



September 4, 2019

VIA ONLINE PORTAL

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U.S. Food and Drug Administration
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Re: Freedom of Information Act Request

Dear FOIA Officers:

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.

On March 5, 2019, the U.S. Food and Drug Administration (FDA) approved a controversial new drug, Spravato (esketamine), to treat depression and suicide.¹ Just two weeks later, the U.S. Department of Veterans Affairs (VA) announced that Spravato would

¹ Press Release, Janssen, Janssen Announces U.S. FDA Approval of SPRAVATO™ (esketamine) CIII Nasal Spray for Adults with Treatment-Resistant Depression (TRD) Who Have Cycled Through Multiple Treatments Without Relief (Mar. 5, 2019), <https://www.janssen.com/janssen-announces-us-fda-approval-spravato-esketamine-ciii-nasal-spray-adults-treatment-resistant>; see Natalie Grover, *J&J's Esketamine, at Current Price, Is 'Low Value for Money'*—ICER, ENDPOINTS NEWS (July 3, 2019, 9:43 AM), <https://endpts.com/jjs-esketamine-at-current-price-is-low-value-for-money-icer/>; Peter Cary, *Trump's Praise Put Drug for Vets on Fast Track, But Experts Aren't Sure It Works*, CTR. FOR PUBLIC INTEGRITY, June 18, 2019, <https://publicintegrity.org/federal-politics/trumps-raves-put-drug-for-vets-on-fast-track-but-experts-arent-sure-it-works/>; Marco A. Ramos et al., *Opinion: The New Ketamine-Based Antidepressant Is a Rip-Off*, VICE, May 17, 2019, https://www.vice.com/en_us/article/pajkky/opinion-the-new-ketamine-based-antidepressant-is-a-rip-off.



be available to veterans through VA health care providers.² The VA's Medical Advisory Panel subsequently approved Spravato for coverage on a prior approval basis.³

During this same period, President Trump has been outspoken in his support for Spravato, including repeatedly calling on the VA to make it widely available to veterans, and offering to assist in negotiations with the drug's manufacturer, Janssen, a subsidiary of Johnson & Johnson (J&J).⁴ In addition, in the run up to Spravato's approval, Janssen reportedly promoted anti-suicide programs at the VA with the assistance of three individuals with close ties to President Trump: Isaac "Ike" Perlmutter, Bruce Moskowitz, and Marc Sherman (commonly referred to as the "Mar-a-Lago trio").⁵

This request seeks to shed light on whether and the extent to which the White House and close allies of the president influenced federal action regarding Spravato.

Requested Records

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

All email communications (including email messages, email attachments, calendar invitations, and calendar invitation attachments) between (1) the FDA officials and employees listed below and (2) anyone in the White House Office (including anyone with an email address ending in "who.eop.gov") regarding Spravato (esketamine) nasal spray:

- a. Scott Gottlieb, former FDA Commissioner;
- b. Amy Abernethy, Principal Deputy Commissioner;

² News Release, VA, VA to Make New Nasal Spray Drug Available for Treatment-Resistant Depression (Mar. 19, 2019),

<https://www.va.gov/opa/pressrel/pressrelease.cfm?id=5220>.

³ Patricia Kime, *VA Imposes Strict Limits on Controversial Ketamine-Based Depression Treatment*, MILITARY.COM, June 24, 2019, <https://www.military.com/daily-news/2019/06/24/va-imposes-strict-limits-controversial-ketamine-based-depression-treatment.html>.

⁴ See Cary, *supra* note 1; Amber Tong, *Get As Much Spravato As You Can, Trump Orders VA While Suggesting J&J Should Offer It to Veterans for Free*, ENDPOINTS NEWS (Aug. 22, 2019, 10:02 AM), <https://endpts.com/get-as-much-spravato-as-you-can-trump-orders-va-while-suggesting-jj-should-offer-it-to-veterans-for-free/>; Tara Copp, *Trump Directs VA to Buy 'A Lot' of Controversial New Drug to Fight Veteran Suicide*, MCCLATCHY, Aug. 21, 2019, <https://www.mcclatchydc.com/news/nation-world/national/national-security/article234228452.html>; Justin Sink, *Trump Offers to Negotiate Price of J&J Anti-Depressant for VA*, BLOOMBERG, June 12, 2019, <https://www.bloomberg.com/news/articles/2019-06-12/trump-offers-to-negotiate-price-of-j-j-anti-depressant-for-va>.

⁵ Cary, *supra* note 1.

- c. Keagan Lenihan, Chief of Staff;
- d. Janet Woodcock, Director, Center for Drug Evaluation and Research (CDER);
- e. Tiffany Farchione, former Deputy Director and current Acting Director, Division of Psychiatry Products (DPP), CDER;
- f. Mitchell Mathis, former Director, DPP, CDER;
- g. Hiren Patel, Regulatory Project Manager, DPP, CDER;
- h. Keith Kiedrow, Regulatory Project Manager, DPP, CDER;
- i. Ellis F. Under, Director, Office of Drug Evaluation I (ODE-I);
- j. Robert Temple, Acting Deputy Director, ODE-I;
- k. Anyone serving in the capacity of Associate Commissioner, Office of External Affairs;
- l. Anyone serving in the capacity of White House Liaison or Advisor.

Please provide all responsive records from September 4, 2018, to March 30, 2019.

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."⁶ The public has a significant interest in drug approval and coverage decisions by the federal government, which have both significant health and financial repercussions.⁷ Records with the potential to shed light on this issue would contribute significantly to public understanding of operations of the federal government, including whether and to what extent federal agencies have given preferential treatment to Spravato due to the influence of the president and his allies. 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.⁸ 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

⁶ 5 U.S.C. § 552(a)(4)(A)(iii).

⁷ See *supra* notes 1 and 4.

⁸ See 5 U.S.C. § 552(a)(4)(A)(iii).

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 has also 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 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

⁹ American Oversight currently has approximately 12,200 page likes on Facebook and 54,400 followers on Twitter. American Oversight, FACEBOOK, <https://www.facebook.com/weareoversight/> (last visited July 17, 2019); American Oversight (@weareoversight), TWITTER, <https://twitter.com/weareoversight> (last visited July 17, 2019).

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>.

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>.

political opponents and allegations of misconduct by the Department of Justice itself and the Federal Bureau of Investigation.¹⁵

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.
- 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; 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.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

¹⁵ *Sessions' Letter Shows DOJ Acted on Trump's Authoritarian Demand to Investigate Clinton*, AMERICAN OVERSIGHT, <https://www.americanoversight.org/sessions-letter>.

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 Mgmt. & Budget, Exec. Office of the President, Memorandum for the Heads of Executive

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 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

Departments & Independent Agencies, "Managing Government Records Directive," M-12-18 (Aug. 24, 2012), <https://www.archives.gov/files/records-mgmt/m-12-18.pdf>.

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, appearing to read "Austin R. Evers", with a long horizontal flourish extending to the left.

Austin R. Evers
Executive Director
American Oversight