September 15, 2020

VIA EMAIL

Brandon Gaylord
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 Accountable 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. Since late 2019, the virus has spread across the globe, sickened more than 29 million people, and resulted in more than 900,000 deaths worldwide.[1] Of particular concern to the public is whether any treatments or vaccines will be safe,[2] and affordable for all who need

[1] *Coronavirus Map: Tracking the Global Outbreak,* N.Y. TIMES (Sept. 14, 2020, 7:52 AM), https://www.nytimes.com/interactive/2020/world/coronavirus-maps.html.
[2] *See, e.g.*, Bill Chappell, *9 Drugmakers Sign Safety Pledge In Rush To Develop Coronavirus Vaccine*, NPR (Sept. 8, 2020, 12:37 PM), https://www.npr.org/sections/coronavirus-live-updates/2020/09/08/910671322/9-drugmakers-sign-safety-pledge-in-race-to-develop-covid-19-vaccine.

them.[3] These questions have taken particularly prominence in the context of decisions regarding federal investment in coronavirus drug and vaccine development,[4] and the federal government's willingness to fast track the approval of coronavirus vaccines.[5]

American Oversight, Lower Drug Prices Now, and Accountable 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:

> Complete copies (including any attachments) of the contract(s), amendment(s), memorandum of understanding(s), or other written agreement(s) between (a) the U.S. Department of Health and Human Services (HHS) (including through the Office of the Assistant Secretary for Preparedness and Response (ASPR) and/or the Biomedical Advanced Research and Development Authority (BARDA)), and (b) the entities listed below regarding the development of a coronavirus vaccine:
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> 1. Novavax, Inc. (including but not limited to the $1.6 billion agreement announced by HHS on July 7, 2020[6])

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[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] Sarah O'Brien, *FDA Willing to Fast Track Coronavirus Vaccine Before Phase Three Trials End*, CNBC (Aug. 30, 2020 10:37 AM), https://www.cnbc.com/2020/08/30/fda-willing-to-fast-track-coronavirus-vaccine-before-phase-three-trials.html.

[6] Press Release, U.S. Dep't of Health and Human Servs., HHS, DOD Collaborate with Novavax to Produce Millions of COVID-19 Investigational Vaccine Doses in Commercial-Scale Manufacturing Demonstration Projects (July 7, 2020), https://www.hhs.gov/about/news/2020/07/07/hhs-dod-collaborate-novavax-produce-millions-covid-19-investigational-vaccine-doses-commercial-scale-manufacturing-demonstration-projects.html.

2. Pfizer (including but not limited to the $1.95 billion agreement with Pfizer and/or BioNTech announced by HHS on July 22, 2020[7])
3. BioNTech (including but not limited to the $1.95 billion agreement with Pfizer and/or BioNTech announced by HHS on July 22, 2020[8])
4. Sanofi Pasteur and/or its subsidiary Protein Sciences (collectively, Sanofi) (including but not limited to the $2.04 billion award to Sanofi in conjunction with GlaxoSmithKline announced on July 31, 2020,[9] and any related awards or agreements with Sanofi that preceded this announcement[10])
5. GlaxoSmithKline (GSK) (including but not limited to the $2.04 billion award to GSK in conjunction with Sanofi announced on July 31, 2020[11])

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[7] Press Release, U.S. Dep't of Health and Human Servs., U.S. Government Engages Pfizer to Produce Millions of Doses of COVID-19 Vaccine (July 22, 2020), https://www.hhs.gov/about/news/2020/07/22/us-government-engages-pfizer-produce-millions-doses-covid-19-vaccine.html#:~:text=The%20U.S.%20Department%20of%20Health,vaccine's%20successful%20manufacture%20and%20approval.

[8] Press Release, U.S. Dep't of Health and Human Servs., U.S. Government Engages Pfizer to Produce Millions of Doses of COVID-19 Vaccine (July 22, 2020), https://www.hhs.gov/about/news/2020/07/22/us-government-engages-pfizer-produce-millions-doses-covid-19-vaccine.html#:~:text=The%20U.S.%20Department%20of%20Health,vaccine's%20successful%20manufacture%20and%20approval; *see also* Press Release, Business Wire, Pfizer and BioNTech Announce an Agreement with U.S. Government for up to 600 Million Doses of mRNA-based Vaccine Candidate Against SARS-CoV-2, https://www.businesswire.com/news/home/20200722005438/en/.

[9] Press Release, U.S. Dep't of Health and Human Servs., HHS, DOD Partner With Sanofi and GSK on Commercial-Scale Manufacturing Demonstration Project to Produce Millions of COVID-19 Investigational Vaccine Doses (July 31, 2020), https://www.hhs.gov/about/news/2020/07/31/hhs-dod-partner-sanofi-gsk-commercial-scale-manufacturing-demonstration-project-produce-millions-covid-19-investigational-vaccine-doses.html.

[10] *See BARDA and Sanofi Prepare for Studies of COVID-19 Vaccine*, MedicalCountermeasures.gov, https://www.medicalcountermeasures.gov/newsroom/2020/psc-sanofi-recombinant/.

[11] Press Release, U.S. Dep't of Health and Human Servs., HHS, DOD Partner With Sanofi and GSK on Commercial-Scale Manufacturing Demonstration Project to Produce Millions of COVID-19 Investigational Vaccine Doses (July 31, 2020), https://www.hhs.gov/about/news/2020/07/31/hhs-dod-partner-sanofi-gsk-commercial-scale-manufacturing-demonstration-project-produce-millions-covid-19-investigational-vaccine-doses.html.

6. Moderna, Inc. (specifically, any documents regarding the $1.525 billion award announced on August 11, 2020[12])

Please search for 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."[13] The public has a significant interest in the federal government's response to the coronavirus, particularly its efforts to ensure the development and distribution of a safe, effective, and affordable 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 safe, accessible, and affordable to everyone who needs them.[14] 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.[15] 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.

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[12] Press Release, U.S. Dep't of Health and Human Servs., Trump Administration Collaborates with Moderna to Produce 100 Million Doses of COVID-19 Investigational Vaccine (Aug. 11, 2020), https://www.hhs.gov/about/news/2020/08/11/trump-administration-collaborates-with-moderna-produce-100-million-doses-covid-19-investigational-vaccine.html#:~:text=Under%20the%20leadership%20of%20President,will%20own%20these%20vaccine%20doses.

[13] 5 U.S.C. § 552(a)(4)(A)(iii).

[14] *See supra* notes 2–5.

[15] *See* 5 U.S.C. § 552(a)(4)(A)(iii).

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.[16]

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.[17] 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;[18] 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;[19] posting records regarding potential self-dealing at the Department of Housing & Urban Development and related analysis;[20] posting records and analysis relating to the federal government's efforts to sell nuclear technology to Saudi Arabia;[21] 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

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[16] American Oversight currently has approximately 15,600 page likes on Facebook and 104,600 followers on Twitter. American Oversight, FACEBOOK, https://www.facebook.com/weareoversight/ (last visited Sept. 14, 2020); American Oversight (@weareoversight), TWITTER, https://twitter.com/weareoversight (last visited Sept. 14, 2020).

[17] *News*, AMERICAN OVERSIGHT, https://www.americanoversight.org/blog.

[18] *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.

[19] *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.

[20] *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.

[21] *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.

political opponents and allegations of misconduct by the Department of Justice itself and the Federal Bureau of Investigation.[22]

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.

Accountable Pharma 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:

- Our request for records includes any attachments to those records or other materials enclosed with those records when they were previously transmitted.

- 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; we have a right to records contained in those files even if material

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

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.

- 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.

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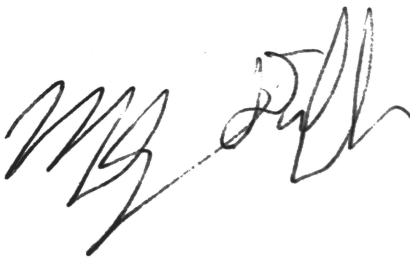
[24] *See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy*, No. 14-cv-765, slip op. at 8 (D.D.C. Dec. 12, 2016).

[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.

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 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,



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