AMERICAN OVERSIGHT

February 02, 2022

VIA ONLINE PORTAL

Food and Drug Administration (FDA)
Sarah Kotler, Director
Division of Freedom of Information, OES
U.S. Food & Drug Administration
5630 Fishers Lane
Room-1035
Rockville, Maryland 20857

Re: Freedom of Information Act Request

Dear FOIA Officer,

Pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, and your agency's implementing regulations, 45 C.F.R. Part 5, American Oversight makes the following request for records.

In November 2020, ten of the 11 members on the U.S. Food and Drug Administration's (FDA's) Peripheral and Central Nervous System Drugs Advisory Committee voted against approving the Biogen-developed drug Aduhelm (aducanumab) for the treatment of Alzheimer's after reviewing its clinical trial data.[1] Despite the committee's recommendation, on June 7, 2021, the FDA approved the drug through an accelerated approval process.[2]

The *Boston Globe* has reported that subsequent to the committee's negative recommendation, Biogen—guided by FDA staffers—sought such accelerated approval for aducanumab based on different criteria from its initial application.[3] The process changes and subsequent approval of aducanumab prompted resignations from several members of the FDA's advisory committee, with some now-former members accusing the FDA of "moving the goalposts" by which the clinical trial results would be

[1] Pam Belluck, *F.D.A. Panel Declines to Endorse Controversial Alzheimer's Drug*, N.Y. Times, Nov. 6, 2020, https://www.nytimes.com/2020/11/06/health/aducanumab-alzheimers-drug-fda-panel.html.
[2] U.S. Food and Drug Administration, *FDA Grants Accelerated Approval for Alzheimer's Drug*, June 7, 2021, https://www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-alzheimers-drug.
[3] Larry Edelman, Boston Globe, *Biogen in a Bind: The High-Stakes Fight Over Alzheimer's and What Makes a Drug Worthwhile*, updated July 25, 2021, https://www.bostonglobe.com/2021/07/25/business/biogen-bind-high-stakes-fight-over-alzheimers-what-makes-drug-worthwhile/.

evaluated.[4] Other scientists involved in earlier phases of Biogen's aducanumab research have stated in interviews with the *New York Times* that they do not agree with the FDA's approval.[5] Moreover, prominent medical centers, including The Cleveland Clinic and Mount Sinai Health System, have stated that they would not administer aducanumab.[6] Additionally, Acting FDA Commissioner Janet Woodcock asked the Department of Health and Human Services (HHS) Office of Inspector General to investigate the approval of the drug, requesting an independent review and assessment covering "interactions between Biogen [...] and the FDA during the process that led to the June approval of the drug."[7]

American Oversight seeks records with the potential to shed light on the FDA's approval process for Aduhelm (aducanumab).

Requested Records

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

> All email communications (including emails, email attachments, complete email chains, and calendar invitations) sent by any individuals in Column A to any external entities and individuals in Column B, regarding Biogen or Aduhelm (aducanumab).

Column A: FDA officials	**Column B**: External Entities
a. Dr. Janet Woodcock (Acting Commissioner) b. Dr. Stephen Hahn (Former Commissioner) c. Dr. Patrizia Cavazzoni (Director, Center for Drug Evaluation and Research) d. Dr. Billy Dunn (Director, Office of Neuroscience)	a. Anyone communicating on behalf of Biogen (including, but not limited to, email addresses ending in @biogen.com) b. Anyone communicating on behalf of Capitol Counsel (including, but not limited to, email addresses ending in @capitolcounsel.com)

[4] Dennis Thompson, *FDA Panel Advisor Who Panned New Alzheimer's Drug Speaks Out*, HealthDay, July 28, 2021, https://consumer.healthday.com/7-28-fda-advisory-panel-who-panned-it-speaks-out-against-new-alzheimer-s-drug-2653982522.html.

[5] Belluck., *How an Unproven Alzheimer's Drug Got Approved*, *supra* note 1.

[6] Pam Belluck, *Cleveland Clinic and Mount Sinai Won't Administer Aduhelm to Patients*, N.Y. Times, July 14, 2021, https://www.nytimes.com/2021/07/14/health/cleveland-clinic-aduhelm.html?campaign_id=60&emc=edit_na_20210715&instance_id=0&nl=breaking-news&ref=headline&regi_id=145327320&segment_id=63531&user_id=ebac11ba9344b466151da49e9daca00f.

[7] Jamie Gumbrecht, *Acting FDA Commissioner Calls for Independent Investigation Into Approval of Alzheimer's Drug*, CNN, July 9, 2021, https://www.cnn.com/2021/07/09/health/aduhelm-fda-requests-inspection/index.html.

e. Dr. Peter W. Marks (Director, Center for Biologics Evaluation and Research) f. Dr. Peter Stein (Director, Office of New Drugs) g. Dr. Richard Pazdur (Director, Oncology Center of Excellence) h. Dr. Sylva Collins (Director, Office of Biostatistics) i. Dr. ShaAvhrée Buckman-Garner (Director, Office of Translational Sciences) j. Dr. Jessica Seo (Designated Federal Officer, Peripheral and Central Nervous System Drugs Advisory Committee)	c. Anyone communicating on behalf of Federal Street Strategies (including, but not limited to, email addresses ending in @federalstreetstrategies.com) d. Anyone communicating on behalf of Jeffrey J. Kimbell & Associates (including, but not limited to, email addresses ending in @kimbell-associates.com, @kimbellassociates.com, or @kimbell.associates.com) e. Anyone communicating on behalf of Thorn Run Partners (including, but not limited to, email addresses ending in @thornrun.com) f. Anyone communicating on behalf of Todd Strategy Group (including, but not limited to, email addresses ending in @toddstrategy.com) g. Anyone communicating on behalf of Alston & Bird (including, but not limited to, email addresses ending in @alston.com)

In an effort to accommodate the FDA and reduce the number of potentially responsive records to be processed and produced, American Oversight has limited its request to emails sent by the custodians listed in Column A. To be clear, however, American Oversight still requests that complete email chains be produced, displaying both sent and received messages. This means, for example, that both the response by an individual in Column A to an email from an individual in Column B, and the initial received message, are responsive to this request and should be produced.

For this request, please provide all responsive records from September 1, 2020, through June 7, 2021.

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 by the general public of

relevant government procedures 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."[8] The public has a significant interest in a potential new Alzheimer's drug, given that the FDA's decision to approve Aduhelm marked the first approval of an Alzheimer's treatment in 18 years.[9] Records with the potential to shed light on this matter would contribute significantly to public understanding of operations of the federal government, including the process by which the FDA approves new drugs. American Oversight is committed to transparency and makes the responses agencies provide to FOIA requests publicly available. 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.[10] 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.[11]

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.[12] Examples reflecting this commitment to the public disclosure of documents and the creation of editorial content include the posting of records related to the Trump Administration's contacts with Ukraine and analyses of those contacts;[13] posting records and editorial content about the federal government's response to the

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[8] 5 U.S.C. § 552(a)(4)(A)(iii).
[9] Pam Belluck and Rebecca Robbins, *Three F.D.A. Advisers Resign Over Agency's Approval of Alzheimer's Drug*, N.Y. Times, updated July 8, 2021, https://www.nytimes.com/2021/06/10/health/aduhelm-fda-resign-alzheimers.html.
[10] *See* 5 U.S.C. § 552(a)(4)(A)(iii).
[11] American Oversight currently has approximately 15,700 page likes on Facebook and 114,500 followers on Twitter. American Oversight, Facebook, https://www.facebook.com/weareoversight/ (last visited Jan. 31, 2022); American Oversight (@weareoversight), Twitter, https://twitter.com/weareoversight (last visited Jan. 31, 2022).
[12] *See generally News*, American Oversight, https://www.americanoversight.org/blog.
[13] *Trump Administration's Contacts with Ukraine*, American Oversight, https://www.americanoversight.org/investigation/the-trump-administrations-contacts-with-ukraine.

Coronavirus pandemic;[14] 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;[15] 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;[16] and posting records and analysis of federal officials' use of taxpayer dollars to charter private aircraft or use government planes for unofficial business.[17]

Accordingly, American Oversight qualifies for a fee waiver.

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.

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[14] *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.*, *CDC Calendars from 2018 and 2019: Pandemic-Related Briefings and Meetings*, American Oversight, https://www.americanoversight.org/cdc-calendars-from-2018-and-2019-pandemic-related-briefings-and-meetings.

[15] *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.

[16] *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.

[17] *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.

- 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.[18] 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.[19]

- 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,[20] 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

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[18] *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).
[19] *See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy*, No. 14-cv-765, slip op. at 8 (D.D.C. Dec. 12, 2016).
[20] 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.

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 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 of promoting 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 Taylor Stoneman at foia@americanoversight.org or (202) 848-1319. 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,

/s/ Taylor Stoneman
Taylor Stoneman
on behalf of
American Oversight