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. _____

Judge: _____

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 FOIA requests to Defendants seeking records concerning Defendants' review of mifepristone.

FOIA Request to FDA

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]

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[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.

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[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/.

FOIA Request to HHS

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.

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[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.

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

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

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

27. 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).

28. Thus, for the Center's July 18 FOIA request to FDA, 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).

29. For the Center's July 21 FOIA request to HHS, 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).

30. 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. 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 to FDA

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

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

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

35. 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.

36. 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.

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

38. 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.

39. 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. The Center is thus entitled to declaratory and injunctive relief requiring FDA 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.[10]

COUNT II

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

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

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

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

44. 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.

[10] *Vaughn v. Rosen*, 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." 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.'"

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

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

47. 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.

48. 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. 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, 2025

Respectfully submitted,

/s/ Amanda Chuzi

Amanda Chuzi (D.D.C. Bar ID D00627)
Ryan Wheeler (DC Bar No. 1737408) (*pro hac vice* forthcoming)
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 the Center for Reproductive Rights