether any treatments or vaccines will be affordable for all who need them.³ This

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

² *Coronavirus Map: Tracking the Global Outbreak*, N.Y. TIMES (Apr. 30, 2020, 2:11 PM), <https://www.nytimes.com/interactive/2020/world/coronavirus-maps.html>.

³ See, e.g., Sarah Karlin-Smith, *How the Drug Industry Got Its Way on the Coronavirus*, POLITICO (Mar. 5, 2020, 5:28 PM), <https://www.politico.com/news/2020/03/05/coronavirus-drug-industry-prices-122412>; Nicholas Florko, *Progressives Push Trump Administration to Ensure a Future Coronavirus Vaccine is Affordable*, STAT, Mar. 5, 2020, <https://www.statnews.com/2020/03/05/progressives-trump-coronavirus-vaccine-affordable/>; Isabel Togoh, *Health Secretary Alex Azar Refuses to Guarantee Coronavirus Vaccine Would be Affordable for All*, FORBES (Feb. 27, 2020, 8:30 AM), <https://www.forbes.com/sites/isabeltogoh/2020/02/27/health-secretary-alex-azar-refuses-to-guarantee-coronavirus-vaccine-would-be-affordable-for-all/#3f14e90a490c>.



question has taken particularly prominence in the context of decisions regarding federal investment in coronavirus drug and vaccine development.⁴

American Oversight and Lower Drug Prices Now seek to shed light on the administration's handling of this issue.

Requested Records

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

1. A complete copy of the contract, amendment, memorandum of understanding, or other written agreement between (a) the Office of the Assistant Secretary for Preparedness and Response (ASPR) and/or the Biomedical Advanced Research and Development Authority (BARDA), and (b) Moderna, Inc. regarding the development of a coronavirus vaccine, as announced by HHS on March 30, 2020.⁵
2. A copy of the \$483 million "award" by BARDA to Moderna, Inc., to accelerate development of Moderna's mRNA vaccine candidate (mRNA-1273), entered into on or before April 16, 2020, including any attachments thereto.⁶

As this request is limited to a narrow set of recently created and readily identifiable documents, American Oversight and Lower Drug Prices Now believe that this request should be assigned to the Simple processing track and will result in an expeditious agency response.

Please search for all responsive records from February 1, 2020, through April 23, 2020.

Fee Waiver Request

In accordance with 5 U.S.C. § 552(a)(4)(A)(iii) and your agency's regulations, American Oversight and Lower Drug Prices Now request a waiver of fees associated with processing

⁴ See, e.g., Mariana Mazzucato & Azzi Momenghalibaf, *Drug Companies Will Make a Killing from Coronavirus*, N.Y. TIMES (Mar. 18, 2020), <https://www.nytimes.com/2020/03/18/opinion/coronavirus-vaccine-cost.html>.

⁵ See News Release, *HHS Accelerates Clinical Trials, Prepares for Manufacturing of COVID-19 Vaccines*, HHS, Mar. 30, 2020, <https://www.hhs.gov/about/news/2020/03/30/hhs-accelerates-clinical-trials-prepares-manufacturing-covid-19-vaccines.html>.

⁶ Press Release, *Moderna Announces Award from U.S. Government Agency BARDA for up to \$483 Million to Accelerate Development of mRNA Vaccine (mRNA-1273) Against Novel Coronavirus*, MODERNA, MODERNA, Apr. 16, 2020, <https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-award-us-government-agency-barda-483-million>.

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 and Lower Drug Prices Now request 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 it is requiring drug and vaccine developers to make sure products developed with taxpayer dollars are affordable to everyone who needs them.⁸ Furthermore, 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 and Lower Drug Prices Now’s analysis and publication of these records.

This request is primarily and fundamentally for non-commercial purposes.⁹ 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.¹⁰

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.¹¹ 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

⁷ 5 U.S.C. § 552(a)(4)(A)(iii).

⁸ See *supra* notes 3 & 4.

⁹ See 5 U.S.C. § 552(a)(4)(A)(iii).

¹⁰ American Oversight currently has approximately 15,500 page likes on Facebook and 102,200 followers on Twitter. American Oversight, FACEBOOK, <https://www.facebook.com/weareoversight/> (last visited May 6, 2020); American Oversight (@weareoversight), TWITTER, <https://twitter.com/weareoversight> (last visited May 6, 2020).

¹¹ News, AMERICAN OVERSIGHT, <https://www.americanoversight.org/blog>.

waivers;¹² 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;¹³ posting records regarding potential self-dealing at the Department of Housing & Urban Development and related analysis;¹⁴ posting records and analysis relating to the federal government’s efforts to sell nuclear technology to Saudi Arabia;¹⁵ 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.¹⁶

Lower Drug Prices Now is a project of the Sixteen Thirty Fund, a 501(c)4 non-profit organization with no commercial purpose. The release of the information requested is not in Lower Drug Prices Now’s financial interest. Our mission is to educate the public about the importance of affordable and accessible prescription drugs and about the role federally funded research plays in the development of new drugs. Any information gathered through this request will be used to educate the public through reports, press releases, or other media.

Accordingly, American Oversight and Lower Drug Prices Now qualify for a fee waiver.

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 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>.

¹⁴ *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>.

¹⁵ *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>.

¹⁶ *Sessions’ Letter Shows DOJ Acted on Trump’s Authoritarian Demand to Investigate Clinton*, AMERICAN OVERSIGHT, <https://www.americanoversight.org/sessions-letter>.

Guidance Regarding the Search & Processing of Requested Records

In connection with its request for records, American Oversight and Lower Drug Prices Now provide 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.
- 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.¹⁷ 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 and Lower Drug Prices Now have a right to records contained in those files even if material has not yet been moved to official

¹⁷ 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).

systems or if officials have, by intent or through negligence, failed to meet their obligations.¹⁸

- 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,¹⁹ 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 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 and Lower Drug Prices Now, please do not hesitate to contact us to discuss this request. We welcome an opportunity to discuss its request with you before you undertake your search or incur search or

¹⁸ See *Competitive Enter. Inst. v. Office of Sci. & Tech. Policy*, No. 14-cv-765, slip op. at 8 (D.D.C. Dec. 12, 2016).

¹⁹ 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>.

duplication costs. By working together at the outset, we 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, please also provide responsive material on a rolling basis.

We share a common mission to promote transparency in government. American Oversight and Lower Drug Prices Now look 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 our request for a fee waiver is not granted in full, please contact us immediately upon making such a determination.

Sincerely,

A handwritten signature in black ink, appearing to read 'Myles Duffy', with a long horizontal line extending to the right.

Myles Duffy
Deputy Director
Lower Drug Prices Now

A handwritten signature in blue ink, appearing to read 'Austin R. Evers', with a long horizontal line extending to the right.

Austin R. Evers
Executive Director
American Oversight