



August 24, 2018

VIA ONLINE PORTAL

Sarah Kotler
Director, Division of Freedom of Information Office
Executive Secretariat Office of the Commissioner
Food and Drug Administration
12420 Parklawn Drive
Room 1020
Rockville, MD 20857

Re: Freedom of Information Act Request

Dear Ms. Kotler:

Pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, and the implementing regulations of the Food and Drug Administration (FDA), 21 C.F.R. Part 20, American Oversight makes the following request for records.

In October 2017, President Trump directed the Department of Health and Human Services to declare the opioid crisis a public health emergency.¹ Millions of Americans are addicted to opioids, with over 42,000 dying from opioid overdoses in 2016. *New York Times* reporting from May 2018 indicates that Purdue Pharma, the company that aggressively marketed OxyContin, “knew of ‘significant’ abuse of OxyContin in the first years after the drug’s introduction in 1996 and concealed that information.”² And this week, Senators Hassan and Whitehouse sent the Drug Enforcement Administration (DEA) and the Department of Justice (DOJ) letters regarding Giuliani Partners’s representation of Purdue Pharma and requesting information and records related to Giuliani Partners’s engagement and communications with DEA and DOJ regarding Purdue Pharma.³

¹ Julie Hirschfeld Davis, *Trump Declares Opioid Crisis a ‘Health Emergency’ but Requests No Funds*, N.Y. TIMES, Oct. 26, 2017, <https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html>.

² Barry Meier, *Origins of an Epidemic: Purdue Pharma Knew Its Opioids Were Widely Abused*, N.Y. TIMES, May 29, 2018, <https://www.nytimes.com/2018/05/29/health/purdue-opioids-oxycontin.html>.

³ Julia Lurie, *Senators are Demanding Information About Giuliani’s History with Opioid Maker Purdue Pharma*, MOTHERJONES (Aug. 24, 2018, 12:34 PM), <https://www.motherjones.com/politics/2018/08/exclusive-senators-are-demanding-information-about-giulianis-opioid-lobbying/> (including Ltr. From Sens. Hassan & Whithouse to Attorney General Jeff Sessions, Aug. 22, 2018; Ltr. From Sens. Hassan & Whithouse to Drug Enforcement Admin. Acting Admin. Uttam Dhillon, Aug. 22, 2018).



Former New York Mayor and defense attorney Rudy Giuliani played a key role in defending Purdue Pharma during multiple federal investigations between 2002 and 2007. His actions on behalf of Purdue Pharma may have implicated potentially serious conflicts of interest issues. In 2002, at the same time that Mr. Giuliani represented Purdue Pharma before DEA and DOJ, he also reportedly obtained a \$1 million-dollar contract with DOJ to consult for a drug task force responsible for helping to investigate OxyContin abuse, and he also fundraised thousands of dollars for a DEA museum exhibit.⁴ Mr. Giuliani's consistent engagement with senior DEA and DOJ officials appeared to help produce favorable settlements in 2004 and 2007 for Purdue Pharma that propelled the public health crisis we see today—allowing the company to continue selling OxyContin⁵ and ultimately avoiding a bar on Purdue business with the federal government.⁶

In April 2018, Mr. Giuliani assumed a high-profile role as part of President Trump's outside legal team.⁷ Given his prominent public role and the continuing importance of the opioid epidemic as a matter of federal policy, it is in the public interest for Americans to understand the nature of Mr. Giuliani's work with Purdue Pharma and federal agencies between 2002 and 2007. American Oversight seeks records to evaluate whether Mr. Giuliani's various engagements related to opioids created any conflicts of interests, and to understand his role in producing favorable settlements for Purdue Pharma that appear to have exacerbated the early years of the opioid crisis and contributed to the epidemic Americans face today.

Requested Records

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

- 1) All records reflecting communications (including emails, email attachments, text messages, messages on messaging platforms, telephone call logs, calendar invitations/entries, meeting notices, meeting agendas, informational material, draft legislation, talking points, any handwritten or electronic notes taken during any oral communications, summaries of any oral communications, or other materials) between or among (including those copied or blind copied on emails) anyone listed in Column A below and anyone listed in Column B below:

⁴ Eric Lipton, *RUDY INC.: A Politician's Empire; Giuliani, Selling His Public Image, Branches Out for Private Profit*, N.Y. TIMES, Feb. 22, 2004, <https://www.nytimes.com/2004/02/22/nyregion/rudy-politician-s-empire-giuliani-selling-his-public-image-branches-for-private.html>.

⁵ Barry Meier & Eric Lipton, *Under Attack, Drug Maker Turned to Giuliani for Help*, N.Y. TIMES, Dec. 28, 2007, <https://www.nytimes.com/2007/12/28/us/politics/28oxycontin.html>

⁶ Chris McGreal, *Rudy Giuliani Won Deal for OxyContin Maker to Continue Sales of Drug Behind Opioid Deaths*, THE GUARDIAN, May 22, 2018, <https://www.theguardian.com/us-news/2018/may/22/rudy-giuliani-opioid-epidemic-oxycontin-purdue-pharma>

⁷ Robert Costa *et al.*, *Trump Hires Giuliani, Two Other Attorneys amid Mounting Legal Turmoil over Russia*, WASH. POST, Apr. 19, 2018, https://www.washingtonpost.com/politics/trump-hires-giuliani-two-other-attorneys-amid-mounting-legal-turmoil-over-russia/2018/04/19/8346a7ca-4418-11e8-8569-26fda6b404c7_story.html

Column A: FDA Officials	Column B: Outside Entities
<ul style="list-style-type: none"> • Any political appointee * in the Office of the Commissioner or the Office of the Chief Counsel during the applicable time period. • Andrew von Eschenback, Commissioner of Food and Drugs • Lester Crawford, Deputy Commissioner • Frank Torti, Principal Deputy Commissioner and Chief Scientist • Virginia Gunderson, Special Assistant to the Commissioner • Amit Sachdev, Deputy Commissioner for Policy • Associate Commissioner for Legislative Affairs • Assistant Commissioner for Legislation • Sheila D. Walcoff, Associate Commissioner for External Relations • Assistant Commissioner for Public Affairs • The Chief Counsel • Dan Troy, Associate General Counsel • Deputy Chief Counsel • Deputy Associate General Counsel for Litigation, Food and Drug Division • Associate Deputy Chief Counsel for Litigation 	<ul style="list-style-type: none"> • Any employee or representative of Giuliani Partners, LLC (including but not limited to any person with a @giulianipartners.com or @giulianisecurity.com email address), including but not limited to Rudy Giuliani, Bernard Kerik, and Daniel Connolly. • Any employee or representative of Purdue Pharma L.P. (including but not limited to any person with a @purduepharma.com or @pharma.com email address). • Any employee or representative of Purdue Frederick Company (including but not limited to any person with a @purduepharma.com or @pharma.com email address). • Michael Freidman • Howard R. Udell • Paul D. Goldenheim • J. David Haddox • Robin Hogen • Russel Portenoy

*“Political appointee” should be understood as any person who is a Presidential Appointee with Senate Confirmation (PAS), a Presidential Appointee (PA), a non-career SES, any Schedule C employees, or any persons hired under Temporary Non-Career SES Appointments, Limited Term SES Appointments, or Temporary Transitional Schedule C Appointments.

Please provide all responsive records from January 1, 2002, through December 31, 2008.

- 2) All records reflecting communications (including emails, email attachments, text messages, messages on messaging platforms, telephone call logs, calendar invitations/entries, meeting notices, meeting agendas, informational material, draft legislation, talking points, any

handwritten or electronic notes taken during any oral communications, summaries of any oral communications, or other materials) between or among (including those copied or blind copied on emails) anyone listed in Column A below and anyone listed in Column B below:

Column A: FDA Officials	Column B: Outside Entities
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“Political appointee” should be understood as any person who is a Presidential Appointee with Senate Confirmation (PAS), a Presidential Appointee (PA), a non-career SES, any Schedule C employees, or any persons hired under Temporary Non-Career SES Appointments, Limited Term SES Appointments, or Temporary Transitional Schedule C Appointments.

For this portion of this request, only records that contain one or more of the following search terms should be considered responsive:

- a. opioid*
- b. opiate*
- c. Giuliani
- d. Purdue
- e. Oxy*
- f. Contin
- g. Rudy

Please note that American Oversight is here using the asterisk (*) to designate the standard use of “wildcards” in the search for responsive records. For example, a search for “separat*” would return all of the following: separate, separates, separated, separation, etc. If you are unable to search for wildcards, please advise so that we may specifically include the variations that we would like searched.

Please provide all responsive records from January 1, 2002, through December 31, 2008.

In addition to the records requested above, American Oversight also requests records describing the processing of this request, including records sufficient to identify search terms used and locations and custodians searched and any tracking sheets used to track the processing of this request. If you use FOIA questionnaires or certifications completed by individual custodians or components to determine whether they possess responsive materials or to describe how they conducted searches, we also request any such records prepared in connection with the processing of this request.

American Oversight seeks all responsive records regardless of format, medium, or physical characteristics. 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 includes any attachments to these records. **No category of material should be omitted from search, collection, and production.**

Please search all records regarding agency business. **You may not exclude searches of files or emails in the personal custody of your officials, such as personal email accounts.** Records of official business conducted using unofficial systems or stored outside of official files are subject to the Federal Records Act and FOIA.⁸ **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, through negligence or willfulness, failed to meet their obligations.**⁹

⁸ 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).

⁹ See *Competitive Enter. Inst. v. Office of Sci. & Tech. Policy*, No. 14-cv-765, slip op. at 8 (D.D.C. Dec. 12, 2016) (“The Government argues that because the agency had a policy requiring [the

In addition, please note that in conducting a “reasonable search” as required by law, you must employ the most up-to-date technologies and tools available, in addition to searches by individual custodians likely to have responsive information. Recent technology may have rendered your agency’s prior FOIA practices unreasonable. **In light of the government-wide requirements to manage information electronically by the end of 2016, it is no longer reasonable to rely exclusively on custodian-driven searches.**¹⁰ Furthermore, agencies that have adopted the National Archives and Records Administration (NARA) Capstone program, or similar policies, now maintain emails in a form that is reasonably likely to be more complete than individual custodians’ files. For example, a custodian may have deleted a responsive email from his or her email program, but your agency’s archiving tools would capture that email under Capstone. Accordingly, American Oversight insists that your agency use the most up-to-date technologies to search for responsive information and take steps to ensure that the most complete repositories of information are searched. American Oversight is available to work with you to craft appropriate search terms. **However, custodian searches are still required; agencies may not have direct access to files stored in .PST files, outside of network drives, in paper format, or in personal email accounts.**

Under the FOIA Improvement Act of 2016, agencies must adopt a presumption of disclosure, withholding information “only if . . . disclosure would harm an interest protected by an exemption” or “disclosure is prohibited by law.”¹¹ If it is your position that any portion of the requested records is exempt from disclosure, American Oversight requests that you provide an index of those documents as required under *Vaughn v. Rosen*, 484 F.2d 820 (D.C. Cir. 1973), *cert. denied*, 415 U.S. 977 (1974). As you are aware, a *Vaughn* index must describe each document claimed as exempt with sufficient specificity “to permit a reasoned judgment as to whether the material is actually exempt under FOIA.”¹² Moreover, the *Vaughn* index “must describe *each* document or portion thereof withheld, and for *each* withholding it must discuss the consequences of disclosing the sought-after information.”¹³ Further, “the withholding agency must supply ‘a relatively detailed

official] to forward all of his emails from his [personal] account to his business email, the [personal] account only contains duplicate agency records at best. Therefore, the Government claims that any hypothetical deletion of the [personal account] emails would still leave a copy of those records intact in [the official’s] work email. However, policies are rarely followed to perfection by anyone. At this stage of the case, the Court cannot assume that each and every work related email in the [personal] account was duplicated in [the official’s] work email account.” (citations omitted).

¹⁰ 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>.

¹¹ FOIA Improvement Act of 2016 § 2 (Pub. L. No. 114-185).

¹² *Founding Church of Scientology v. Bell*, 603 F.2d 945, 949 (D.C. Cir. 1979).

¹³ *King v. U.S. Dep’t of Justice*, 830 F.2d 210, 223-24 (D.C. Cir. 1987) (emphasis in original).

justification, specifically identifying the reasons why a particular exemption is relevant and correlating those claims with the particular part of a withheld document to which they apply.”¹⁴

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 it is your position that a document contains non-exempt segments, but that those non-exempt segments are so dispersed throughout the document as to make segregation impossible, please state what portion of the document is non-exempt, and how the material is dispersed throughout the document.¹⁵ Claims of nonsegregability must be made with the same degree of detail as required for claims of exemptions in a *Vaughn* index. If a request is denied in whole, please state specifically that it is not reasonable to segregate portions of the record for release.

You should institute a preservation hold on information responsive to this request. American Oversight intends to pursue all legal avenues to enforce its right of access under FOIA, including litigation if necessary. Accordingly, you are on notice that litigation is reasonably foreseeable.

To ensure that this request is properly construed, that searches are conducted in an adequate but efficient manner, and that extraneous costs are not incurred, 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, we can decrease the likelihood of costly and time-consuming litigation in the future.

Where possible, please provide responsive material in electronic format by email or in PDF or TIF 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.

Fee Waiver Request

In accordance with 5 U.S.C. § 552(a)(4)(A)(iii) and 21 C.F.R. § 20.46(e), 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 government operations by the general public in a significant way.¹⁶ Moreover, the request is primarily and fundamentally for non-commercial purposes.¹⁷

American Oversight requests a waiver of fees because disclosure of the requested information “[i]s in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Government.”¹⁸ The requested records will help American Oversight

¹⁴ *Id.* at 224 (citing *Mead Data Central, Inc. v. U.S. Dep’t of the Air Force*, 566 F.2d 242, 251 (D.C. Cir. 1977)).

¹⁵ *Mead Data Central*, 566 F.2d at 261.

¹⁶ 21 C.F.R. § 20.46(b).

¹⁷ 21 C.F.R. § 20.46(c).

¹⁸ 21 C.F.R. § 20.46(a)(1).

and the general public understand whether and to what extent Mr. Giuliani’s opioid consultation and fundraising efforts with the federal government affected FDA’s investigation of or response to the abuse of OxyContin and any actions taken against Purdue Pharma. American Oversight is committed to transparency and makes the responses agencies provide in response to FOIA requests publicly available. The subject of this request is a matter of public interest, and American Oversight would make these records publicly available.

This request is primarily and fundamentally for non-commercial purposes.¹⁹ 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.²⁰ American Oversight has demonstrated its commitment to the public disclosure of documents and creation of editorial content. For example, after receiving records regarding an ethics waiver received by a senior DOJ attorney,²¹ American Oversight promptly posted the records to its website and published an analysis of what the records reflected about DOJ’s process for ethics waivers.²² As another example, American Oversight has a project called “Audit the Wall,” where the organization is gathering and analyzing information and commenting on public releases of information related to the administration’s proposed construction of a barrier along the U.S.-Mexico border.²³

Accordingly, American Oversight qualifies for a fee waiver.

Conclusion

We share a common mission to promote transparency in government. American Oversight looks forward to working with FDA on this request. If you do not understand any part of this request, have any questions, or foresee any problems in fully releasing the requested records, please contact Dan McGrath at foia@americanoversight.org or 202-897-4213. Also, if American Oversight’s

¹⁹ 21 C.F.R. § 20.46(c).

²⁰ American Oversight currently has approximately 11,900 page likes on Facebook, and 44,500 followers on Twitter. American Oversight, FACEBOOK, <https://www.facebook.com/weareoversight/> (last visited Aug. 20, 2018); American Oversight (@weareoversight), TWITTER, <https://twitter.com/weareoversight> (last visited Aug. 20, 2018).

²¹ *DOJ Civil Division Response Noel Francisco Compliance*, AMERICAN OVERSIGHT, <https://www.americanoversight.org/document/doj-civil-division-response-noel-francisco-compliance>.

²² *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>.

²³ *Audit the Wall*, AMERICAN OVERSIGHT, <https://www.americanoversight.org/investigation/audit-the-wall>.

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". The signature is fluid and cursive, with a long horizontal flourish extending to the left.

Austin R. Evers
Executive Director
American Oversight