July 18, 2025

Food and Drug Administration
Division of Headquarters Freedom of Information
Office of Disclosure, Information, Governance
and Accessibility, ODIGA
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: Request under the Freedom of Information Act

To Whom It May Concern:

This letter constitutes a request made pursuant to the Freedom of Information Act, 5 U.S.C. § 552, and implementing regulations of the U.S. Food and Drug Administration ("FDA"), 21 C.F.R. § 20.2.

On April 24, 2025, FDA Commissioner Dr. Marty Makary stated he "ha[d] no plans to take action on mifepristone" but also emphasized that he is a "data guy" and believes in the need to "evolve" as more data is presented.[1] Dr. Makary went on to say that "an ongoing set of data [] is coming into FDA on mifepristone" and depending on what the data indicates, he could not "promise [they were] not going to act on that data."[2] Four days later, on April 28, 2025, the Ethics and Public Policy Center ("EPPC") released a publication on mifepristone, claiming the medication causes 1 in 10 patients to experience what EPPC calls a "serious adverse event."[3] The publication does not meet scientific review standards: its authors, Jamie Bryan Hall and Ryan T. Anderson, do not have medical training; the publication was not published in a peer-reviewed scientific journal; and the authors did not disclose data sources, meaning that the findings cannot be reproduced or verified.[4] That same day, Senator Josh Hawley sent a letter to Dr. Makary, citing the report and asking Dr. Makary whether the FDA would: (1) take action to restore barriers to mifepristone access; (2) adjust the drug label for mifepristone; and (3) review mifepristone's effects on users.[5] On May 22, 2025, in response to questions about the EPPC publication during a Senate Appropriations Committee hearing, Dr. Makary committed that the FDA was "going to take a hard look at it."[6] On June 3, 2025, Dr. Makary replied to Senator

[1] Amna Nawaz, *What the New FDA Commissioner Says About Possible Restrictions on Abortion Medication*, PBS NEWS HOUR (Apr. 24, 2025, 6:30 PM), https://www.pbs.org/newshour/show/what-the-new-fda-commissioner-says-about-possible-restrictions-on-abortion-medication.
[2] *Id.*
[3] JAMIE BRYAN HALL & RYAN T. ANDERSON, THE ABORTION PILL HARMS WOMEN: INSURANCE DATA REVEALS ONE IN TEN PATIENTS EXPERIENCES A SERIOUS ADVERSE EVENT (2025).
[4] Sara Moniuszko, *FDA to "Review the Latest Data" On Mifepristone. What Could it Mean for Access to the Abortion Pill?*, CBS NEWS (June 5, 2025, 10:46 AM), https://www.cbsnews.com/news/fda-review-mifepristone-abortion-pill-access/.
[5] Letter from Senator Josh Hawley to Marty Makary, Comm'r, U.S. Food & Drug Admin. (Apr. 28, 2025), https://www.hawley.senate.gov/wp-content/uploads/2025/04/2025-04-28-Hawley-FDA-Letter-to-Makary.pdf.
[6] *Agriculture-FDA on FDA FY26 Budget Before the Subcomm. on Agric., Rural Dev., Food and Drug Admin., and Related Agencies of the S. Comm. on Appropriations*, 119th Cong. (2025).

Hawley and "committed to conducting a review of mifepristone and working with the professional career scientists at the Agency who review this data."[7]

The Center for Reproductive Rights ("Center") seeks to better understand FDA's decision to review mifepristone, the process FDA plans to use to conduct this review, and whether FDA will be considering data from EPPC and/or other third parties in such a review. Releasing this information is vital to the public interest as mifepristone has been declared safe and effective for abortion by the FDA for over 20 years, with more than 99% of patients reporting no serious complications.[8] Any potential risk to mifepristone access will harm the millions of patients who rely on the drug for essential health care.

Records Requested

Please provide all responsive records from January 20, 2025, through date of the search. As used herein, "records" means all records as defined in 22 C.F.R. § 171.1(b). Additionally, as used herein, any reference to FDA encompasses all regional offices (both current and past) as well as the central offices located in Silver Spring, Maryland. Please note that "communications" requested include, but are not limited to, e-mails, messaging platforms (including, but not limited to Signal, Slack, GChat or Google Hangouts, Lync, Skype, X (formerly Twitter) direct messages, Facebook messages, Truth Social messages, WhatsApp, Telegram, or Parler), and communications and relevant materials that may have been distributed via personal phones or devices. For ease of search, we have included e-mail addresses for individuals whose e-mail addresses are publicly available—lack of e-mail address availability should not hinder the agency's ability to conduct searches based on individual names or keywords.

We request the following to be produced within twenty business days:

1. All communications, meeting notices, meeting agendas, informational materials, draft legislation, draft rules, talking points, reports, disclosures, or other documents sent to, received by, or exchanged with any FDA employee (temporary or permanent), official, appointee, or contractor and any employee of EPPC including, but not limited to, anyone with a domain name "@eppc.org" and/or the following individuals:

    a. Ryan T. Anderson, President
    b. Erika Bachiochi, Fellow, Life and Family Initiative
    c. Nathanael Blake, Fellow, Life and Family Initiative
    d. Patrick T. Brown, Fellow, Life and Family Initiative
    e. Alexandra DeSanctis, Fellow, Life and Family Initiative

[7] Josh Hawley (@HawleyMO), X (June 2, 2025, 8:27 PM), https://x.com/HawleyMO/status/1929696353010987013; Alejandra O'Connell-Domenech, *FDA Commissioner Pledges to Investigate Mifepristone*, THE HILL (June 3, 2025, 2:31 PM), https://thehill.com/policy/healthcare/5330774-marty-makary-fda-mifepristone-review/.

[8] FOOD & DRUG ADMIN., Reference ID 5509490, MIFEPRISTONE U.S. POST-MARKETING ADVERSE EVENTS SUMMARY THROUGH 12/31/2024 (2025), https://www.fda.gov/media/185245/download?attachment; Irving Washington, Hagere Yilma & Joel Luther, *Flawed Report Aims to Undercut Established Research on Abortion Pill Safety, Plus How a Federal Initiative to Study Autism May Overemphasize Environmental Toxins*, KAISER FAM. FOUND. (June 12, 2025), https://www.kff.org/the-monitor/flawed-report-aims-to-undercut-established-research-on-abortion-pill-safety-plus-how-a-federal-initiative-to-study-autism-may-overemphasize-environmental-toxins/.

f. Jamie Bryan Hall, Director of Data Analysis and Fellow
g. John McCormack, Visiting Fellow, Life and Family Initiative
h. Mitchell S. Muncy, Executive Vice President

2. All communications, meeting notices, meeting agendas, informational materials, draft legislation, draft rules, talking points, reports, disclosures, or other documents sent to, received by, or exchanged with any FDA employee (temporary or permanent), official, appointee, or contractor and Senator Josh Hawley or any employee within the Senator's office using an email address with the domain name "@hawley.senate.gov" including, but not limited to:

    a. Chris Weihs, Chief of Staff (chris_weihs@hawley.senate.gov)
    b. Corey Messervy, Deputy Chief of Staff (corey_messervy@hawley.senate.gov)
    c. Kelli Burke, Deputy Chief of Staff, External Affairs (kelli_burke@hawley.senate.gov)
    d. Natalie Ford, Assistant Chief of Staff (natalie_ford@hawley.senate.gov)
    e. Vijay Menon, Legislative Director (vijay_menon@hawley.senate.gov)
    f. Ryan Moonka, Research Director (ryan_moonka@hawley.senate.gov)
    g. Bern Breslin, Deputy Communications Director/Press Secretary (benen_obrien@hawley.senate.gov)
    h. Stephen Andrews, Counsel (stephen_andrews@hawley.senate.gov)
    i. Alex Lawrence, Legislative Correspondent (alex_lawrence@hawley.senate.gov)
    j. Ashton Hedgepeth, Assistant to the Chief of Staff (natalie_ford@hawley.senate.gov)

3. All communications, meeting notices, meeting agendas, informational materials, draft legislation, draft rules, talking points, reports, disclosures, or other documents sent to, received by, or exchanged with any FDA employee (temporary or permanent), official, appointee, or contractor regarding the EPPC report on mifepristone.

4. All communications, meeting notices, meeting agendas, informational materials, draft legislation, draft rules, talking points, reports, disclosures, or other documents sent to, received by, or exchanged with any FDA employee (temporary or permanent), official, appointee, or contractor regarding FDA's decision to review mifepristone.

5. All electronic communications (including emails, email attachments, complete email chains, calendar invitations, and calendar invitation attachments), or messages on messaging platforms (including, but not limited to Signal, Slack, GChat or Google Hangouts, Lync, Skype, X (formerly Twitter) direct messages, Facebook messages, Truth Social messages, WhatsApp, Telegram, or Parler), including communications and relevant materials that may have been distributed via personal phones or devices regarding FDA's decision to review mifepristone to or from the following FDA personnel who may have influence on the decision to review mifepristone:

    a. Sara Brenner, FDA, Principal Deputy Commissioner

b. Grace Graham, FDA, Deputy Commissioner for the Office of Policy, Legislation and International Affairs
c. Tracy Beth Hoeg, FDA, Senior Advisor for Clinical Sciences
d. Dr. Martin Makary, FDA, Commissioner of Food and Drugs
e. Karim Mikhail, FDA, Senior Advisor
f. Vinay Prasad, FDA, Chief Medical and Scientific Officer, Director of the Center for Biologics Evaluation and Research (CBER) (vinay.prasad@fda.hhs.gov)
g. James Traficant, FDA Chief of Staff
h. Lowell Zeta, FDA, Deputy Commissioner for Strategic Initiatives (lowell.zeta@fda.hhs.gov)
i. Jacqueline Corrigan-Curay, Acting Center Director of the Center for Drug Evaluation and Research (CDER) (Jacqueline.Corrigan-Curay@fda.hhs.gov)

6. All data, records, documents, memoranda, and communications related to FDA's review and assessment process of mifepristone, including, but not limited to, review matrices, data analysis, and any criteria used to review the safety of mifepristone.

7. Records sufficient to identify all persons, whether or not employed directly by FDA, tasked with conducting FDA's reviews of mifepristone.

The Center 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.

In addition to the records requested above, the Center also requests records describing the processing of this request, including records sufficient to identify search terms used, locations and custodians searched, and any tracking sheets used to track the processing of this request. If your agency uses 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.

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 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. 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; the Center 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.

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. Furthermore, agencies, including FDA, that have adopted the National Archives and Records Agency ("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, the Center requests that FDA 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. The Center 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.

We request that you produce all responsive materials in their entirety; however, should you determine the materials contain information which falls within the statutory exemptions provided in 5 U.S.C. § 552 or 22 C.F.R. § 171.11, we request the information be reviewed for possible discretionary disclosure. We furthermore request that all reasonably segregable portions of the exempt material be provided. We request that any deleted material be described in detail, and that you specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies in each instance. Please separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements will be helpful in deciding whether to appeal an adverse determination.

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." If it is your position that any portion of the requested records is exempt from disclosure, the Center requests that you provide an index of those documents as required under *Vaughn v. Rosen*.[9] 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."[10] 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."[11] Further, "the withholding agency must supply 'a relatively detailed 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.'"[12]

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[9] 484 F.2d 820 (D.C. Cir. 1973), *cert. denied*, 415 U.S. 977 (1974) (mem.).
[10] Founding Church of Scientology v. Bell, 603 F.2d 945, 949 (D.C. Cir. 1979) (per curiam).
[11] King v. U.S. Dep't of Just., 830 F.2d 210, 223-24 (D.C. Cir. 1987).
[12] *Id.* at 224.

You should institute a preservation hold on information responsive to this request. The Center intends to pursue all legal avenues to enforce its right of access under FOIA, including litigation if necessary. Accordingly, your agency is 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, the Center welcomes an opportunity to discuss their request with you before you undertake your search or incur search or duplication costs. By working together at the outset, the Center and your agency can decrease the likelihood of costly and time-consuming litigation in the future.

Waiver or Limitation of Fees

Pursuant to 5 U.S.C. § 552(a)(4)(A)(iii), documents are required to be provided to requesters without any charge or at reduced fees "if disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester." We request a waiver (or, in the alternative, a reduction) of all fees because disclosure of the information would be in the public interest by increasing the transparency of any efforts to exert political influence on Commissioner Makary's commitment "to conduct[] a review of mifepristone and work[] with the professional career scientists at FDA who review this data."[13]

Founded in 1992, the Center is the only global legal advocacy organization dedicated to reproductive rights, and its litigation and advocacy has played a key role in expanding access to reproductive health care around the world. The Center uses information gathered, and its analysis of information gathered, to educate the public through reports, briefing papers, fact sheets, periodicals, articles, blog posts, and other educational materials. Likewise, the Center also makes the materials gathered available on its public website and promotes their availability on social media platforms, such as Facebook, X (formerly known as Twitter), and Instagram. The Center receives hundreds of thousands of website page views monthly and publishes newsletters for public dissemination. Thus, the Center has a demonstrated commitment to the public disclosure of documents and creation of editorial content.

The Center does not make this request for commercial use. 45 C.F.R. § 5.54(b)(3). As a 501(c)(3) nonprofit organization, the Center does not have a commercial purpose, and the release of the information requested is not in the organization's financial interest. Accordingly, the Center qualifies for a fee waiver.

In the event that you determine you are unable to waive the fees, please provide us with prior notice if the total fees authorized will exceed $200 so that we can discuss arrangements.

[13] Alejandra O'Connell-Domenech, *FDA Commissioner Pledges to Investigate Mifepristone*, THE HILL (June 3, 2025, 2:31 PM), https://thehill.com/policy/healthcare/5330774-marty-makary-fda-mifepristone-review/.

Conclusion

The Center looks forward to working with your agency on this request. Thank you for your prompt attention to this matter.

With respect to the form of production, 5 U.S.C. § 552(a)(3)(B), the Center requests that responsive materials be provided electronically by email or in PDF or TIF format on a USB drive. Please send any responsive material being provided and acknowledgement of receipt of this request to:

Vidhi Bamzai
c/o Julia Long
Center for Reproductive Rights
1600 K Street, NW, 7th Floor
Washington, DC 20006
Phone: (202) 524-5534
Email: vbamzai@reprorights.org

If it will accelerate release of responsive records, please also provide responsive material on a rolling basis.

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 Vidhi Bamzai at (202) 524-5534. Thank you for your assistance.

Sincerely,

Vidhi Bamzai