



A PROJECT OF
ACCOUNTABLE.US

June 11, 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, Lower Drug Prices Now, and Patients Over Pharma, a project of Accountable.US, 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 across the globe, sickened millions of people, and resulted in more than 416,000 deaths worldwide.² Of particular concern to the public is

¹ *Coronavirus Disease 2019 (COVID-19) Situation Summary*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fcases-updates%2Fsummary.html.

² *Coronavirus Map: Tracking the Global Outbreak*, N.Y. TIMES (June 11, 2020, 8:05 AM), <https://www.nytimes.com/interactive/2020/world/coronavirus-maps.html>.

whether any treatments or vaccines will be affordable for all who need them.³ This question has taken particularly prominence in the context of decisions regarding federal investment in coronavirus drug and vaccine development.⁴

American Oversight, Lower Drug Prices Now, and Patients Over Pharma (Requesters) seek to shed light on the administration's handling of this issue.

Requested Records

We request 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 Jabber, 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 Office of the Assistant Secretary for Preparedness and Response (ASPR) and/or the Biomedical Advanced Research and Development Authority (BARDA), and (b) any employees or representatives of AstraZeneca, including any affiliate thereof, **regarding the pricing, cost, or affordability of any future coronavirus vaccine, including AZD1222.**⁵

At a minimum, a search for responsive records should include a search of the officials listed or described below.

ASPR:

- i. Assistant Secretary Robert Kadlec

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/#f772d54490c3>.

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, *Trump Administration's Operation Warp Speed Accelerates AstraZeneca COVID-19 Vaccine to be Available Beginning in October*, HHS, May 21, 2020, <https://www.hhs.gov/about/news/2020/05/21/trump-administration-accelerates-astrazeneca-covid-19-vaccine-to-be-available-beginning-in-october.html>.

- ii. Anyone serving as chief of staff or assistant to Assistant Secretary Kadlec
- iii. Principal Deputy Assistant Secretary Kevin Yeskey
- iv. Anyone serving as a chief of staff or assistant to Principal Deputy Assistant Secretary Yeskey
- v. Any deputies, directors, advisors (including senior advisors), or analysts (including senior analysts) within the immediate office of the Assistant Secretary for Preparedness and Response
- vi. Anyone serving as director of the External Affairs office, and any of their assistants
- vii. Anyone leading the Stakeholder Engagement branch of the External Affairs office, and any of their assistants

BARDA:

- i. Former Director Rick Bright
- ii. Acting Director Gary L. Disbrow
- iii. Anyone serving as a chief of staff or assistant to the BARDA Director or Acting Director
- iv. Any deputies, directors, advisors (including senior advisors), or analysts (including senior analysts) within the immediate office of the BARDA Director
- v. Anyone serving as director or acting director of the Contract Management and Acquisitions and Business Planning and Strategy division of BARDA, and any of their assistants
- vi. Anyone serving as director or acting director of the BARDA Division of Research, Innovation, and Ventures (DRIVE), and any of their assistants

Please provide all responsive records from January 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, Requesters seek 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.

We 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."⁶ The public has a significant interest in the

⁶ 5 U.S.C. § 552(a)(4)(A)(iii).

federal government's response to the coronavirus, particularly its efforts to ensure the development of a vaccine. 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 ensure products developed with taxpayer dollars are affordable to everyone who needs them.⁷ Furthermore, Requesters will make the responses agencies provide to FOIA requests publicly available, and the public's understanding of the government's activities would be enhanced through the Requesters' analysis and publication of these records.

This request is primarily and fundamentally for non-commercial purposes.⁸ As explained below, none of the Requesters have a commercial purpose and the release of the information is not in their financial interest.

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 also has 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" 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

⁷ See *supra* notes 3 & 4.

⁸ See 5 U.S.C. § 552(a)(4)(A)(iii).

⁹ American Oversight currently has approximately 15,500 page likes on Facebook and 102,200 followers on Twitter. American Oversight, FACEBOOK, <https://www.facebook.com/weareoversight/> (last visited June 1, 2020); American Oversight (@weareoversight), TWITTER, <https://twitter.com/weareoversight> (last visited June 1, 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>.

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

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. Its 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.

Patients Over Drugs is a project of Accountable.US. In May 2020, Accountable.US was recognized as a not for profit, 501(c)(3) organization, with the Internal Revenue Service. Accordingly, Accountable.US does not have a commercial purpose and the release of the information requested is not in Accountable.US's financial interest. Accountable.US's mission is to ensure public officials are advancing policies in the public's interest not for special interests.

Accordingly, the Requesters qualify for a fee waiver.

Guidance Regarding the Search & Processing of Requested Records

In connection with its request for records, we provide the following guidance regarding the scope of the records sought and the search and processing of records:

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>.

- 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.¹⁶ 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; we have 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.¹⁷
- 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,¹⁸ and many agencies

¹⁶ 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).

¹⁷ See *Competitive Enter. Inst. v. Office of Sci. & Tech. Policy*, No. 14-cv-765, slip op. at 8 (D.D.C. Dec. 12, 2016).

¹⁸ 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

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, 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 duplication costs. By working together at the outset, we can decrease the likelihood of costly and time-consuming litigation in the future.

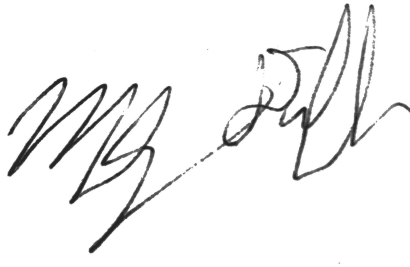
Where possible, please provide responsive material in an electronic format by email. Alternatively, please provide responsive material in native format or in PDF format on a USB drive. Please send any responsive material being sent by mail to American Oversight, 1030 15th Street NW, Suite B255, Washington, DC 20005. If it will accelerate release of responsive records, please also provide responsive material on a rolling basis.

We look forward to working with your agency on this request. If you do not understand any part of this request, please contact Christine Monahan of American Oversight at

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>.

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,

Handwritten signature of Myles Duffy in black ink, positioned to the left of a vertical yellow line.

Myles Duffy
Deputy Director
Lower Drug Prices Now

Handwritten signature of Austin R. Evers in blue ink.

Austin R. Evers
Executive Director
American Oversight

Handwritten signature of Kyle Herrig in black ink.

Kyle Herrig
President
Accountable.US