

September 30, 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 U.S. Food and Drug Administration (FDA) has drafted and U.S. Secretary for Health and Human Services (HHS) Alex Azar has approved new guidelines governing the standards for granting emergency use authorization of coronavirus vaccines. Yet—although the FDA insists that it expects vaccine developers to comply with at least some of these guidelines, including that clinical trials not be stopped early—this guidance may never be publicly released, due to objections from the White House.

American Oversight seeks records that may shed light on the standards the FDA will use in reviewing any requests for emergency use authorization of coronavirus vaccines and the standards that the agency is communicating it will use to vaccine developers.

## Requested Records

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

<sup>&</sup>lt;sup>2</sup> Brennan, *supra* note 1.



<sup>&</sup>lt;sup>1</sup> Zachary Brennan, Top FDA Vaccine Official Says Vaccine Guidance May Never Be Released, Politico (Sept. 28, 2020, 3:32 PM),

https://www.politico.com/news/2020/09/28/fda-vaccine-guidance-may-not-be-released-422648; Laurie McGinley & Carolyn Y. Johnson, FDA Poised to Announce Tougher Standards for a COVID-19 Vaccine That Make It Unlikely One Will Be Cleared by Election Day, Wash. Post (Sept. 22, 2020, 3:16 PM),

https://www.washingtonpost.com/health/2020/09/22/fda-covid-vaccine-approval-standard/.

All records reflecting guidance given by the FDA to companies developing and/or manufacturing coronavirus vaccines (including, but not limited to, Pfizer, Moderna Therapeutics, AstraZeneca, Novavax, Inovio Pharmaceuticals, Sanofi, GlaxoSmithKline, Johnson & Johnson, Merck, and CureVac), or representatives thereof, regarding any conditions, criteria, standards, requirements, or processes governing emergency use authorization of coronavirus vaccines.<sup>3</sup>

American Oversight notes that FDA Deputy Director Phillip Krause recently stated that "[i]t's a point of significant importance to make sure that the companies understand what's needed for an emergency authorization"<sup>4</sup>; broadly speaking, this request seeks records that will shed light on the FDA's efforts to achieve this goal. It encompasses any electronic communications (including emails, email attachments, text messages, messages on messaging platforms (such as Slack, GChat or Google Hangouts, Lync, Skype, or WhatsApp) or (summaries, notes, or descriptions of or talking points for oral communications from FDA to the companies on the subject matter described above. To reduce the burden on the agency and facilitate processing, however, American Oversight is willing to exclude public statements made by the FDA, including to reporters or in public forums, such as a congressional hearing, that were intended to provide guidance to vaccine manufacturers.

The search for responsive records should include all individuals and locations where records are likely to exist, including <u>but not limited to</u> the Immediate Office of the Commissioner, the Office of the Executive Secretariat, the Office of External Affairs, the Center for Biologics Evaluation & Research, as well as any other offices or individuals charged with engaging with companies developing coronavirus vaccines.

Please search for responsive records from August 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

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<sup>&</sup>lt;sup>3</sup> Press reporting indicates that elements of FDA's recent guidance are already being shared with vaccine developers. At a minimum, those portions of the guidance are responsive to this request. *See* McGinley & Carolyn Y. Johnson.

<sup>&</sup>lt;sup>4</sup> Brennan, *supra* note 1.

public understanding of operations or activities of the government."<sup>5</sup> The public has a significant interest in the federal government's response to the coronavirus pandemic, including any potential review and authorization or approval of a vaccine.<sup>6</sup> Records with the potential to shed light on this matter would contribute significantly to public understanding of operations of the federal government, including what standards are or will be applied to requests for emergency use authorization for any coronavirus vaccines and whether they are adequate to ensure vaccine efficacy and safety.<sup>7</sup> 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.<sup>8</sup> 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.<sup>9</sup>

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

https://docs.google.com/forms/d/e/1FAIpQLSdXaVo9BWAhMMej\_KUL2sTB6jt3H 2j90aagVXymWWS-luudzA/viewform (last visited Sept. 29, 2020);

https://www.cnn.com/2020/09/13/health/coronavirus-vaccine-eua-explainer-gupta/index.html.

<sup>&</sup>lt;sup>5</sup> 5 U.S.C. § 552(a)(4)(A)(iii).

<sup>6</sup> See, e.g., Alec Tyson, Courtney Johnson & Cary Funk, U.S. Public Now Divided Over Whether to Get COVID-19 Vaccine, Pew Res. Ctr., Sept. 17, 2020, https://www.pewresearch.org/science/2020/09/17/u-s-public-now-divided-over-whether-to-get-covid-19-vaccine/; Open Letter to Stephen M. Hahn, M.D. Commissioner of the Food and Drug Administration: #ProtectTheFDA,

<sup>&</sup>lt;sup>7</sup> See, e.g., McGinley & Johnson, supra note 1; Dr. Sanjay Gupta & Andrea Kane, What Is an EUA, and What Does It Have to Do with How Quickly We Get a Coronavirus Vaccine?, CNN (Sept. 14, 2020, 8:30 AM),

<sup>&</sup>lt;sup>8</sup> See 5 U.S.C. § 552(a)(4)(A)(iii).

<sup>&</sup>lt;sup>9</sup> American Oversight currently has approximately 15,600 page likes on Facebook and 105,400 followers on Twitter. American Oversight, Facebook, <a href="https://www.facebook.com/weareoversight/">https://www.facebook.com/weareoversight/</a> (last visited Sept. 29, 2020); American Oversight (@weareoversight), Twitter, <a href="https://twitter.com/weareoversight">https://twitter.com/weareoversight</a> (last visited Sept. 29, 2020).

<sup>&</sup>lt;sup>10</sup> See generally News, American Oversight, <a href="https://www.americanoversight.org/blog">https://www.americanoversight.org/blog</a>.

the Trump Administration's contacts with Ukraine and analyses of those contacts;<sup>11</sup> posting records and editorial content about the federal government's response to the Coronavirus pandemic;<sup>12</sup> 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;<sup>13</sup> 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;<sup>14</sup> and posting records and analysis of federal officials' use of taxpayer dollars to charter private aircraft or use government planes for unofficial business.<sup>15</sup>

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, 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 there is a compelling need for expedited processing of the above requests because the information requested is urgently needed to inform the public concerning actual or alleged government activity and American Oversight is primarily engaged in disseminating the information it receives from public records requests to the public. 45 C.F.R. § 5.27(b)(2).

funding-no-timeline-no-wall.

<sup>11</sup> Trump Administration's Contacts with Ukraine, American Oversight, <a href="https://www.americanoversight.org/investigation/the-trump-administrations-contacts-with-ukraine">https://www.americanoversight.org/investigation/the-trump-administrations-contacts-with-ukraine</a>.

<sup>12</sup> 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. 'We've All Given Up Getting a Straight Answer From You Guys: Frustrated Emails Between Illinois Governor's Office and White House, https://www.americanoversight.org/weve-all-given-up-getting-a-straight-answer-from-you-guys-frustrated-emails-between-illinois-governors-office-and-white-house.

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-

<sup>14</sup> 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.

<sup>15</sup> 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.

There is clearly an urgent need to inform the public regarding the matters that are the subject of American Oversight's FOIA requests. As several coronavirus vaccines moved into Stage III clinical trials and President Trump repeatedly predicted that one or more vaccines would be ready for distribution by Election Day,<sup>16</sup> FDA Commissioner Stephen Hahn made clear that the FDA would consider granting emergency use authorization for a coronavirus vaccine to fast track its public use before clinical trials are completed.<sup>17</sup> This controversial decision<sup>18</sup> raised many questions in the public regarding what standards the FDA would apply to requests for emergency use authorization of any coronavirus vaccines,<sup>19</sup> and came in the midst of decreasing public confidence in the safety and efficacy of coronavirus vaccines.<sup>20</sup> Shortly thereafter, the FDA—in a blog post by Commissioner Hahn and Peter Marks, Director for the Center for Biologics Evaluation and Research—announced that it "intends to issue additional guidance

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<sup>&</sup>lt;sup>16</sup> See, e.g., Berkeley Lovelace Jr. & Noah Niggins-Dunn, Trump Says U.S. Could Start Distributing a Coronavirus Vaccine in October, Contradicting CDC's Timeline, CNBC (Sept. 16, 2020, 6:51 PM), <a href="https://www.cnbc.com/2020/09/16/trump-says-he-thinks-us-could-start-distributing-a-coronavirus-vaccine-in-october.html">https://www.cnbc.com/2020/09/16/trump-says-he-thinks-us-could-start-distributing-a-coronavirus-vaccine-in-october.html</a>; Jordyn Phelps, Trump Makes Rosy Vaccine Timing Front and Center in Campaign, Predicting It's Possible Before Election Day, ABC News (Sept. 8 2020, 2:25 PM), <a href="https://abcnews.go.com/Politics/trump-makes-rosy-vaccine-timing-front-center-campaign/story?id=72877119">https://abcnews.go.com/Politics/trump-makes-rosy-vaccine-timing-front-center-campaign/story?id=72877119</a>.

<sup>17</sup> Sarah O'Brien, FDA Willing to Fast Track Coronavirus Vaccine Before Phase Three Trials End, CNBC (Aug. 31, 2020, 7:58 AM), https://www.cnbc.com/2020/08/30/fda-willing-to-fast-track-coronavirus-vaccine-before-phase-three-trials.html; Jamie Gumbrecht, FDA Leader Says Agency Could Consider Authorization for Covid-19 Vaccine Before Phase 3 Trials Are Complete, Financial Times Reports, CNN (Aug. 30, 2020, 1:18 PM), https://www.cnn.com/2020/08/30/health/fda-covid-19-vaccine-eua/index.html. >

<sup>&</sup>lt;sup>18</sup> Laurie McGinley & Carolyn Y. Johnson, *Debate Rages Over Whether FDA Should Use Emergency Powers to Clear a Coronavirus Vaccine Early*, Wash. Post (Sept. 2, 2020, 8:20 PM), <a href="https://www.washingtonpost.com/health/2020/09/02/fda-coronavirus-vaccine-emergency-authority/">https://www.washingtonpost.com/health/2020/09/02/fda-coronavirus-vaccine-emergency-authority/</a>.

<sup>&</sup>lt;sup>19</sup> See, e.g., Gupta & Kane, supra note 6; Smriti Mallapaty & Heidi Ledford, COVID-Vaccine Results Are on the Way – And Scientists' Concerns Are Growing, Nature, Sept. 25, 2020, <a href="https://www.nature.com/articles/d41586-020-02706-6">https://www.nature.com/articles/d41586-020-02706-6</a>.

<sup>&</sup>lt;sup>20</sup> See, e.g., Tyson, Johnson & Funk, supra note 5; Sarah Owermohle, Vaccine-Makers Promise Safety Amid Shaky Public Confidence in Covid Developments, Politico (Sept. 8, 2020, 2:31 PM), <a href="https://www.politico.com/news/2020/09/08/vaccine-makers-safety-pledge-409784">https://www.politico.com/news/2020/09/08/vaccine-makers-safety-pledge-409784</a>; Paige Winfield Cunningham, The Health 2020: Americans Worry a Coronvirus Vaccine Will be Rushed. Trump's Rhetoric Isn't Helping, Wash. Post (Sept. 9, 2020, 7:58 AM), <a href="https://www.washingtonpost.com/politics/2020/09/09/health-202-americans-worry-coronavirus-vaccine-will-be-rushed-trump-rhetoric-isnt-helping/">https://www.washingtonpost.com/politics/2020/09/09/health-202-americans-worry-coronavirus-vaccine-will-be-rushed-trump-rhetoric-isnt-helping/</a>; Jennifer De Pinto, Voters Skeptical About Potential COVID-19 Vaccine and Say That One This Year Would Be Rished – CBS News Poll, CBS News (Sept. 6, 2020, 12:14 PM), <a href="https://www.cbsnews.com/news/voters-covid-19-vaccine-opinion-poll/">https://www.cbsnews.com/news/voters-covid-19-vaccine-opinion-poll/</a>; Letters, <a href="Distrust of a Rushed Covid Vaccine">Distrust of a Rushed Covid Vaccine</a>, N.Y. Times, Sept. 3, 2020, <a href="https://www.nytimes.com/2020/09/03/opinion/letters/coronavirus-vaccine.html">https://www.nytimes.com/2020/09/03/opinion/letters/coronavirus-vaccine.html</a>.

shortly to provide sponsors of requests for Emergency Use Authorization (EUA) for COVID-19 Vaccines with Recommendations Regarding the Data and Information Needed to Support the Issuance of an EUA."<sup>21</sup> In making this announcement, these officials acknowledged that "[w]ith so much at stake, we understand the importance of being as transparent as possible about the work we do, including how we will make decisions regarding COVID-19 vaccines," and that "transparency regarding the FDA's thinking about the scientific data needed to support approval of safe and effective vaccines will help build public confidence in the FDA's evaluation process, which will be critical in ensuring the use of COVID-19 vaccines once available."<sup>22</sup>

It since has come to light that these standards—which were signed off on by HHS Secretary Azar<sup>23</sup> and endorsed by Moncef Slaoui, chief advisor to Operation Warp Speed<sup>24</sup>—may never be publicly released, due to objections from the White House.<sup>25</sup> Yet, statements from FDA officials and other reports indicate that the FDA's standards continue to govern how the agency will review any requests for emergency use authorization and are being shared with vaccine manufacturers.<sup>26</sup>

This request seeks records that will shed light on the standards that, formally or informally, the FDA is sharing with vaccine manufacturers and ultimately will use to determine whether or not to grant emergency use authorization for a coronavirus vaccine. With the FDA's own acknowledgment of the importance of transparency regarding the standards to be applied for the emergency authorization of any coronavirus vaccine,<sup>27</sup> calls for transparency from vaccine manufacturers,<sup>28</sup> and

<sup>&</sup>lt;sup>21</sup> Stephen Hahn & Peter Marks, *The FDA's Scientific and Regulatory Oversight of Vaccines is Vital to Public Health*, FDA, Sept. 11, 2020, <a href="https://www.fda.gov/news-events/fda-voices/fdas-scientific-and-regulatory-oversight-vaccines-vital-public-health">https://www.fda.gov/news-events/fda-voices/fdas-scientific-and-regulatory-oversight-vaccines-vital-public-health</a>.

<sup>&</sup>lt;sup>22</sup> Id.

<sup>&</sup>lt;sup>23</sup> Brennan, *supra* note 1.

<sup>&</sup>lt;sup>24</sup> Julie Steenhusen, U.S. Vaccine Program Chief Backs Stricter Rules for Emergency Use of COVID-19 Shot, Reuters (Sept. 24, 2020, 3:43 PM),

https://www.reuters.com/article/health-coronavirus-vaccine-guidance/update-1-u-s-vaccine-program-chief-backs-stricter-rules-for-emergency-use-of-covid-19-shot-idUSL2N2GL24M;

<sup>&</sup>lt;sup>25</sup> Brennan, *supra* note 1.

<sup>&</sup>lt;sup>26</sup> Id. ("Nevertheless, the FDA wants vaccine developers to know that it will insist on seeing through clinical trials for any shot that receives emergency authorization, said Phillip Krause, deputy director for the FDA's Center for Biologics Evaluation and Research. 'It's a point of significant importance to make sure that the companies understand what's needed for an emergency authorization,' he said at the World Vaccine Congress."); McGinley & Johnson, supra note 2 ("While it is being reviewed by the White House Office of Management and Budget, elements of it are already being shared with vaccine makers.").

<sup>&</sup>lt;sup>27</sup> Hahn & Marks, *supra* note 20.

<sup>&</sup>lt;sup>28</sup> Brennan, *supra* note 1.

widespread acknowledgment that public trust in vaccines is in peril,<sup>29</sup> it is indisputable that there is an urgent need to inform the public about these standards.

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,<sup>30</sup> 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." 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 media platforms, such as Facebook and Twitter. As discussed previously, American Oversight has demonstrated its commitment to the public disclosure of documents and creation of editorial content.

https://www.facebook.com/weareoversight

<sup>&</sup>lt;sup>29</sup> See supra note 19; see also Opinion, Robert Califf et al., 7 Former FDA Commissioners: The Trump Administration Is Undermining the Credibility of the FDA, Wash. Post (Sept. 29, 2020, 5:16 PM),

https://www.washingtonpost.com/opinions/2020/09/29/former-fda-commissioners-coronavirus-vaccine-trump/; Editorial, *COVID Vaccine Confidence Requires Radical Transparency*, Nature, Sept. 29, 2020, <a href="https://www.nature.com/articles/d41586-020-02738-y">https://www.nature.com/articles/d41586-020-02738-y</a>.

<sup>&</sup>lt;sup>30</sup> 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).

<sup>&</sup>lt;sup>31</sup> ACLU, 321 F. Supp. 2d at 29 n.5 (quoting EPIC, 241 F. Supp. 2d at 11).

<sup>&</sup>lt;sup>32</sup> American Oversight currently has approximately 15,600 page likes on Facebook and 105,400 followers on Twitter. American Oversight, Facebook,

<sup>(</sup>last visited Sept. 29, 2020); American Oversight (@weareoversight), Twitter, <a href="https://twitter.com/weareoversight">https://twitter.com/weareoversight</a> (last visited Sept. 29, 2020).

<sup>33</sup> See generally News, American Oversight, <a href="https://www.americanoversight.org/blog">https://www.americanoversight.org/blog</a>; see, e.g., Emails and Resume of Trump's Pick to Head Government Personnel Office, American Oversight, <a href="https://www.americanoversight.org/emails-and-resume-of-trumps-pick-to-head-government-personnel-office">https://www.americanoversight.org/emails-and-resume-of-trumps-pick-to-head-government-personnel-office</a>; CDC Calendars from 2018 and 2019: Pandemic-Related Briefings and Meetings, American Oversight, <a href="https://www.americanoversight.org/cdc-calendars-from-2018-and-2019-pandemic-related-briefings-and-meetings">https://www.americanoversight.org/cdc-calendars-from-2018-and-2019-pandemic-related-briefings-and-meetings</a>; State Department Releases Ukraine Documents to American Oversight, American Oversight, <a href="https://www.americanoversight.org/state-department-releases-ukraine-documents-to-american-oversight">https://www.americanoversight.org/state-department-releases-ukraine-documents-to-american-oversight</a>; 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

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. 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.<sup>34</sup> 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

Authoritarian Demand to Investigate Clinton, American Oversight, https://www.americanoversight.org/sessions-letter.

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.<sup>35</sup>
- 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,<sup>36</sup> 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, 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

<sup>&</sup>lt;sup>35</sup> See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, No. 14-cv-765, slip op. at 8 (D.D.C. Dec. 12, 2016).

<sup>36</sup> Presidential Memorandum—Managing Government Records, 76 Fed. Reg. 75,423 (Nov. 28, 2011), <a href="https://obamawhitehouse.archives.gov/the-press-office/2011/11/28/presidential-memorandum-managing-government-records">https://obamawhitehouse.archives.gov/the-press-office/2011/11/28/presidential-memorandum-managing-government-records</a>; 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), <a href="https://www.archives.gov/files/records-mgmt/m-12-18.pdf">https://www.archives.gov/files/records-mgmt/m-12-18.pdf</a>.

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 <a href="mailto:foia@americanoversight.org">foia@americanoversight.org</a> or (202) 492-9798. Also, if American Oversight's request for expedition is not granted or its 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