

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

The Center for Reproductive Rights
199 Water Street,
New York, N.Y. 10038,

Plaintiff,

v.

U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993,

Defendants.

Civil Action No. 1:25-cv-03023-RCL

Judge Royce Lamberth

CONSENT MOTION FOR LEAVE TO FILE AMENDED COMPLAINT

Pursuant to Rule 15 of the Federal Rules of Civil Procedure and Local Civil Rule 7, Plaintiff respectfully requests that the Court grant Plaintiff leave to file the Amended Complaint attached hereto. Clean and redline copies of the Amended Complaint are attached hereto, as required by Local Civil Rule 15.1. Plaintiff has met and conferred with Defendants, and Defendants consent to the relief sought in this motion.

Plaintiff, the Center for Reproductive Rights, filed its Complaint on September 5, 2025. Dkt. No. 1. The Complaint seeks to compel Defendants to comply with their obligations under the Freedom of Information Act, 5 U.S.C. § 552 (“FOIA”). *Id.* at 1. As discussed in the Complaint, the information Plaintiff seeks is related to Defendants’ decision to review mifepristone. *Id.* at 1.

Because of the recent lapse in government appropriations, Defendants’ deadline to respond to the Complaint was tolled until December 8, 2025. In the interim period since the Complaint was

filed, Defendant U.S. Food and Drug Administration failed to adequately respond to three additional FOIA requests submitted by Plaintiff, which are also related to Defendants' review of mifepristone. Accordingly, Plaintiff seeks leave to amend the Complaint to add claims for those three FOIA requests. The amendment adds no new parties and does not alter the existing claims other than to include these additional FOIA requests.

Under Rule 15(a)(2) of the Federal Rules of Civil Procedure, a party may amend its pleading if the opposing party consents to the amendment in writing. Fed. R. Civ. P. 15(a)(2); *see also In re Domestic Airline Travel Antitrust Litig.*, 2017 WL 11565557, at *1 (D.D.C. Aug. 31, 2017) (under Rule 15(a)(2), leave to amend "should be freely given unless there is a good reason to the contrary.") (citing *Willoughby v. Potomac Elec. Power Co.*, 100 F.3d 999, 1003 (D.C. Cir. 1996)). Courts in this district have routinely granted motions to amend complaints where defendants have consented to such amendments. *See, e.g.*, Minute Order, *United States v. Deutsche Telekom AG*, No. 19-02232 (November 8, 2019) (granting consent motion to amend complaint); Minute Order, *Boykin v. United States*, No. 17-2569 (May 25, 2018) (same).

Therefore, Plaintiff respectfully requests that the Court grant Plaintiff leave to file the Amended Complaint attached hereto at Exhibit 1 (clean) and Exhibit 2 (redline). A proposed order granting this motion is attached hereto.

December 6, 2025

/s/ Amanda K. Chuzi

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CERTIFICATE OF SERVICE

I certify that on December 6, 2025, I filed this document with the Court's Electronic Case Filing (ECF) system, which will send a Notice of Electronic Filing to counsel of record.

/s/ Amanda K. Chuzi
Amanda K. Chuzi

Exhibit 1

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

The Center for Reproductive Rights
199 Water Street,
New York, N.Y. 10038,

Plaintiff,

v.

U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993,

Defendants.

Civil Action No. 1:25-cv-03023-RCL

Judge Royce Lamberth

AMENDED COMPLAINT

NATURE OF ACTION
(Freedom of Information Act)

Plaintiff, the Center for Reproductive Rights (“the Center” or “Plaintiff”), brings this action against Defendants, the U.S. Department of Health and Human Services (“HHS”) and the U.S. Food and Drug Administration (“FDA”), to compel compliance with the Freedom of Information Act (“FOIA”), 5 U.S.C. § 552, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, seeking declaratory and injunctive relief to compel compliance with the requirements of FOIA.

As further alleged below, the information that the Center seeks about HHS’ and FDA’s decision to review mifepristone, the process FDA plans to use to conduct such a review, the influence HHS or other parties have in the FDA’s review, and whether FDA has considered or will consider data from third parties in the review are directly relevant to the Center’s mission. Founded in 1992, the Center works to ensure reproductive rights are protected in law as fundamental human rights for the dignity, equality, health, and well-being of every person. The Center uses its legal

expertise to defend access to sexual and reproductive health services. The Center is particularly concerned with potential risks to mifepristone access, which will harm the millions of patients who rely on the drug for essential health care. 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.

Defendants have not claimed that the requested information is subject to any FOIA exceptions or privilege and have not advanced any other reason why it should not be disclosed. Despite the clear statutory requirement that an agency respond to a FOIA request within 20 days, Defendants failed to provide a final determination or produce any documents in response to the Center's FOIA requests. The Center seeks to compel Defendants to comply with their obligations under FOIA and promptly produce the requested records.

PARTIES

1. Plaintiff, the Center for Reproductive Rights, is a 501(c)(3) non-profit corporation incorporated under the laws of the State of New York and headquartered at 199 Water Street, New York, NY 10038. The Center for Reproductive Rights is dedicated to using the power of law to advance reproductive rights as fundamental human rights around the world. It 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.

2. Defendant U.S. Department of Health and Human Services ("HHS") is an agency of the United States government under 5 U.S.C. § 552(f)(1) and 5 U.S.C. § 551(1). HHS is headquartered at 200 Independence Avenue, S.W., Washington, D.C. 20201. HHS has possession, custody, and control of the documents that Plaintiff seeks in response to the FOIA request.

3. Defendant U.S. Food and Drug Administration ("FDA") is an agency of the United States government under 5 U.S.C. § 552(f)(1) and 5 U.S.C. § 551(1). FDA is headquartered at

10903 New Hampshire Avenue, Silver Spring, MD 20993. FDA has possession, custody, and control of the documents that Plaintiff seeks in response to the FOIA request.

JURISDICTION AND VENUE

4. This Court has jurisdiction over this claim pursuant to 28 U.S.C. §§ 1331, 2201, and 2202, and 5 U.S.C. § 552(a)(4)(B).

5. Venue is proper in this district pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(e).

6. Because Defendants failed to comply with the requirements to respond set forth in 5 U.S.C. § 552(a)(6)(A), the Center is deemed to have constructively exhausted its administrative remedies pursuant to 5 U.S.C. § 552(a)(6)(C)(i) and is now entitled to judicial action enjoining Defendants from continuing to withhold responsive records and ordering the production of improperly withheld records, *see* 5 U.S.C. § 552(a)(4)(B).

STATEMENT OF FACTS

7. The Center filed five FOIA requests with Defendants seeking records concerning Defendants' review of mifepristone.

I. July 18, 2025 FOIA Request to FDA Regarding Review of Mifepristone

8. On July 18, 2025, the Center submitted through the FDA's FOIA Submission Site a FOIA request seeking records concerning the FDA's review of mifepristone, a drug approved by the FDA for medical termination of pregnancy, and the role third-party data will play in such a review.

9. On April 24, 2025, FDA Commissioner Dr. Marty Makary stated that he "ha[d] no plans to take action on mifepristone" but emphasized that he is a "data guy" and believes in the

need to “evolve” as more data is presented.¹ In an interview with PBS News Hour, Dr. Makary stated 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

10. Four days after Dr. Makary’s remarks, 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 refers to as a “serious adverse event.”³ The publication was not published in a peer-reviewed scientific journal, its authors lack medical training, and its authors did not disclose the data source, so the findings cannot be reproduced or verified.⁴

11. On April 28, 2025, Senator Josh Hawley sent a letter to Dr. Makary, which cited the EPPC publication and asked Dr. Makary whether the FDA would (1) take action to restore barriers to mifepristone access; (2) adjust the drug label for mifepristone “given this new information”; and (3) review mifepristone’s effects on users.⁵

¹ Amna Nawaz, *What the New FDA Commissioner Says About Possible Restrictions on Abortion Medication*, PBS NEWSHOUR (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*, ETHICS & PUBLIC POLICY CENTER (Apr. 28, 2025), <https://eppc.org/publication/insurance-data-reveals-one-in-ten-patients-experiences-a-serious-adverse-event/>.

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>.

12. During a Senate Appropriations Committee hearing on May 22, 2025, following questions about the EPPC publication, Dr. Makary committed that the FDA was “going to take a hard look at [mifepristone].”⁶

13. On June 3, 2025, Dr. Makary replied to Senator Hawley’s letter and “committed to conducting a review of mifepristone and working with the professional career scientists at the Agency who review this data.”⁷

14. Accordingly, the Center’s July 18 FOIA request to the FDA seeks information to better understand the FDA’s decision to review mifepristone, the process the FDA plans to use to conduct this review, and whether the FDA will be considering data from EPPC and/or other third parties during such review.

15. A true and correct copy of the FOIA request to FDA is attached as Exhibit A.

16. Shortly following the submission of the FOIA request on the FDA’s FOIA Submission Site, the Center received an automated response acknowledging receipt of the FOIA request. A true and correct copy of this acknowledgement is attached as Exhibit B.

17. In a letter dated July 22, 2025, the FDA confirmed receipt of the FOIA request. The letter further provided a tracking number of FDA-FOIA-2025-8830 for this request.

18. A true and correct copy of the FDA’s July 22, 2025, letter confirming receipt of the FOIA request is attached as Exhibit C.

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).

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/>.

II. July 21, 2025 FOIA Request to HHS Regarding Review of Mifepristone

19. On July 21, 2025, the Center submitted through HHS' FOIA Submission Site a FOIA request seeking records concerning HHS' and the FDA's decision to review mifepristone.

20. During a Senate Health, Education, Labor, and Pensions (HELP) Committee hearing on May 14, 2025, HHS Secretary Robert F. Kennedy, Jr. addressed the EPPC publication on mifepristone and stated that "[i]t's alarming, and it indicates that at the very least, the label should be changed," noting that he had asked Dr. Makary to "do a complete review and report back."⁸

21. During a Senate Finance Committee hearing on September 4, 2025, when asked about the ongoing FDA mifepristone review and its timing, HHS Secretary Robert F. Kennedy, Jr. stated, "I can't give you the exact timing. I talked to Marty Makary about it yesterday, and he said it is progressing at pace. We're getting data in all the time, new data that we're reviewing....we're following gold standard science on that. I will keep you abreast on that."⁹

22. Accordingly, the Center's FOIA request to HHS seeks information on whether the FDA will be considering data from EPPC and/or other third parties during the review, and what influence HHS leadership and staff may exert over the FDA's review of mifepristone and decision making.

23. A true and correct copy of the FOIA request to HHS is attached as Exhibit D.

⁸ Press Release, Senator Josh Hawley, Hawley Secures Pledge from RFK to Review 'Alarming' Mifepristone Data, Support Bill Cracking Down on Big Pharma Ads (May 14, 2025), <https://www.hawley.senate.gov/hawley-secures-pledge-from-rfk-to-review-alarming-mifepristone-data-support-bill-cracking-down-on-big-pharma-ads/>.

⁹ The President's 2026 Health Care Agenda: Hearing Before the S. Fin. Comm., 119 Cong. 1st Sess., Sept. 4, 2025, available at <https://www.finance.senate.gov/hearings/the-presidents-2026-health-care-agenda> (last accessed Sept. 4, 2025).

24. Shortly following the submission of the FOIA request on HHS' FOIA Submission Site, the Center received a response acknowledging receipt of the FOIA request and assigning the tracking number #2025-03366-FOIA-OS. A true and correct copy of this acknowledgement is attached as Exhibit E.

III. September 19, 2025 FOIA Request to FDA Regarding AI Tool Elsa

25. On September 19, 2025, the Center submitted through the FDA's FOIA Submission Site a FOIA request seeking records concerning the FDA's use of Elsa in general and in relation to the FDA's review of mifepristone.

26. On June 2, 2025, FDA announced the launch of Elsa, a generative AI tool that was designated to be used by FDA employees including its scientific reviewers.¹⁰ FDA has publicly remarked that “[t]he agency is already using Elsa to accelerate clinical protocol reviews, shorten the time needed for scientific evaluations, and identify high-priority inspection targets.”¹¹

27. Elsa has cost taxpayers \$13.8 million to develop the original database and an additional \$14.7 million to scale across FDA.¹²

28. Users of Elsa have reported its unreliability and that it sometimes “hallucinates” and cites studies that do not exist.¹³ Concerns have been raised that there is insufficient oversight

¹⁰ Press Release, U.S. Food & Drug Admin., FDA Launches Agency-Wide AI Tool to Optimize Performance for the American People, FDA (June 2, 2025), <https://www.fda.gov/news-events/press-announcements/fda-launches-agency-wide-ai-tool-optimize-performance-american-people>.

¹¹ *Id.*

¹² Beth Mole, *FDA rushed out agency-wide AI tool—it's not going well*, Ars Technica (June 5, 2025), <https://arstechnica.com/health/2025/06/fda-rushed-out-agency-wide-ai-tool-its-not-going-well/>.

¹³ Chris Mazzolini & Mike Hollan, *FDA's Elsa AI Tool Raises Accuracy and Oversight Concerns*, Applied Clinical Trials (July 23, 2025), <https://www.appliedclinicaltrials.com/view/fda-elsa-ai-tool-raises-accuracy-and-oversight->

of Elsa to understand what guardrails exist, for instance human review of the information generated by Elsa, to ensure that regulatory decisions are accurate and based on reliable information and science.¹⁴

29. Around the same time, on June 3, 2025, FDA Commissioner Dr. Makary replied to a letter from Senator Josh Hawley and “committed to conducting a review of mifepristone[.]”¹⁵

30. Accordingly, the Center’s September 19 FOIA request to the FDA seeks information to better understand how the FDA is using Elsa and any role Elsa is playing in FDA’s review of mifepristone. The Center seeks to increase transparency about the FDA’s use of AI in drug reviews.

31. A true and correct copy of the FOIA request to FDA is attached as Exhibit F.

32. In a letter dated September 22, 2025, the FDA confirmed receipt of the FOIA request. The letter further provided a tracking number of FDA-FOIA-2025-11105 for this request.

33. A true and correct copy of the FDA’s September 22, 2025, letter acknowledging receipt of the FOIA request is attached as Exhibit G.

IV. September 26, 2025 FOIA Request to FDA Regarding FAERS Reporting

34. On September 26, 2025, the Center submitted through the FDA’s FOIA Submission Site a FOIA request seeking (1) summary FAERS reporting for mifepristone for Quarter Two of

concerns; Sarah Owerhohle, *FDA’s artificial intelligence is supposed to revolutionize drug approvals. It’s making up studies*, CNN (July 23, 2025), <https://www.cnn.com/2025/07/23/politics/fda-ai-elsa-drug-regulation-makary>.

¹⁴ *Id.*

¹⁵ 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/>.

2025 (April 1 – July 31, 2025) through the present, and (2) records concerning whether the FDA will be considering data from Operation Rescue in its review of mifepristone.

35. The FDA is currently actively considering policy changes regarding access to mifepristone.

36. On September 18, 2025, Operation Rescue announced it submitted “one-of-a-kind abortion data” to Department of Health and Human Services Secretary Robert F. Kennedy regarding mifepristone.¹⁶ The following day, Secretary Kennedy and FDA Commissioner Dr. Makary sent a letter to state Attorney Generals which claimed that the FDA will conduct a study of the safety of the current Risk Evaluation and Mitigation Strategy (REMS) for mifepristone to determine whether modifications are necessary.¹⁷ The letter claimed that the FDA will conduct its own review of “real-world outcomes and evidence” relating to mifepristone.¹⁸

37. Accordingly, the Center’s September 19 FOIA request to the FDA seeks information to better understand the FDA’s decision to review mifepristone, including its reliance on FAERS reporting for Quarter Two of 2025 for mifepristone, and communications with and data received from Operation Rescue as part of the review.

38. A true and correct copy of the FOIA request to FDA is attached as Exhibit H.

39. In a letter dated September 29, 2025, the FDA confirmed receipt of the FOIA request. The letter further provided a tracking number of FDA-FOIA-2025-11324 for this request.

¹⁶ Sarah Neely, *Operation Rescue Submits One-Of-A-Kind Abortion Data to RFK and His Review of Mifepristone*, Operation Rescue (Sept. 18, 2025), <https://www.operationrescue.org/operation-rescue-submits-one-of-a-kind-abortion-data-to-rfk-and-his-review-of-mifepristone/>.

¹⁷ *Trump Admin., RFK Jr., Moves to Address, Assess, Safety of Abortion Pill After Years of FDA Negligence*, The Gateway Pundit (Sept. 2025), <https://www.thegatewaypundit.com/2025/09/trump-admin-rfk-jr-moves-address-assess-safety/>.

¹⁸ *Id.*

40. A true and correct copy of the FDA's September 29, 2025, letter confirming receipt of the FOIA request is attached as Exhibit I.

V. **September 26, 2025 FOIA Request to FDA Regarding Environmental Impact**

41. On September 26, 2025, the Center submitted through the FDA's FOIA Submission Site a FOIA request seeking records concerning the FDA's review of mifepristone, whether the FDA is reviewing the approval on an environmental basis, and whether the FDA will be considering any information from Students for Life, Liberty Counsel, and/or additional third parties in the review.

42. The FDA approved the medication abortion Mifeprex (known by its active ingredient mifepristone) in 2000.¹⁹ As part of that approval, the sponsor of Mifeprex submitted an environmental assessment in support of the drug application in accordance with the National Environmental Policy Action's requirements.²⁰ The assessment and the FDA both agreed that the excretion of Mifeprex by patients who used the drug was unlikely to have a significant impact on the environment.²¹

¹⁹ Mifeprex, Drug Approval Package, U.S. Food & Drug Admin., https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_mifepristone.cfm.

²⁰ Response Letter from FDA CDER to Students for Life of America at 2-4 (Jan. 15, 2025), <https://www.regulations.gov/document/FDA-2023-P-3328-0004>.

²¹ *Id.*

43. Students for Life and Liberty Counsel have made claims regarding the environmental impact of mifepristone.²² Scientists, including the FDA, have found no credible evidence of any environmental impact.²³

44. HHS Secretary Kennedy recently published The MAHA Report, which raises broad concerns about environmental toxins in the water.²⁴

45. As such, the Center's September 26 FOIA request to the FDA seeks information to better understand whether the FDA is reviewing the approval of mifepristone on an environmental basis and considering any information from third parties, such as Students for Life and Liberty Counsel, regarding environmental impacts in the review.

46. A true and correct copy of the FOIA request to FDA is attached as Exhibit J.

47. In a letter dated September 29, 2025, the FDA confirmed receipt of the FOIA request. The letter further provided a tracking number of FDA-FOIA-2025-11316 for this request.

48. A true and correct copy of the FDA's September 29, 2025, letter confirming receipt of the FOIA request is attached as Exhibit K.

²² See, e.g., Liberty Counsel Action, *Abortion in Our Water: A Special Report* (2025), <https://lcaction.org/LCA-PDFs/AbortionInOurWater-.pdf>; Ariel Wittenberg & Alice Miranda Ollstein, *'Using the devil's own tools against them': Abortion opponents turn to environmental laws*, Politico (Jan. 30, 2025), <https://www.politico.com/news/2025/01/30/abortion-opponents-environmental-laws-00201423>.

²³ See, e.g., Response Letter from FDA CDER to Students for Life of America at 7–21 (Jan. 15, 2025), <https://www.regulations.gov/document/FDA-2023-P-3328-0004>; Joedy McCreary, *Abortion Contaminants in the Water Supply: Are the Rumors True?*, MedPage Today (Sept. 16, 2025), <https://www.medpagetoday.com/obgyn/abortion/117489>.

²⁴ The MAHA Report at 43-45 (2025), <https://www.whitehouse.gov/wp-content/uploads/2025/05/MAHA-Report-The-White-House.pdf>.

VI. FDA and HHS' Failure to Adequately Respond to the Center's FOIA Requests

49. Pursuant to FOIA, within 20 business days of receipt of the Center's requests, FDA and HHS were required to "determine . . . whether to comply with such request" and to "immediately notify" the Center of "such determination and the reasons therefor," and, in the case of an adverse determination, the Center's appeal rights. 5 U.S.C. § 552(a)(6)(A)(i).

a. July 18, 2025 FOIA Request to FDA Regarding Review of Mifepristone

50. On July 18, 2025, the FDA acknowledged receipt of the Center's FOIA request to FDA.

51. Thus, the agency was required to "determine . . . whether to comply with such request" and notify the Center of such determination no later than August 15, 2025. 5 U.S.C. § 552(a)(6)(A)(i).

b. July 21, 2025 FOIA Request to HHS Regarding Review of Mifepristone

52. On July 21, 2025, HHS acknowledged receipt of the Center's FOIA request to HHS.

53. Thus, the agency was required to "determine . . . whether to comply with such request" and notify the Center of such determination no later than August 18, 2025. 5 U.S.C. § 552(a)(6)(A)(i).

d. September 19, 2025 FOIA Request to FDA Regarding AI Tool Elsa

54. On September 22, 2025, the FDA acknowledged receipt of the Center's FOIA request to FDA.

55. Thus, the agency was required to "determine . . . whether to comply with such request" and notify the Center of such determination no later than October 21, 2025. 5 U.S.C. § 552(a)(6)(A)(i).

e. September 26, 2025 FOIA Request to FDA Regarding FAERS Reporting

56. On September 29, 2025, the FDA acknowledged receipt of the Center’s FOIA request to FDA.

57. Thus, the agency was required to “determine . . . whether to comply with such request” and notify the Center of such determination no later than October 28, 2025. 5 U.S.C. § 552(a)(6)(A)(i).

f. September 26, 2025 FOIA Request to FDA Regarding Environmental Impact

58. On September 29, 2025, the FDA acknowledged receipt of the Center’s FOIA request to FDA.

59. Thus, the agency was required to “determine . . . whether to comply with such request” and notify the Center of such determination no later than October 28, 2025. 5 U.S.C. § 552(a)(6)(A)(i).

* * *

60. As of the date of this Complaint, HHS and FDA have failed to (a) notify the Center of any determination regarding its FOIA requests, including the scope of any responsive records HHS and FDA intend to produce or withhold and the reasons for any withholding; or (b) produce the requested records or demonstrate that the requested records are lawfully exempt from production.

61. Through HHS and the FDA’s failure to respond to the Center’s FOIA requests with a determination regarding the requests or the production of the requested records within the time period required by law, the Center has constructively exhausted its administrative remedies and seeks immediate judicial review.

COUNT I

Violation of FOIA, 5 U.S.C. § 552 – FOIA Requests to FDA

62. The Center repeats the allegations in the foregoing paragraphs and incorporates them as though fully set forth herein.

63. FDA is an agency subject to FOIA and must therefore make reasonable efforts to search for requested records.

64. Pursuant to FOIA, 5 U.S.C. § 552(a), the Center has a statutory right to access requested, non-exempt agency records.

65. On July 18, 2025, the Center properly requested records within the possession, custody, and control of the FDA concerning the FDA's decision to review mifepristone and the role third-party data will play in such a review.

66. On September 19, 2025, the Center properly requested records within the possession, custody, and control of the FDA concerning the FDA's use of the generative artificial intelligence (AI) tool Elsa in general and in relation to the FDA's review of mifepristone.

67. On September 26, 2025, the Center properly requested records within the possession, custody, and control of the FDA concerning (1) summary FAERS reporting for mifepristone for Quarter Two of 2025 (April 1 – July 31, 2025) through the present, and (2) whether the FDA will be considering data from Operation Rescue in its review of mifepristone.

68. On September 26, 2025, the Center properly requested records within the possession, custody, and control of the FDA concerning whether the FDA is reviewing the approval of mifepristone on an environmental basis and considering any information from third parties, such as Students for Life and Liberty Counsel, regarding environmental impacts.

69. The FDA failed to comply with the time limits prescribed by FOIA, 5 U.S.C. § 552(a)(6)(A)(i), in responding to the FOIA requests.

70. The FDA is wrongfully withholding non-exempt agency records requested by the Center by failing to produce materials responsive to the Center's FOIA requests.

71. The FDA is wrongfully withholding non-exempt agency records requested by the Center by failing to segregate non-exempt information from otherwise exempt records responsive to the FOIA requests.

72. When an agency has "improperly withheld" records, this Court may "enjoin the agency from withholding agency records" and "order the[ir] production." 5 U.S.C. § 552(a)(4)(B).

73. The Center is thus entitled to declaratory and injunctive relief requiring FDA to promptly produce all non-exempt records responsive to the FOIA requests and to provide a *Vaughn* index explaining, with specificity, the bases on which any responsive records are withheld as exempt.²⁵

COUNT II

Violation of FOIA, 5 U.S.C. § 552 – FOIA Request to HHS

74. The Center repeats the allegations in the foregoing paragraphs and incorporates them as though fully set forth herein.

²⁵ 484 F.2d 820 (D.C. Cir. 1973), cert. denied, 415 U.S. 977 (1974) (mem.). 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." 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.'"

75. HHS is an agency subject to FOIA and must therefore make reasonable efforts to search for requested records.

76. Pursuant to FOIA, 5 U.S.C. § 552(a), the Center has a statutory right to access requested, non-exempt agency records.

77. On July 21, 2025, the Center properly requested records within the possession, custody, and control of HHS concerning HHS' and the FDA's decision to review mifepristone and what influence HHS leadership and staff may exert over the FDA's review of mifepristone and decision making.

78. HHS failed to comply with the time limits prescribed by FOIA, 5 U.S.C. § 552(a)(6)(A)(i), in responding to the FOIA request.

79. HHS is wrongfully withholding non-exempt agency records requested by the Center by failing to produce materials responsive to the FOIA request.

80. HHS is wrongfully withholding non-exempt agency records requested by the Center by failing to segregate non-exempt information from otherwise exempt records responsive to the FOIA request.

81. When an agency has "improperly withheld" records, this Court may "enjoin the agency from withholding agency records" and "order the[ir] production." 5 U.S.C. § 552(a)(4)(B).

82. The Center is thus entitled to declaratory and injunctive relief requiring HHS to promptly produce all non-exempt records responsive to the FOIA request and to provide a *Vaughn* index explaining, with specificity, the bases on which any responsive records are withheld as exempt.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter a judgment for Plaintiff and award the following relief:

- a. Order Defendants, by a date certain, to conduct a search that is reasonably likely to lead to the discovery of any and all records responsive to Plaintiff's FOIA requests;
- b. Order Defendants, by a date certain, to demonstrate that they have conducted an adequate search;
- c. Order Defendants, by a date certain, to produce to Plaintiff any and all non-exempt records or portions of records responsive to Plaintiff's FOIA requests, as well as a *Vaughn* index of any records or portions of records withheld due to a claim of exemption;
- d. Enjoin Defendants from continuing to withhold any and all non-exempt records responsive to Plaintiff's FOIA requests;
- e. Award Plaintiff its costs and attorneys' fees reasonably incurred in this action, pursuant to 5 U.S.C. § 552(a)(4)(E); and
- f. Grant Plaintiff such other and further relief as the Court may deem just and proper.

DATED: December 6, 2025

Respectfully submitted,

By: /s/ Amanda K. Chuzi
Amanda Chuzi (D.D.C. Bar ID D00627)
Ryan Wheeler (DC Bar No. 1737408) (*pro hac vice*)
achuzi@cohenmilstein.com
rwheeler@cohenmilstein.com
COHEN MILSTEIN SELLERS & TOLL
PLLC
1100 New York Ave. NW, Eighth Floor
Washington, DC 20005

Tel.: (202) 408-4600
Fax: (202) 408-4699

Counsel for Center for Reproductive Rights

Exhibit A

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

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

Exhibit B



FOIA Request Confirmation

Confirmation Number: FDA25115569

Requester:

General

Description of Requester:	Consumer
Max Amount Willing to Pay:	\$200

Organization

Organization Name:	Center for Reproductive Rights		
Primary Phone:	202-524-5534	Other Phone:	
Email:	vbamzai@reprorights.org		

Mailing Address

Address 1:	1600 K St. NW
Address 2:	7th Floor
City:	Washington
State:	DC
Zip Code:	20006
Country:	US

Billing Address

Address 1:	1600 K St. NW
Address 2:	7th Floor
City:	Washington
State:	DC
Zip Code:	20006
Country:	US

Details

Requester Name:	Vidhi Bamzai		
Requester File #:		Request Letter:	20250718_FDA_MifepristoneReviewFOIARequest.pdf
Requested Date From:	01/20/2025	Requested Date To:	07/18/2025
Subject of Request:	The Center for Reproductive Rights ("Center") seeks to better understand HHS' and FDA's decision to review mifepristone, the process FDA plans to use to conduct this		

Waiver of Fees

Justification:	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 Secretary Kennedy and/or Commissioner Makary's on the mifepristone review process.
----------------	---

Expedited Processing

Reason:	
Justification:	

[Print](#) [Create Another Request](#) [Close](#)

Within 10 business days of the submission of your online request, you will receive by electronic mail an FOIA Control Number. If you need to communicate with FDA regarding your request, please refer to this Control Number. Requests received after 4:00 P.M. E.S.T. will be considered to have been received on the following business day.

If your informational needs change, and you need to cancel your request, please contact the Division of Freedom of Information by telephone, mail, or fax. Please include your control number in the correspondence. For contact information, please see [FDA's FOIA page](#).

Exhibit C

07/22/2025

FDA FOIA Request Number: FDA-FOIA-2025-8830

Requester Reference Number: None Provided

Vidhi Bamzai
Center for Reproductive Rights
1600 K St. NW
7th Floor
Washington, DC 20006

Your FOIA request has been received and is being processed. Your case number is:

FDA-FOIA-2025-8830

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

The Center for Reproductive Rights ("Center") seeks to better understand HHS' and FDA's decision to review mifepristone, the process FDA plans to use to conduct this review, whether FDA will be considering data from EPPC and/or other third parties in such a review, and what influence HHS or other parties have in FDA's review of mifepristone.

In processing your FOIA request, FDA will apply, as appropriate, the FOIA exemptions in 5 USC 552(b) and the foreseeable harm standard in 5 USC 552(a)(8). We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see:

<http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm>

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other agencies are involved.

If you have any questions about your request, please call (301) 796- 3900 or write to us at:

Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

If you call or write, use the FOIA case number provided above which will help us to answer your questions more quickly.

You also have the right to seek dispute resolution services from:

Office of Government Information Services
National Archives and Administration
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903



8601 Adelphi Road - OGIS
College Park, MD 20740-6001
Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
Email: ogis@nara.gov
Fax: 202-741-5769

Sincerely,
Meredith Schlaifer
Deputy Director, Division of Headquarters Freedom of
Information
Office of Management and Enterprise Services
Office of the Commissioner
U.S. Food and Drug Administration

Cc:

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Exhibit D

July 21, 2025

Ms. Arianne Perkins
Freedom of Information Act Officer
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 729H
200 Independence Avenue, SW
Washington, D.C. 20201

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. Department of Health and Human Services (HHS), 45 C.F.R. Part 5.

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 14, 2025, in a Senate Health, Education, Labor and Pensions (HELP) Committee hearing, HHS Secretary Robert F. Kennedy, Jr. addressed the report, stating that “[i]t’s alarming, and it indicates that at the very least, the label should be changed,” going on to say that he had asked Dr. Makary to “to do a complete review and report

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>.

back.”⁶ 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.”⁷ On June 3, 2025, Dr. Makary replied to Senator Hawley’s letter and “committed to conducting a review of mifepristone and working with the professional career scientists at the Agency who review this data.”⁸

FDA is a Department of Health and Human Services (HHS) agency that “regulates clinical investigations of products under its jurisdiction.” As a sub-agency, FDA is subject to guidance and delegation of authority from HHS, including the Secretary. Although any mifepristone review will likely occur under FDA purview, HHS has a significant role in influencing policy decisions around the potential review of mifepristone.

The Center for Reproductive Rights (“Center”) seeks to better understand HHS’ and FDA’s decision to review mifepristone, the process FDA plans to use to conduct this review, whether FDA will be considering data from EPPC and/or other third parties in such a review, and what influence HHS or other parties have in FDA’s review of mifepristone. HHS leadership and staff may exert influence over FDA’s decision making. Understanding HHS’s role in this process and releasing related 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.⁹ 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 HHS encompasses all regional offices (both current and past) as well as the central offices located in Washington, D.C. 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

⁶ Press Release, Senator Josh Hawley, Hawley Secures Pledge from RFK to Review 'Alarming' Mifepristone Data, Support Bill Cracking Down on Big Pharma Ads (May 14, 2025), <https://www.hawley.senate.gov/hawley-secures-pledge-from-rfk-to-review-alarming-mifepristone-data-support-bill-cracking-down-on-big-pharma-ads/>.

⁷ *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).

⁸ 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/>.

⁹ 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/>.

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 HHS 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
 - 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 HHS 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 HHS 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 HHS employee (temporary or permanent), official, appointee, or contractor regarding HHS or 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 HHS or FDA's decision to review mifepristone to or from the following HHS personnel who may have influence on the decision to review mifepristone:
 - a. Gary Anders, HHS, Assistant Secretary for Legislation
 - b. Hannah Anderson, HHS, Deputy Chief of Staff, Policy
 - c. Anthony Archeval, HHS, Acting Director for Office for Civil Rights
 - d. Robert Foster, HHS, Deputy General Counsel/Chief Counsel for FDA (robert.foster@hhs.gov)
 - e. Robert F. Kennedy, Jr., HHS Secretary
 - f. Sean R. Keveney, HHS, Acting General Counsel (sean.keveney@hhs.gov)
 - g. Heather Flick Melanson, HHS, then-Chief of Staff (heather.melanson@hhs.gov)
 - h. Cortney McCormick, HHS, Executive Secretary to the Department (cortney.mccormick@hhs.gov)
 - i. Jim O'Neill, Deputy Secretary of HHS (jim.o'neill@hhs.gov)
 - j. Jonathan Osborne, HHS, Acting Assistant Secretary for Legislation (Jonathan.Osborne@hhs.gov)
 - k. Eric Osterhues, HHS, Deputy General Counsel (eric.osterhues@hhs.gov)
 - l. Stefanie Spear, HHS, Principal Deputy Chief of Staff/Senior Counselor to the Secretary (stefanie.spear@hhs.gov)
6. All data, records, documents, memoranda, and communications related to HHS or 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 HHS, tasked with engaging FDA staff on the possible oversight of 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 the HHS Office of the Assistant Secretary for Health, 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 HHS 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*.¹⁰ 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.”¹¹ 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.”¹² 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.’”¹³

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 Secretary Kennedy and/or Commissioner Makary’s on the mifepristone review process.

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,

¹⁰ 484 F.2d 820 (D.C. Cir. 1973), *cert. denied*, 415 U.S. 977 (1974) (mem.).

¹¹ *Founding Church of Scientology v. Bell*, 603 F.2d 945, 949 (D.C. Cir. 1979) (per curiam).

¹² *King v. U.S. Dep’t of Just.*, 830 F.2d 210, 223-24 (D.C. Cir. 1987).

¹³ *Id.* at 224.

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.

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

Exhibit E

Julia Long

From: foiarequest@hhs.gov
Sent: Monday, July 21, 2025 2:35 PM
To: Julia Long
Subject: Request Acknowledgement by U.S. Department of Health & Human Services

You don't often get email from foiarequest@hhs.gov. [Learn why this is important](#)

Dear Julia Long,

Request #2025-03366-FOIA-OS has been assigned to the request you submitted. In all future correspondence regarding this request please reference request #2025-03366-FOIA-OS.

Regards,
U.S.
Department of Health & Human Services

Exhibit F

September 19, 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. Part 20.

On June 2, 2025, FDA announced its launch of Elsa, a generative artificial intelligence (AI) tool that was designated to be used by FDA employees, including scientific reviewers.¹ In FDA’s press release, it stated “[t]he agency is already using Elsa to accelerate clinical protocol reviews, shorten the time needed for scientific evaluations, and identify high-priority inspection targets.”² It also stated that Elsa does not “train on data submitted by regulated industry, safeguarding the sensitive research and data handled.”³ However, users of the tool have reportedly explained that it is unreliable and sometimes “hallucinates” and cites studies that do not exist, which has been a problem with AI tools writ large.⁴ There is also concern that there is not sufficient oversight of Elsa to understand what guardrails exist, such as human review of information generated by Elsa, and ensure that regulatory decisions are accurate and based on good information and science.⁵ Elsa is based on the AI company Anthropic’s Claude large language model (“LLM”) which was developed by Deloitte; Elsa has cost taxpayers \$13.8 million to develop the original database and an additional \$14.7 million to scale across FDA.⁶

In parallel, on June 3, 2025, FDA Commissioner Dr. Makary replied to a letter from Senator Josh Hawley, committing to “conducting a review of mifepristone” based on a newly release publication from the Ethics and Public Policy Center about mifepristone.⁷ The

¹ FDA Launches Agency-Wide AI Tool to Optimize Performance for the American People, FOOD & DRUG ADMIN., Jun. 2, 2025, <https://www.fda.gov/news-events/press-announcements/fda-launches-agency-wide-ai-tool-optimize-performance-american-people>.

² *Id.*

³ *Id.*

⁴ Chris Mazzolini and Mike Hollan, *FDA’s Elsa AI Tool Raises Accuracy and Oversight Concerns*, APP. CLIN. TRIALS, Jul. 23, 2025, <https://www.appliedclinicaltrials.com/view/fda-elsa-ai-tool-raises-accuracy-and-oversight-concerns>; Sarah Owerhohle, *FDA’s artificial intelligence is supposed to revolutionize drug approvals. It’s making up studies*, CNN, Jul. 23, 2025, <https://www.cnn.com/2025/07/23/politics/fda-ai-elsa-drug-regulation-makary>.

⁵ *Id.*

⁶ Beth Mole, *FDA rushed out agency-wide AI tool—it’s not going well*, ARS TECHNICA, Jun. 5, 2025, <https://arstechnica.com/health/2025/06/fda-rushed-out-agency-wide-ai-tool-its-not-going-well/>.

⁷ Josh Hawley (@HawleyMO), X (June 2, 2025, 8:27 PM), <https://x.com/HawleyMO/status/1929696353010987013>; Alejandra O’Connell-Domenech, *FDA Commissioner*

publication does not meet scientific review standards: neither of its authors, Jamie Bryan Hall and Ryan T. Anderson, have clinical experience or 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.⁸

The Center for Reproductive Rights (“Center”) seeks to better understand FDA’s use of Elsa generally as well as specifically as it relates to any FDA review of mifepristone. Releasing this information is vital to the public interest in order to increase transparency about the use of AI by FDA in drug reviews, including related to mifepristone.

Records Requested

Please provide all responsive records from January 20, 2025, through the date the search is conducted. 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 district 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.

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

1. Any and all contracts between FDA and Deloitte, including its parent companies, subsidiaries and/or entities in the Deloitte network, as applicable, for the services rendered to develop Elsa for the Agency;
2. Any and all contracts between FDA and Anthropic including its parent companies and/or subsidiaries, as applicable, for the use of Elsa by the Agency, including but not limited to agreements that cover the data privacy and data security requirements for the use of Elsa by the Agency;
3. All data, records, documents, guidance, memoranda, 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 related to FDA employees’ and contractors’ use of Elsa, including, but not limited to, use of Elsa for drug application reviews, drug safety reviews, and data analysis; and

Pledges to Investigate Mifepristone, THE HILL, Jun. 3, 2025, <https://thehill.com/policy/healthcare/5330774-marty-makary-fda-mifepristone-review/>.

⁸ Jamie Bryan Hall and Ryan T. Anderson, THE ABORTION PILL HARMS WOMEN: INSURANCE DATA REVEALS ONE IN TEN PATIENTS EXPERIENCES A SERIOUS ADVERSE EVENT (2025); UCLA Law Center for Reproductive Health, Law, and Policy and UCSF Advancing New Standards in Reproductive Health, Letter to FDA: Reproductive Health Researchers’ Comment (Aug. 27, 2025), FDA-2025-P-1576, <https://www.regulations.gov/comment/FDA-2025-P-1576-0151>.

4. All data, records, documents, guidance, memoranda, 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 about the use of Elsa for any review 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 the FDA 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 the HHS Office of the Assistant Secretary for Health, that have adopted the National Archives and Records Agency 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 the 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 this 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*, 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.”⁹ 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.”¹⁰ 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.’”¹¹

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 its 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

⁹ *Founding Church of Scientology v. Bell*, 603 F. 2d 945, 949 (D.C. Cir. 1979).

¹⁰ *King v. U.S. Dep’t of Just.*, 830 F.2d 210, 223-24 (D.C. Cir. 1987).

¹¹ *Id.* at 224.

request a waiver (or, in the alternative, a reduction) of all fees because disclosure of the information would be in the public interest by contributing significantly to the public understanding of the hiring processes in place at FDA.

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 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.

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, *see* 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:

Liz McCaman Taylor
c/o Julia Long
Center for Reproductive Rights
1600 K Street, NW
Washington, DC 20006
Phone: (202) 524-5533
Email: ltaylor@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 Liz McCaman Taylor at (202) 524-5533 if you have any questions. Thank you for your assistance.

Sincerely,

Liz McCaman Taylor

Exhibit G



09/22/2025

FDA FOIA Request Number: FDA-FOIA-2025-11105

Requester Reference Number: None Provided

Liz Taylor
Center for Reproductive Rights
1600 K St NW
7th Floor
Washington, District of Columbia 20006

Your FOIA request has been received and is being processed. Your case number is:

FDA-FOIA-2025-11105

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

The Center for Reproductive Rights (Center) seeks to better understand FDA's use of Elsa generally as well as specifically as it relates to any FDA review of mifepristone. Releasing this information is vital to the public interest in order to increase transparency about the use of AI by FDA in drug reviews, including related to mifepristone. Please provide all responsive records from January 20, 2025, through the date the search is conducted. 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 district 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. We request the following to be produced within twenty business days: 1. Any and all contracts between FDA and Deloitte, including its parent companies, subsidiaries and/or entities in the Deloitte network, as applicable, for the services rendered to develop Elsa for the Agency; 2. Any and all contracts between FDA and Anthropic including its parent companies and/or subsidiaries, as applicable, for the use of Elsa by the Agency, including but not limited to agreements that cover the data privacy and data security requirements for the use of Elsa by the Agency; 3. All data, records, documents, guidance, memoranda, 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 related to FDA employees and contractors use of Elsa, including, but not limited to, use of Elsa for drug application reviews, drug safety reviews, and data analysis; and 4. All data, records, documents, guidance, memoranda, 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 about the use of Elsa for any review 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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903



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 the FDA 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.

In processing your FOIA request, FDA will apply, as appropriate, the FOIA exemptions in 5 USC 552(b) and the foreseeable harm standard in 5 USC 552(a)(8). We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see:

<http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm>

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other agencies are involved.

If you have any questions about your request, please call (301) 796- 3900 or write to us at:
Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

If you call or write, use the FOIA case number provided above which will help us to answer your questions more quickly.

You also have the right to seek dispute resolution services from:

Office of Government Information Services
National Archives and Administration
8601 Adelphi Road - OGIS
College Park, MD 20740-6001
Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
Email: ogis@nara.gov
Fax: 202-741-5769

Sincerely,
Meredith Schlaifer
Deputy Director, Division of Headquarters Freedom of

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903



FDA

U.S. FOOD & DRUG
ADMINISTRATION

Information
Office of Management and Enterprise Services
Office of the Commissioner
U.S. Food and Drug Administration

Cc:

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

www.fda.gov

Exhibit H

September 26, 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. Part 20.

Mifepristone has a longstanding record of overwhelming safety and efficacy. In April, FDA Commissioner Marty Makary gave an interview where he announced that he has no plans to change the FDA policy around mifepristone; however, he caveated this pronouncement by noting “an ongoing set of data that is coming into the FDA on mifepristone” could present new evidence requiring the FDA to take action.¹

It is clear the FDA is now actively considering policy changes that would negatively impact access to mifepristone. On September 18, 2025, anti-abortion organization Operation Rescue announced it submitted “one-of-a-kind abortion data” to Department of Health and Human Services (“HHS”) Secretary Robert F. Kennedy regarding mifepristone.² The next day, Secretary Kennedy and Commissioner Makary sent a letter to Attorneys General responding to a July 2025 letter regarding mifepristone review.³ This letter claimed that the FDA will conduct a study of the safety of the current Risk Evaluation and Mitigation Strategy (“REMS”), in order to determine whether modifications to the REMS are necessary. To do so, the letter claimed FDA will conduct its own review of “real-world outcomes and evidence” relating to mifepristone.⁴

The FDA is already responsible for tracking adverse side effects and reactions to approved drug products through the FDA Adverse Event Reporting System (“FAERS”), which supports the FDA’s post-market safety surveillance program. The Center for Reproductive Rights (“Center”) seeks to better understand the decision to review mifepristone, whether FDA will be considering data from Operation Rescue in such a review, all summary FAERS reporting for mifepristone for Quarter Two of 2025 (April 1-July 31, 2025) through the present, and any data provided up until the day of the search. Releasing this information is vital to public interest, as mifepristone has been declared safe and effective for abortion by FDA for 25 years, with more

¹ Nathaniel Weixel, *FDA Chief Says No Current Plans To Restrict Mifepristone Access*, THE HILL, Apr. 20, 2025, available at <https://thehill.com/policy/healthcare/5267781-fda-commissioner-marty-makary-mifepristone/>.

² Sarah Neely, *Operation Rescue Submits One-of-a-Kind Abortion Data to RFK and His Review of Mifepristone*, Operation Rescue, Sept. 18, 2025, available at <https://www.operationrescue.org/operation-rescue-submits-one-of-a-kind-abortion-data-to-rfk-and-his-review-of-mifepristone/>.

³ *Trump Admin., RFK Jr., Moves to Address, Assess, Safety of Abortion Pill After Years of FDA Negligence*, THE GATEWAY PUNDIT, Sept. 22, 2025, available at <https://www.thegatewaypundit.com/2025/09/trump-admin-rfk-jr-moves-address-assess-safety/>.

⁴*Id.*

than 99% of patients reporting no serious complications.⁵ Any potential risk to mifepristone access will harm the millions of people 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 summary FAERS reports for the following case ID numbers available on the FAERS Public Dashboard indicating patient use of mifepristone, also known as Mifeprex or RU-486, to exclude reports that are clearly related to Korlym (a brand name mifepristone drug used that is not used for reproductive health care):
 - a. 25330719
 - 25395424
 - 25412752
 - 25417144
 - 25419419
 - 25429793
 - 25454977
 - 25498612
 - 25503680
 - 25508717
 - 25524570
 - 25535039
 - 25550351
 - 25557845
 - 25598095
 - 25613668
 - 25665825

⁵ 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/>.

25680549
25699926
25714370
25775436
25785728
25814472
25819578
25839685

2. All summary FAERS reports on mifepristone, Mifeprex, and/or RU-486 (excluding all reports clearly related to Korlym) that appear on the public dashboard between the time of this submission and the time of the search.
3. All case reports for Case ID numbers listed in request #1, as well as any additional case reports from the requested period on mifepristone, Mifeprex, and/or RU0486 (excluding all reports clearly related to Korlym), including:
 - a. reaction information;
 - b. patient outcomes;
 - c. information on the source of the case record.
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 between any FDA employee (temporary or permanent), official, appointee, or contractor and any employee, representative, or affiliate of Operation Rescue. This request includes, but is not limited to, communications with individuals using the @operationrescue.org email domain, as well as current or former Operation Rescue officials including, but not limited to, Troy Newman (President), Sarah Neely (Chief Operating Officer), and Cheryl Sullenger (Senior VP Emeritus).

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 the FDA 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 the HHS Office of the Assistant Secretary for Health, that have adopted the National Archives and Records Agency 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 the 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 this 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*.⁶ 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.”⁷ 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.”⁸ Further, “the

⁶ 484 F.2d 820 (D.C. Cir. 1973), *cert. denied*, 415 U.S. 977 (1974) (mem.).

⁷ *Founding Church of Scientology v. Bell*, 603 F.2d 945, 949 (D.C. Cir. 1979) (per curiam).

⁸ *King v. U.S. Dep’t of Just.*, 830 F.2d 210, 223-24 (D.C. Cir. 1987).

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.’”⁹

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 its 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 contributing significantly to the public understanding of FDA’s review of mifepristone.

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 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.

⁹ *Id.* at 224.

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, *see* 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:

Liz McCaman Taylor
c/o Julia Long
Center for Reproductive Rights
1600 K Street, NW
Washington, DC 20006
Phone: (202) 524-5533
Email: ltaylor@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 Liz McCaman Taylor at (202) 524-5533 if you have any questions. Thank you for your assistance.

Sincerely,

Liz McCaman Taylor

Exhibit I

09/29/2025

FDA FOIA Request Number: FDA-FOIA-2025-11324

Requester Reference Number: None Provided

Elizabeth Taylor
Center for Reproductive Rights
1600 K St NW
7th Floor
Washington, District of Columbia 20006

Your FOIA request has been received and is being processed. Your case number is:

FDA-FOIA-2025-11324

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

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 summary FAERS reports for the following case ID numbers available on the FAERS Public Dashboard indicating patient use of mifepristone, also known as Mifeprex or RU-486, to exclude reports that are clearly related to Korlym (a brand name mifepristone drug used that is not used for reproductive health care): a. 25330719 25395424 25412752 25417144 25419419 25429793 25454977 25498612 25503680 25508717 25524570 25535039 25550351 25557845 25598095 25613668 25665825 25680549 25699926 25714370 25775436 25785728 25814472 25819578 25839685
2. All summary FAERS reports on mifepristone, Mifeprex, and/or RU-486 (excluding all reports clearly related to Korlym) that appear on the public dashboard between the time of this submission and the time of the search.
3. All case reports for Case ID numbers listed in request #1 above, as well as any additional case reports from the requested period on mifepristone, Mifeprex, and/or RU0486 (excluding all reports clearly related to Korlym), including: a. reaction information; b. patient outcomes; c. information on the source of the case record.
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 between any FDA employee (temporary or permanent), official, appointee, or contractor and any employee, representative, or affiliate of Operation Rescue. This request includes, but is not limited to, communications with individuals using the @operationrescue.org email domain, as well as current or former Operation Rescue officials including, but not limited to, Troy Newman (President), Sarah Neely

U.S. Food & Drug Administration
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Silver Spring, MD 20903



(Chief Operating Officer), and Cheryl Sullenger (Senior VP Emeritus). Please see additional detail in attached PDF.

In processing your FOIA request, FDA will apply, as appropriate, the FOIA exemptions in 5 USC 552(b) and the foreseeable harm standard in 5 USC 552(a)(8). We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see: <http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm>

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other agencies are involved.

If you have any questions about your request, please call (301) 796- 3900 or write to us at:
Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

If you call or write, use the FOIA case number provided above which will help us to answer your questions more quickly.

You also have the right to seek dispute resolution services from:
Office of Government Information Services
National Archives and Administration
8601 Adelphi Road - OGIS
College Park, MD 20740-6001
Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
Email: ogis@nara.gov
Fax: 202-741-5769

Sincerely,
Meredith Schlaifer
Deputy Director, Division of Headquarters Freedom of
Information
Office of Management and Enterprise Services
Office of the Commissioner
U.S. Food and Drug Administration

Cc:

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Exhibit J

September 26, 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. Part 20.

In 2000, FDA approved the medication abortion Mifeprex, colloquially known by its active ingredient, mifepristone.¹ As part of that approval, the sponsor of Mifeprex submitted an environmental assessment in support of its drug application in accordance with the requirements of the National Environmental Policy Action (“NEPA”)². This assessment included a section discussing excretion of pharmaceutical waste and relevant environmental impacts; specifically, the assessment and FDA agreed that the excretion of Mifeprex by patients who used the drug was unlikely to have a significant effect on the environment.³

However, anti-abortion groups such as Students for Life and Liberty Counsel have used misinformation to make false environmental impact claims about mifepristone and fetal remains from self-managed abortions.⁴ While these claims have been thoroughly debunked by scientists, including the FDA,⁵ this issue continues to be discussed due to the Trump Administration and Health and Human Services Secretary Robert F. Kennedy’s recent publication of “The MAHA Report,” which raises broad concerns about environmental toxins in the water.⁶

The Center for Reproductive Rights (“Center”) seeks to better understand FDA’s decision to review mifepristone, specifically if it is reviewing the approval on an environmental basis and

¹ Response Letter from FDA CDER to Students for Life of America, Docket No. FDA-2023-P-3328, FOOD & DRUG ADMIN., Jan. 15, 2025, <https://www.regulations.gov/document/FDA-2023-P-3328-0004> (hereinafter “FDA Response”).

² *Id.* at 2-4.

³ *Id.* at 4.

⁴ See e.g., Requests that the FDA revoke its actions to improve Mifepristone and modify the associated regimen (including the Risk Evaluation and Mitigation Strategy) until the agency determines that it has complied with the various states’ water quality standards as compelled by the Clean Water Act, FDA-2023-P-3328, <https://www.regulations.gov/docket/FDA-2023-P-3328>; Abigail Forman, et. al., *Abortion in Our Water: A Special Report Chemical Home Abortions & the Disposition of Aborted Fetal Remains*, LIBERTY COUNSEL, <https://lcaction.org/LCA-PDFs/AbortionInOurWater-.pdf>; Ariel Wittenberg & Alice Miranda Ollstein, ‘Using the devil’s own tools against them’: *Abortion opponents turn to environmental laws*, POLITICO, Jan. 30, 2025, <https://www.politico.com/news/2025/01/30/abortion-opponents-environmental-laws-00201423>.

⁵ See FDA Response *supra* n.1 at 7-21; see also Joedy McCreary, *Abortion Contaminants in the Water Supply: Are the Rumors True?*, MEDPAGE TODAY, Sept. 16, 2025, <https://www.medpagetoday.com/obgyn/abortion/117489>.

⁶ *The MAHA Report, Make Our Children Healthy Again Assessment*, at 43-45, WHITE HOUSE, Sept. 9, 2025, <https://www.whitehouse.gov/wp-content/uploads/2025/05/MAHA-Report-The-White-House.pdf>

whether FDA will be considering any information from Students for Life, Liberty Counsel, 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 FDA for 25 years, with more than 99% of patients reporting no serious complications.⁷ Any potential risk to mifepristone access will harm the millions of people who rely on the drug for essential health care.

Records Requested

Please provide all responsive records from January 20, 2025, through the date the search is conducted. 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 district 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.

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 (temporary or permanent) or contractor working for or representing Students for Life;
- 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 any employee (temporary or permanent) or contractor working for or representing Liberty Counsel or Liberty Counsel Action;
- 3) All data, records, documents, guidance, memoranda, communications meeting notices, meeting agendas, meeting minutes, 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 related to FDA employees’ and contractors’ review of the MAHA report in order to take potential regulatory action involving mifepristone;
- 4) All data, records, documents, guidance, memoranda, communications, meeting notices, meeting agendas, meeting minutes, informational materials, draft legislation, draft rules,

⁷ 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/>.

talking points, reports, disclosures, or other documents sent to, received by, or exchanged with any FDA employee (temporary or permanent), official, appointee, or contractor in connection with the Steering Committee and interagency workgroups established under MOU 225-22-015⁸ discussing mifepristone;

- 5) All data, records, documents, guidance, memoranda, communications, meeting notices, meeting agendas, meeting minutes, 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 related to any updates of FDA Regulations Implementing the Procedural Provisions of the National Environmental Policy Act⁹ as it may relate to 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 the FDA 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

⁸ MOU 225-22-015, Memorandum of Understanding on Sustainability of Federal Collaboration on Pharmaceuticals in Drinking Water between the U.S. Environmental Protection Agency (EPA) Office of Water (OW), and the U.S. Department of Agriculture (USDA) Agricultural Research Service (ARS) and the U.S. Department of Health and Human Services (HHS) Food and Drug Administration (FDA) and the U.S. Department of Interior (DOI) U.S. Geological Survey (USGS), Aug. 30, 2022, <https://www.fda.gov/about-fda/domestic-mous/mou-225-22-015>.

⁹ Update of FDA Regulations Implementing the Procedural Provisions of the National Environmental Policy Act, RIN 0910-AJ04, Spring 2025 Unified Agenda, <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202504&RIN=0910-AJ04>.

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 the HHS Office of the Assistant Secretary for Health, that have adopted the National Archives and Records Agency 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 the 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 this 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*, 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."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

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.

¹⁰ *Founding Church of Scientology v. Bell*, 603 F. 2d 945, 949 (D.C. Cir. 1979).

¹¹ *King v. U.S. Dep't of Just.*, 830 F.2d 210, 223-24 (D.C. Cir. 1987).

¹² *Id.* at 224.

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 its 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 contributing significantly to the public understanding of outside influence on the Executive Branch’s potential review of mifepristone regulation.

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 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.

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, *see* 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:

Liz McCaman Taylor
c/o Julia Long

Center for Reproductive Rights
1600 K Street, NW
Washington, DC 20006
Phone: (202) 524-5533
Email: ltaylor@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 Liz McCaman Taylor at (202) 524-5533 if you have any questions. Thank you for your assistance.

Sincerely,

Liz McCaman Taylor

Exhibit K



09/29/2025

FDA FOIA Request Number: FDA-FOIA-2025-11316

Requester Reference Number: None Provided

Elizabeth Taylor
Center for Reproductive Rights
1600 K St NW
7th Floor
Washington, District of Columbia 20006

Your FOIA request has been received and is being processed. Your case number is:

FDA-FOIA-2025-11316

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

Please provide all responsive records from January 20, 2025, through the date the search is conducted. 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 district 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. 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 (temporary or permanent) or contractor working for or representing Students for Life; 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 any employee (temporary or permanent) or contractor working for or representing Liberty Counsel or Liberty Counsel Action; 3. All data, records, documents, guidance, memoranda, communications meeting notices, meeting agendas, meeting minutes, 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 related to FDA employees and contractors review of the MAHA report in order to take potential regulatory action involving mifepristone; 4. All data, records, documents, guidance, memoranda, communications, meeting notices, meeting agendas, meeting minutes, 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 in connection with the Steering Committee and interagency workgroups established under MOU 225-22-0158 discussing mifepristone; 5. All data, records, documents, guidance, memoranda, communications, meeting notices, meeting agendas, meeting minutes, informational materials, draft legislation, draft rules, talking points, reports, disclosures, or other

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903



documents sent to, received by, or exchanged with any FDA employee (temporary or permanent), official, appointee, or contractor related to any updates of FDA Regulations Implementing the Procedural Provisions of the National Environmental Policy Act as it may relate to mifepristone. Please see attached PDF for additional information.

In processing your FOIA request, FDA will apply, as appropriate, the FOIA exemptions in 5 USC 552(b) and the foreseeable harm standard in 5 USC 552(a)(8). We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see:

<http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm>

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other agencies are involved.

If you have any questions about your request, please call (301) 796- 3900 or write to us at:

Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

If you call or write, use the FOIA case number provided above which will help us to answer your questions more quickly.

You also have the right to seek dispute resolution services from:

Office of Government Information Services
National Archives and Administration
8601 Adelphi Road - OGIS
College Park, MD 20740-6001
Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
Email: ogis@nara.gov
Fax: 202-741-5769

Sincerely,
Meredith Schlaifer
Deputy Director, Division of Headquarters Freedom of
Information
Office of Management and Enterprise Services
Office of the Commissioner
U.S. Food and Drug Administration

Cc:

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Exhibit 2

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

The Center for Reproductive Rights
199 Water Street,
New York, N.Y. 10038,

Plaintiff,

v.

U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993,

Defendants.

Civil Action No.

1:25-cv-03023-RCL

Judge: Royce
Lamberth

AMENDED COMPLAINT

NATURE OF ACTION
(Freedom of Information Act)

Plaintiff, the Center for Reproductive Rights (“the Center” or “Plaintiff”), brings this action against Defendants, the U.S. Department of Health and Human Services (“HHS”) and the U.S. Food and Drug Administration (“FDA”), to compel compliance with the Freedom of Information Act (“FOIA”), 5 U.S.C. § 552, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, seeking declaratory and injunctive relief to compel compliance with the requirements of FOIA.

As further alleged below, the information that the Center seeks about HHS’ and FDA’s decision to review mifepristone, the process FDA plans to use to conduct such a review, the influence HHS or other parties have in the FDA’s review, and whether FDA has considered or will consider data from third parties in the review are directly relevant to the Center’s mission. Founded in 1992, the Center works to ensure reproductive rights are protected in law as fundamental human rights for the dignity, equality, health, and well-being of every person. The Center uses its legal

expertise to defend access to sexual and reproductive health services. The Center is particularly concerned with potential risks to mifepristone access, which will harm the millions of patients who rely on the drug for essential health care. 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.

Defendants have not claimed that the requested information is subject to any FOIA exceptions or privilege and have not advanced any other reason why it should not be disclosed. Despite the clear statutory requirement that an agency respond to a FOIA request within 20 days, Defendants failed to provide a final determination or produce any documents in response to ~~either~~ ~~of~~ the Center's FOIA requests. The Center seeks to compel Defendants to comply with their obligations under FOIA and promptly produce the requested records.

PARTIES

1. Plaintiff, the Center for Reproductive Rights, is a 501(c)(3) non-profit corporation incorporated under the laws of the State of New York and headquartered at 199 Water Street, New York, NY 10038. The Center for Reproductive Rights is dedicated to using the power of law to advance reproductive rights as fundamental human rights around the world. It 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.

2. Defendant U.S. Department of Health and Human Services ("HHS") is an agency of the United States government under 5 U.S.C. § 552(f)(1) and 5 U.S.C. § 551(1). HHS is headquartered at 200 Independence Avenue, S.W., Washington, D.C. 20201. HHS has possession, custody, and control of the documents that Plaintiff seeks in response to the FOIA request.

3. Defendant U.S. Food and Drug Administration ("FDA") is an agency of the United States government under 5 U.S.C. § 552(f)(1) and 5 U.S.C. § 551(1). FDA is headquartered at

10903 New Hampshire Avenue, Silver Spring, MD 20993. FDA has possession, custody, and control of the documents that Plaintiff seeks in response to the FOIA request.

JURISDICTION AND VENUE

4. This Court has jurisdiction over this claim pursuant to 28 U.S.C. §§ 1331, 2201, and 2202, and 5 U.S.C. § 552(a)(4)(B).

5. Venue is proper in this district pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(e).

6. Because Defendants failed to comply with the requirements to respond set forth in 5 U.S.C. § 552(a)(6)(A), the Center is deemed to have constructively exhausted its administrative remedies pursuant to 5 U.S.C. § 552(a)(6)(C)(i) and is now entitled to judicial action enjoining Defendants from continuing to withhold responsive records and ordering the production of improperly withheld records, *see* 5 U.S.C. § 552(a)(4)(B).

STATEMENT OF FACTS

7. The Center filed ~~two~~five FOIA requests ~~to~~with Defendants seeking records concerning Defendants' review of mifepristone.

I. July 18, 2025 FOIA Request to FDA Regarding Review of Mifepristone

8. On July 18, 2025, the Center submitted through the FDA's FOIA Submission Site a FOIA request seeking records concerning the FDA's review of mifepristone, a drug approved by the FDA for medical termination of pregnancy, and the role third-party data will play in such a review.

9. On April 24, 2025, FDA Commissioner Dr. Marty Makary stated that he "ha[d] no plans to take action on mifepristone" but emphasized that he is a "data guy" and believes in the

need to “evolve” as more data is presented.¹ In an interview with PBS News Hour, Dr. Makary stated 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

10. Four days after Dr. Makary’s remarks, 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 refers to as a “serious adverse event.”³ The publication was not published in a peer-reviewed scientific journal, its authors lack medical training, and its authors did not disclose the data source, so the findings cannot be reproduced or verified.⁴

11. On April 28, 2025, Senator Josh Hawley sent a letter to Dr. Makary, which cited the EPPC publication and asked Dr. Makary whether the FDA would (1) take action to restore barriers to mifepristone access; (2) adjust the drug label for mifepristone “given this new information”; and (3) review mifepristone’s effects on users.⁵

¹ Amna Nawaz, *What the New FDA Commissioner Says About Possible Restrictions on Abortion Medication*, PBS NEWSHOUR (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*, ETHICS & PUBLIC POLICY CENTER (Apr. 28, 2025), <https://eppc.org/publication/insurance-data-reveals-one-in-ten-patients-experiences-a-serious-adverse-event/>.

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>.

12. During a Senate Appropriations Committee hearing on May 22, 2025, following questions about the EPPC publication, Dr. Makary committed that the FDA was “going to take a hard look at [mifepristone].”⁶

13. On June 3, 2025, Dr. Makary replied to Senator Hawley’s letter and “committed to conducting a review of mifepristone and working with the professional career scientists at the Agency who review this data.”⁷

14. Accordingly, the Center’s July 18 FOIA request to the FDA seeks information to better understand the FDA’s decision to review mifepristone, the process the FDA plans to use to conduct this review, and whether the FDA will be considering data from EPPC and/or other third parties during such review.

15. A true and correct copy of the FOIA request to FDA is attached as Exhibit A.

16. Shortly following the submission of the FOIA request on the FDA’s FOIA Submission Site, the Center received an automated response acknowledging receipt of the FOIA request. A true and correct copy of this acknowledgement is attached as Exhibit B.

17. In a letter dated July 22, 2025, the FDA confirmed receipt of the FOIA request. The letter further provided a tracking number of FDA-FOIA-2025-8830 for this request.

18. A true and correct copy of the FDA’s July 22, 2025, letter confirming receipt of the FOIA request is attached as Exhibit C.

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).

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/>.

II. July 21, 2025 FOIA Request to HHS Regarding Review of Mifepristone

19. On July 21, 2025, the Center submitted through HHS' FOIA Submission Site a FOIA request seeking records concerning HHS' and the FDA's decision to review mifepristone.

20. During a Senate Health, Education, Labor, and Pensions (HELP) Committee hearing on May 14, 2025, HHS Secretary Robert F. Kennedy, Jr. addressed the EPPC publication on mifepristone and stated that "[i]t's alarming, and it indicates that at the very least, the label should be changed," noting that he had asked Dr. Makary to "do a complete review and report back."⁸

21. During a Senate Finance Committee hearing on September 4, 2025, when asked about the ongoing FDA mifepristone review and its timing, HHS Secretary Robert F. Kennedy, Jr. stated, "I can't give you the exact timing. I talked to Marty Makary about it yesterday, and he said it is progressing at pace. We're getting data in all the time, new data that we're reviewing....-we're following gold standard science on that. I will keep you abreast on that."⁹

22. Accordingly, the Center's FOIA request to HHS seeks information on whether the FDA will be considering data from EPPC and/or other third parties during the review, and what influence HHS leadership and staff may exert over the FDA's review of mifepristone and decision making.

23. A true and correct copy of the FOIA request to HHS is attached as Exhibit D.

⁸ Press Release, Senator Josh Hawley, Hawley Secures Pledge from RFK to Review 'Alarming' Mifepristone Data, Support Bill Cracking Down on Big Pharma Ads (May 14, 2025), <https://www.hawley.senate.gov/hawley-secures-pledge-from-rfk-to-review-alarming-mifepristone-data-support-bill-cracking-down-on-big-pharma-ads/>.

⁹ The President's 2026 Health Care Agenda: Hearing Before the S. Fin. Comm., 119 Cong. 1st Sess., Sept. 4, 2025, available at <https://www.finance.senate.gov/hearings/the-presidents-2026-health-care-agenda> (last accessed Sept. 4, 2025).

24. Shortly following the submission of the FOIA request on HHS' FOIA Submission Site, the Center received a response acknowledging receipt of the FOIA request and assigning the tracking number #2025-03366-FOIA-OS. A true and correct copy of this acknowledgement is attached as Exhibit E.

III. September 19, 2025 FOIA Request to FDA Regarding AI Tool Elsa

25. On September 19, 2025, the Center submitted through the FDA's FOIA Submission Site a FOIA request seeking records concerning the FDA's use of Elsa in general and in relation to the FDA's review of mifepristone.

26. On June 2, 2025, FDA announced the launch of Elsa, a generative AI tool that was designated to be used by FDA employees including its scientific reviewers.¹⁰ FDA has publicly remarked that "[t]he agency is already using Elsa to accelerate clinical protocol reviews, shorten the time needed for scientific evaluations, and identify high-priority inspection targets."¹¹

27. Elsa has cost taxpayers \$13.8 million to develop the original database and an additional \$14.7 million to scale across FDA.¹²

28. Users of Elsa have reported its unreliability and that it sometimes "hallucinates" and cites studies that do not exist.¹³ Concerns have been raised that there is insufficient oversight

¹⁰ Press Release, U.S. Food & Drug Admin., FDA Launches Agency-Wide AI Tool to Optimize Performance for the American People, FDA (June 2, 2025), <https://www.fda.gov/news-events/press-announcements/fda-launches-agency-wide-ai-tool-optimize-performance-american-people>.

¹¹ *Id.*

¹² Beth Mole, FDA rushed out agency-wide AI tool—it's not going well, *Ars Technica* (June 5, 2025), <https://arstechnica.com/health/2025/06/fda-rushed-out-agency-wide-ai-tool-its-not-going-well/>.

¹³ Chris Mazzolini & Mike Hollan, FDA's Elsa AI Tool Raises Accuracy and Oversight Concerns, *Applied Clinical Trials* (July 23, 2025), <https://www.appliedclinicaltrials.com/view/fda-elsa-ai-tool-raises-accuracy-and-oversight->

of Elsa to understand what guardrails exist, for instance human review of the information generated by Elsa, to ensure that regulatory decisions are accurate and based on reliable information and science.¹⁴

29. Around the same time, on June 3, 2025, FDA Commissioner Dr. Makary replied to a letter from Senator Josh Hawley and “committed to conducting a review of mifepristone[.]”¹⁵

30. Accordingly, the Center’s September 19 FOIA request to the FDA seeks information to better understand how the FDA is using Elsa and any role Elsa is playing in FDA’s review of mifepristone. The Center seeks to increase transparency about the FDA’s use of AI in drug reviews.

31. A true and correct copy of the FOIA request to FDA is attached as Exhibit F.

32. In a letter dated September 22, 2025, the FDA confirmed receipt of the FOIA request. The letter further provided a tracking number of FDA-FOIA-2025-11105 for this request.

33. A true and correct copy of the FDA’s September 22, 2025, letter acknowledging receipt of the FOIA request is attached as Exhibit G.

IV. September 26, 2025 FOIA Request to FDA Regarding FAERS Reporting

34. On September 26, 2025, the Center submitted through the FDA’s FOIA Submission Site a FOIA request seeking (1) summary FAERS reporting for mifepristone for Quarter Two of

concerns; Sarah Owerhohle, *FDA’s artificial intelligence is supposed to revolutionize drug approvals. It’s making up studies*, CNN (July 23, 2025), <https://www.cnn.com/2025/07/23/politics/fda-ai-elsa-drug-regulation-makary>.

¹⁴ *Id.*

¹⁵ 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/>.

2025 (April 1 – July 31, 2025) through the present, and (2) records concerning whether the FDA will be considering data from Operation Rescue in its review of mifepristone.

35. The FDA is currently actively considering policy changes regarding access to mifepristone.

36. On September 18, 2025, Operation Rescue announced it submitted “one-of-a-kind abortion data” to Department of Health and Human Services Secretary Robert F. Kennedy regarding mifepristone.¹⁶ The following day, Secretary Kennedy and FDA Commissioner Dr. Makary sent a letter to state Attorney Generals which claimed that the FDA will conduct a study of the safety of the current Risk Evaluation and Mitigation Strategy (REMS) for mifepristone to determine whether modifications are necessary.¹⁷ The letter claimed that the FDA will conduct its own review of “real-world outcomes and evidence” relating to mifepristone.¹⁸

37. Accordingly, the Center’s September 19 FOIA request to the FDA seeks information to better understand the FDA’s decision to review mifepristone, including its reliance on FAERS reporting for Quarter Two of 2025 for mifepristone, and communications with and data received from Operation Rescue as part of the review.

38. A true and correct copy of the FOIA request to FDA is attached as Exhibit H.

39. In a letter dated September 29, 2025, the FDA confirmed receipt of the FOIA request. The letter further provided a tracking number of FDA-FOIA-2025-11324 for this request.

¹⁶ Sarah Neely, *Operation Rescue Submits One-Of-A-Kind Abortion Data to RFK and His Review of Mifepristone*, Operation Rescue (Sept. 18, 2025), <https://www.operationrescue.org/operation-rescue-submits-one-of-a-kind-abortion-data-to-rfk-and-his-review-of-mifepristone/>.

¹⁷ *Trump Admin., RFK Jr., Moves to Address, Assess, Safety of Abortion Pill After Years of FDA Negligence*, The Gateway Pundit (Sept. 2025), <https://www.thegatewaypundit.com/2025/09/trump-admin-rfk-jr-moves-address-assess-safety/>.

¹⁸ *Id.*

40. A true and correct copy of the FDA's September 29, 2025, letter confirming receipt of the FOIA request is attached as Exhibit I.

V. September 26, 2025 FOIA Request to FDA Regarding Environmental Impact

41. On September 26, 2025, the Center submitted through the FDA's FOIA Submission Site a FOIA request seeking records concerning the FDA's review of mifepristone, whether the FDA is reviewing the approval on an environmental basis, and whether the FDA will be considering any information from Students for Life, Liberty Counsel, and/or additional third parties in the review.

42. The FDA approved the medication abortion Mifeprex (known by its active ingredient mifepristone) in 2000.¹⁹ As part of that approval, the sponsor of Mifeprex submitted an environmental assessment in support of the drug application in accordance with the National Environmental Policy Action's requirements.²⁰ The assessment and the FDA both agreed that the excretion of Mifeprex by patients who used the drug was unlikely to have a significant impact on the environment.²¹

¹⁹ Mifeprex, Drug Approval Package, U.S. Food & Drug Admin., https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_mifepristone.cfm.

²⁰ Response Letter from FDA CDER to Students for Life of America at 2-4 (Jan. 15, 2025), <https://www.regulations.gov/document/FDA-2023-P-3328-0004>.

²¹ Id.

43. Students for Life and Liberty Counsel have made claims regarding the environmental impact of mifepristone.²² Scientists, including the FDA, have found no credible evidence of any environmental impact.²³

44. HHS Secretary Kennedy recently published The MAHA Report, which raises broad concerns about environmental toxins in the water.²⁴

45. As such, the Center's September 26 FOIA request to the FDA seeks information to better understand whether the FDA is reviewing the approval of mifepristone on an environmental basis and considering any information from third parties, such as Students for Life and Liberty Counsel, regarding environmental impacts in the review.

46. A true and correct copy of the FOIA request to FDA is attached as Exhibit J.

47. In a letter dated September 29, 2025, the FDA confirmed receipt of the FOIA request. The letter further provided a tracking number of FDA-FOIA-2025-11316 for this request.

48. A true and correct copy of the FDA's September 29, 2025, letter confirming receipt of the FOIA request is attached as Exhibit K.

²² See, e.g., Liberty Counsel Action, Abortion in Our Water: A Special Report (2025), <https://lcaction.org/LCA-PDFs/AbortionInOurWater-.pdf>; Ariel Wittenberg & Alice Miranda Ollstein, 'Using the devil's own tools against them': Abortion opponents turn to environmental laws, Politico (Jan. 30, 2025), <https://www.politico.com/news/2025/01/30/abortion-opponents-environmental-laws-00201423>.

²³ See, e.g., Response Letter from FDA CDER to Students for Life of America at 7–21 (Jan. 15, 2025), <https://www.regulations.gov/document/FDA-2023-P-3328-0004>; Joedy McCreary, *Abortion Contaminants in the Water Supply: Are the Rumors True?*, MedPage Today (Sept. 16, 2025), <https://www.medpagetoday.com/obgyn/abortion/117489>.

²⁴ The MAHA Report at 43-45 (2025), <https://www.whitehouse.gov/wp-content/uploads/2025/05/MAHA-Report-The-White-House.pdf>.

III.VI. FDA and HHS' Failure to Adequately Respond to the Center's FOIA Requests

~~25.1. On July 18, 2025, the FDA acknowledged receipt of the Center's FOIA request to FDA.~~

~~26.1. On July 21, 2025, HHS acknowledged receipt of the Center's FOIA request to HHS.~~

27.49. Pursuant to FOIA, within 20 business days of receipt of the Center's requests, FDA and HHS were required to "determine . . . whether to comply with such request" and to "immediately notify" the Center of "such determination and the reasons therefor," and, in the case of an adverse determination, the Center's appeal rights. 5 U.S.C. § 552(a)(6)(A)(i).

a. Thus, for the Center's July 18, 2025 FOIA request Request to FDA Regarding Review of Mifepristone

50. On July 18, 2025, the FDA acknowledged receipt of the Center's FOIA request to FDA.

28.51. Thus, the agency was required to "determine . . . whether to comply with such request" and notify the Center of such determination no later than August 15, 2025. 5 U.S.C. § 552(a)(6)(A)(i).

b. For the Center's July 21, 2025 FOIA request Request to HHS Regarding Review of Mifepristone

52. On July 21, 2025, HHS acknowledged receipt of the Center's FOIA request to HHS.

29.53. Thus, the agency was required to "determine . . . whether to comply with such request" and notify the Center of such determination no later than August 18, 2025. 5 U.S.C. § 552(a)(6)(A)(i).

d. September 19, 2025 FOIA Request to FDA Regarding AI Tool Elsa

54. On September 22, 2025, the FDA acknowledged receipt of the Center’s FOIA request to FDA.

55. Thus, the agency was required to “determine . . . whether to comply with such request” and notify the Center of such determination no later than October 21, 2025. 5 U.S.C. § 552(a)(6)(A)(i).

e. September 26, 2025 FOIA Request to FDA Regarding FAERS Reporting

56. On September 29, 2025, the FDA acknowledged receipt of the Center’s FOIA request to FDA.

57. Thus, the agency was required to “determine . . . whether to comply with such request” and notify the Center of such determination no later than October 28, 2025. 5 U.S.C. § 552(a)(6)(A)(i).

f. September 26, 2025 FOIA Request to FDA Regarding Environmental Impact

58. On September 29, 2025, the FDA acknowledged receipt of the Center’s FOIA request to FDA.

59. Thus, the agency was required to “determine . . . whether to comply with such request” and notify the Center of such determination no later than October 28, 2025. 5 U.S.C. § 552(a)(6)(A)(i).

* * *

30.60. As of the date of this Complaint, HHS and FDA have failed to (a) notify the Center of any determination regarding its FOIA requests, including the scope of any responsive records HHS and FDA intend to produce or withhold and the reasons for any withholding; or (b) produce

the requested records or demonstrate that the requested records are lawfully exempt from production.

~~31.61.~~ Through HHS and the FDA's failure to respond to the Center's FOIA requests with a determination regarding the requests or the production of the requested records within the time period required by law, the Center has constructively exhausted its administrative remedies and seeks immediate judicial review.

COUNT I

Violation of FOIA, 5 U.S.C. § 552 – FOIA ~~Request~~Requests to FDA

~~32.62.~~ The Center repeats the allegations in the foregoing paragraphs and incorporates them as though fully set forth herein.

~~33.63.~~ FDA is an agency subject to FOIA and must therefore make reasonable efforts to search for requested records.

~~34.64.~~ Pursuant to FOIA, 5 U.S.C. § 552(a), the Center has a statutory right to access requested, non-exempt agency records.

~~35.65.~~ On July 18, 2025, the Center properly requested records within the possession, custody, and control of the FDA concerning the FDA's decision to review mifepristone and the role third-party data will play in such a review.

66. On September 19, 2025, the Center properly requested records within the possession, custody, and control of the FDA concerning the FDA's use of the generative artificial intelligence (AI) tool Elsa in general and in relation to the FDA's review of mifepristone.

67. On September 26, 2025, the Center properly requested records within the possession, custody, and control of the FDA concerning (1) summary FAERS reporting for

mifepristone for Quarter Two of 2025 (April 1 – July 31, 2025) through the present, and (2) whether the FDA will be considering data from Operation Rescue in its review of mifepristone.

68. On September 26, 2025, the Center properly requested records within the possession, custody, and control of the FDA concerning whether the FDA is reviewing the approval of mifepristone on an environmental basis and considering any information from third parties, such as Students for Life and Liberty Counsel, regarding environmental impacts.

36.69. The FDA failed to comply with the time limits prescribed by FOIA, 5 U.S.C. § 552(a)(6)(A)(i), in responding to the FOIA ~~request~~requests.

37.70. The FDA is wrongfully withholding non-exempt agency records requested by the Center by failing to produce materials responsive to the Center's FOIA ~~request~~requests.

38.71. The FDA is wrongfully withholding non-exempt agency records requested by the Center by failing to segregate non-exempt information from otherwise exempt records responsive to the FOIA ~~request~~requests.

39.72. When an agency has “improperly withheld” records, this Court may “enjoin the agency from withholding agency records” and “order the[ir] production.” 5 U.S.C. § 552(a)(4)(B).

40.73. The Center is thus entitled to declaratory and injunctive relief requiring FDA to promptly produce all non-exempt records responsive to the FOIA ~~request~~requests and to provide a *Vaughn* index explaining, with specificity, the bases on which any responsive records are withheld as exempt.²⁵

²⁵ 484 F.2d 820 (D.C. Cir. 1973), cert. denied, 415 U.S. 977 (1974) (mem.). 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.”

COUNT II

Violation of FOIA, 5 U.S.C. § 552 – FOIA Request to HHS

~~41.74.~~ The Center repeats the allegations in the foregoing paragraphs and incorporates them as though fully set forth herein.

~~42.75.~~ HHS is an agency subject to FOIA and must therefore make reasonable efforts to search for requested records.

~~43.76.~~ Pursuant to FOIA, 5 U.S.C. § 552(a), the Center has a statutory right to access requested, non-exempt agency records.

~~44.77.~~ On July 21, 2025, the Center properly requested records within the possession, custody, and control of HHS concerning HHS' and the FDA's decision to review mifepristone and what influence HHS leadership and staff may exert over the FDA's review of mifepristone and decision making.

~~45.78.~~ HHS failed to comply with the time limits prescribed by FOIA, 5 U.S.C. § 552(a)(6)(A)(i), in responding to the FOIA request.

~~46.79.~~ HHS is wrongfully withholding non-exempt agency records requested by the Center by failing to produce materials responsive to the FOIA request.

~~47.80.~~ HHS is wrongfully withholding non-exempt agency records requested by the Center by failing to segregate non-exempt information from otherwise exempt records responsive to the FOIA request.

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.’”

~~48.81.~~ When an agency has “improperly withheld” records, this Court may “enjoin the agency from withholding agency records” and “order the[ir] production.” 5 U.S.C. § 552(a)(4)(B).

~~49.82.~~ The Center is thus entitled to declaratory and injunctive relief requiring HHS to promptly produce all non-exempt records responsive to the FOIA request and to provide a *Vaughn* index explaining, with specificity, the bases on which any responsive records are withheld as exempt.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter a judgment for Plaintiff and award the following relief:

- a. Order Defendants, by a date certain, to conduct a search that is reasonably likely to lead to the discovery of any and all records responsive to Plaintiff’s FOIA requests;
- b. Order Defendants, by a date certain, to demonstrate that they have conducted an adequate search;
- c. Order Defendants, by a date certain, to produce to Plaintiff any and all non-exempt records or portions of records responsive to Plaintiff’s FOIA requests, as well as a *Vaughn* index of any records or portions of records withheld due to a claim of exemption;
- d. Enjoin Defendants from continuing to withhold any and all non-exempt records responsive to Plaintiff’s FOIA requests;
- e. Award Plaintiff its costs and attorneys’ fees reasonably incurred in this action, pursuant to 5 U.S.C. § 552(a)(4)(E); and

f. Grant Plaintiff such other and further relief as the Court may deem just and proper.

DATED: ~~September 5~~December 6, 2025

Respectfully submitted,

By: /s/ Amanda K. Chuzi
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Counsel for Center for Reproductive Rights

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

The Center for Reproductive Rights
199 Water Street,
New York, N.Y. 10038,

Plaintiff,

v.

U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993,

Defendants.

Civil Action No. 1:25-cv-03023-RCL

Judge Royce Lamberth

**[PROPOSED] ORDER CONSENT MOTION FOR LEAVE TO FILE AMENDED
COMPLAINT**

Upon consideration of Plaintiff's Consent Motion for Leave to File Amended Complaint, it is hereby ORDERED that the Motion is GRANTED; and it is further ORDERED that, pursuant to Federal Rule of Civil Procedure 15(a)(2) and Local Civil Rule 15.1, Plaintiff is granted leave to file the Amended Complaint submitted with the Motion; and it is further ORDERED that the Clerk shall docket the Amended Complaint attached to the Motion.

SO ORDERED.

Entered this _____ day of

U.S. District Judge Royce Lamberth