



July 22, 2019

**VIA CERTIFIED MAIL**

Darshini Satchi  
Division of Information Disclosure, FOI  
Center for Drug Evaluation and Research  
U.S. Food and Drug Administration  
10001 New Hampshire Avenue  
Silver Spring, MD 20993

**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, American Oversight makes the following request for records.

The Comprehensive Addiction and Recovery Act of 2016 directed the Secretary of the Department of Health and Human Services (HHS), in cooperation with the Department of Veterans Affairs (VA) and the Department of Defense (DOD), to convene a Pain Management Best Practices Inter-Agency Task Force (the Task Force) charged with providing recommendations on best practices and recommendations in the area of chronic and acute pain management.<sup>1</sup> A subsequent enactment expanded the Task Force's scope to include collaborating with the Secretary of HHS to make recommendations related to Medicare and Medicaid payment and coverage policies affecting the opioid crisis.<sup>2</sup>

The Task Force has since been convened and issued its first report, which criticizes guidance from the U.S. Centers for Disease Control and Prevention (CDC) regarding limiting opioid prescribing.<sup>3</sup> But questions have been raised in the media<sup>4</sup> and by members

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<sup>1</sup> Comprehensive Addiction and Recovery Act of 2017, P.L. 114-198, Sec. 101.

<sup>2</sup> Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, P.L. 115-271, Sec. 6032.

<sup>3</sup> U.S. Department of Health & Human Services, *Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations* 69–72 (May 9, 2019), available at <https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf>.

<sup>4</sup> Ben Goodwin et al., *Industry-Funded Attacks on the CDC's Opioid Prescribing Guideline Are Eroding Public Health*, STAT, June 11, 2019, <https://www.statnews.com/2019/06/11/attacks-cdc-opioids-prescribing-guideline/>.



of Congress<sup>5</sup> about potential conflicts of interest between members of the Task Force and opioid and medical device manufacturers that may have influenced the Task Force's recommendations on this and other topics.

American Oversight seeks records to shed light on communications between Task Force members and drug and device manufacturers.

### **Requested Records**

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

All email communications (including emails, email attachments, calendar invitations, and any attachments thereto) between or among (1) Sharon Hertz, M.D., Director, Division of Anesthesia, Analgesia, and Addiction Products, Center for Drug Evaluation and Research, Food and Drug Administration, and (2) any employee or representative of the following drug and device manufacturers and their subsidiaries or affiliates:

- a. Purdue, including Purdue Pharma L.P.; Purdue Pharma, Inc.; and The Purdue Frederick Company, Inc. (@purduepharma.com)
- b. Allergan, including Allergan PLC; Allergan Finance, LLC; Allergan USA, Inc.; and Allergan Sales, LLC (@allergan.com)
- c. Teva, including Teva Pharmaceuticals Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Watson Laboratories, Inc.; Warner Chilcott Company, LLC; Actavis Pharma, Inc.; Actavis South Atlantic LLC; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC, Actavis Totowa LLC; Actavis LLC; Actavis Kadian LLC; Actavis Laboratories UT, Inc.; Actavis Laboratories FL, Inc.; and Andrx Corporation (@tevapharm.com)
- d. Johnson & Johnson, including Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc.; and Janssen Pharmaceutica, Inc. (@its.jnj.com; @jnj.com)
- e. Endo, including Endo Health Solutions Inc., Endo Pharmaceuticals, Inc.; Endo International plc; Par Pharmaceutical, Inc.; and Par Pharmaceuticals Companies, Inc. (@endo.com)
- f. Mallinckrodt, including Mallinckrodt plc; Mallinckrodt LLC; and SpecGx LLC (@mnk.com)
- g. Insys Therapeutics, Inc. (@insysrx.com)
- h. Noramco, Inc. (@noramco.com)

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<sup>5</sup> Ltr. from Senator Ron Wyden, Ranking Member, U.S. Senate Committee on Finance, to Alex Azar, Secretary, U.S. Dep't of Health & Human Servs. (Dec. 18, 2018), <https://www.finance.senate.gov/imo/media/doc/121818%20Senator%20Wyden%20to%20Secretary%20Azar%20re%20Pain%20Task%20Force.pdf>.

- i. Assertio Therapeutics, Inc. (f/k/a Depomed, Inc.) (@assertiotx.com; @depomed.com)
- j. Eli Lilly and Company (@lilly.com)
- k. Pfizer, including Pfizer Inc. and King Pharmaceuticals LLC (@pfizer.com)
- l. Iroko Pharmaceuticals, including Iroko Pharmaceuticals, LLC and Iroko Pharmaceuticals, Inc. (@iroko.com)
- m. Daiichi Sankyo, including Daiichi Sankyo, Inc. and American Regent (@dsi.com)
- n. Stimwave, including Stimwave Technologies, Inc. and Stimwave LLC (@stimwave.com)
- o. Braeburn Inc. (@braeburnrx.com)
- p. Medtronic plc (@medtronic.com)

This request includes all prior messages (whether incoming or outgoing) reflected in the responsive correspondence and any attachments thereto.

To the extent that an email address or domain is listed in parentheses for a drug or device manufacturer, American Oversight requests that your agency search for email communications from anyone at that organization including *but not limited to* any person using the parenthetical email address or domain.

Please provide all responsive records since May 1, 2018, 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 public understanding of operations or activities of the government."<sup>6</sup> The public has a significant interest in the issuance of unbiased health and safety recommendations and guidelines. Records with the potential to shed light on whether members of government panels tasked with making such recommendations are inappropriately influenced by product manufacturers would contribute significantly to public understanding of operations of the federal government. American Oversight is committed to transparency and makes the responses agencies provide to FOIA requests publicly available, and the

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<sup>6</sup> 5 U.S.C. § 552(a)(4)(A)(iii).

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>7</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>8</sup>

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.<sup>9</sup> 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;<sup>10</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>11</sup> posting records regarding potential self-dealing at the Department of Housing & Urban Development and related analysis;<sup>12</sup> posting records and analysis relating to the

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<sup>7</sup> See *id.*

<sup>8</sup> American Oversight currently has approximately 12,200 page likes on Facebook and 54,200 followers on Twitter. American Oversight, FACEBOOK, <https://www.facebook.com/weareoversight/> (last visited May 29, 2019); American Oversight (@weareoversight), TWITTER, <https://twitter.com/weareoversight> (last visited May 29, 2019).

<sup>9</sup> News, AMERICAN OVERSIGHT, <https://www.americanoversight.org/blog>.

<sup>10</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>11</sup> 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>.

<sup>12</sup> *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>.

federal government's efforts to sell nuclear technology to Saudi Arabia;<sup>13</sup> 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.<sup>14</sup>

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.
- 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.

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<sup>13</sup> *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>.

<sup>14</sup> *Sessions' Letter Shows DOJ Acted on Trump's Authoritarian Demand to Investigate Clinton*, AMERICAN OVERSIGHT, <https://www.americanoversight.org/sessions-letter>.

- 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>15</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 systems or if officials have, by intent or through negligence, failed to meet their obligations.<sup>16</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>17</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

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<sup>15</sup> 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).

<sup>16</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>17</sup> 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>.

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 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 [foia@americanoversight.org](mailto:foia@americanoversight.org) or (202) 788-0606. 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,

A handwritten signature in blue ink that reads "Austin R. Evers". The signature is fluid and cursive, with a long horizontal line extending to the left.

Austin R. Evers  
Executive Director  
American Oversight