IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ADVANCING AMERICAN FREEDOM, 801 Pennsylvania Avenue, NW Suite 930 Washington, D.C. 20004, Plaintiff, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, 200 Independence Avenue, SW Washington, DC 20201, Defendant.	)	Civil Action No.

COMPLAINT

Plaintiff Advancing American Freedom brings this action against Defendant U.S. Department of Health and Human Services to compel compliance with the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA"). As grounds therefor, Plaintiff alleges as follows:

JURISDICTION AND VENUE

1. The Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331.

2. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e).

PARTIES

3. Plaintiff Advancing American Freedom is a 501(c)(3) not-for-profit organization incorporated under the laws of the State of Indiana and headquartered at 1801 Pennsylvania Avenue, N.W., Washington, D.C. 20004. Plaintiff, through research, policy proposals, and participation in the legal process through the writing of *amicus* briefs, promotes and defends the

policies that elevate traditional American values, including the uniquely American idea that all people are created equal and endowed by their Creator with unalienable rights to life, liberty, and the pursuit of happiness

4. Defendant U.S. Department of Health and Human Services is an agency of the U.S. Government and is headquartered at 200 Independence Avenue, SW, Washington, DC 20201. Defendant has possession, custody, and control of records to which Plaintiff seeks access.

STATEMENT OF FACTS

5. On May 31, 2024, Plaintiff sent an identical FOIA request to U.S. Department of Health & Human Services ("HHS") and the Food & Drug Administration ("FDA"), a component of HHS, seeking access to the following records:

1. Any and all records of communications:

a. to these communications) between the FDA and the House Committee on Commerce Subcommittee on Oversight and Investigations ("Subcommittee") concerning letters from the Subcommittee dated June 27, 1996; July 1, 1996; and September 17, 1996.

b. Please provide all records requested in the September 17, 1996 letter from Subcommittee Chairman Joe Barton to FDA Commissioner David A. Kessler (attached for Please provide all copies of communications (including records produced in response

your reference) including, but not limited to:

- **1. Meetings that were not reported on "the public calendar as required by Agency regulations (21 C.F.R. 10.100). These meetings concerning RU-486 appear to have involved senior FDA officials and persons outside the executive branch."**
- **2. "…all materials relating to all ethical issues concerning each member of the [Reproductive Health Drugs] Committee."**
- **3. "…FDA's consideration of the issue of the possible breast cancer risk factor in connection with RU-486 [mifepristone]."**

• 4. "All precedents and legal authority that support the propriety of FDA officials encouraging, urging or soliciting a submission of an IND or new drug application."

• 5. "…mentioning or pertaining to FDA's implementation of President Clinton's memorandum of January 22, 1993 concerning RU-486."

2. Any and all records of communications:

a. Between any FDA personnel and the Office of White House Counsel between November 1, 1992 and January 31, 2001 regarding the approval of "mifepristone" (which includes, but is not limited to, such terms as Mifeprex, Mifegyne, Korlym, abortion pill, RU-486, RU-38486, ZK-98296, and/or the mifepristone chemical description of "11β- (4-(dimethylamino)phenyl)-17α-(1-propynyl)estra-4,9-dien-17β-ol-3-one"or other names used by the same compound in its generic form) for use as an abortifacient,

b. Including but not limited to, communications or drafts of communications with, mentioning, copying, or blind-copying Associate White House Counsel Elena Kagan.

3. Any and all records of communications between any FDA personnel and any person or entity between November 1, 1992 and January 31, 2001 (including but not limited to any organization, association, corporation, Federal employees, and or non- Federal employees)

a. regarding FDA Commissioner David Kessler's overseas trip or trips to meet with individuals from Roussel Uclaf on an unknown date, but on information or belief took place in April or May 1994.

b. Including but not limited to, travel receipts, calendar invitations and acceptances, public and private calendars, travel logs, travel authorizations,or meeting minutes. These communications should also include drafts of communications, as well as those in which the FDA is copied or blind-copied.

c. Including but not limited to, communications with or mentioning the Population Council ("PC").

4. Any and all records of communications:

a. Between any FDA personnel and any person or entity between November 1, 1992 and January 31, 2001 (including but not limited to any organization, association, corporation, Federal employees, and or non- Federal employees)

regarding the April 14, 1994 meeting between FDA Commissioner David Kessler and Lester Hyman.

b. Including but not limited to, travel receipts, calendar invitations and acceptances, public and private calendars, travel logs, travel authorizations, or meeting minutes. These communications should also include, drafts of communications, as well as those in which the FDA is copied or blind-copied.

c. Including but not limited to, communications with or mentioning the Population Council ("PC").

5. Any and all records of communications:

a. Between any FDA personnel and any person or entity between November 1, 1992 and January 31, 2001 (including but not limited to any organization, association, corporation, Federal employees, and or non- Federal employees) regarding the July 19, 1996 Reproductive Health Drugs Advisory Committee's meeting to discuss the New Drug Application for "mifepristone" (which includes, but is not limited to, such terms as Mifeprex, Mifegyne, Korlym, abortion pill, RU-486, RU-38486, ZK-98296, and/or the mifepristone chemical description of "11β- (4-(dimethylamino)phenyl)-17α-(1-propynyl)estra-4,9-dien-17β-ol-3-one"or other names used by the same compound in its generic form) for use as an abortifacient.

b. Including but not limited to, travel receipts, calendar invitations and acceptances, public and private calendars, travel logs, travel authorizations, or meeting minutes. These communications should also include, drafts of communications, as well as those in which the FDA is copied or blind-copied.

c. Including but not limited to, communications with or mentioning the Population Council ("PC").

6. Any other records which, though not specifically requested, would have a reasonable relationship to the subject matter of this request, including any record or document.

6. NIH acknowledged receipt of the request on DATE and advised Plaintiff that the request had been assigned tracking number FOIA Case No. 54522.

7. As of the date of this Complaint, HHS has failed to (i)determine whether to comply with the request; (ii) notify Plaintiff of any such determination or the reasons therefor; (iii) advise Plaintiff of the right to appeal any adverse determination; or (iv) produce the

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

COUNT I
(Violation of FOIA, 5 U.S.C. § 552)

8. Plaintiff realleges paragraphs 1 through 7 as if fully stated herein.

9. Defendant is in violation of FOIA.

10. Plaintiff is being irreparably harmed by Defendant's violation of FOIA, and Plaintiff will continue to be irreparably harmed unless Defendant is compelled to comply with the law.

11. Plaintiff has no adequate remedy at law.

12. To trigger FOIA's administrative exhaustion requirement, Defendant HHS was required to make a final determination on Plaintiff's request by June 30, 2024. Because Defendant failed to make a final determination on Plaintiff's request within the time limits set by FOIA, Plaintiff is deemed to have exhausted its administrative appeal remedies.

WHEREFORE, Plaintiff respectfully requests that the Court: (1) order Defendant to conduct a search for any and all records responsive to Plaintiff's FOIA request and demonstrate that it employed search methods reasonably likely to lead to the discovery of records responsive to Plaintiff's FOIA request; (2) order Defendant to produce, by a date certain, any and all non-exempt records responsive to Plaintiff's FOIA request and a *Vaughn* index of any responsive records withheld under claim of exemption; (3) enjoin Defendant from continuing to withhold any and all non-exempt records responsive to Plaintiff's FOIA request; (4) grant Plaintiff an award of attorneys' fees and other litigation costs reasonably incurred in this action pursuant to 5 U.S.C. § 552(a)(4)(E); and (5) grant Plaintiff such other relief as the Court deems just and proper.

Dated: October 2, 2024

Respectfully submitted,

/s/ Meredith Di Liberto

MEREDITH DI LIBERTO
D.C. Bar No. 487733
JUDICIAL WATCH, INC.
425 Third Street SW, Suite 800
Washington, DC 20024
Tel: (202) 646-5172
Fax: (202) 646-5199
Email: mdiliberto@judicialwatch.org

Attorney for Plaintiff