

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

AMERICA FIRST LEGAL FOUNDATION,
611 Pennsylvania Ave SE #231
Washington, DC 20003

Plaintiff,

v.

U.S. FOOD AND DRUG
ADMINISTRATION,
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Defendant.

Civil Action No.: 23-528

COMPLAINT

1. Plaintiff America First Legal Foundation (“AFL”) brings this action against the Defendant Food and Drug Administration (“FDA”) to compel compliance with the Freedom of Information Act (“FOIA”), 5 U.S.C. § 552.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331. Additionally, it may grant declaratory relief pursuant to 28 U.S.C. § 2201, *et seq.*

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

PARTIES

4. AFL is a nonprofit organization working to promote the rule of law in the United States, prevent executive overreach, ensure due process and equal protection for all Americans,

and encourage public knowledge and understanding of the law and individual rights guaranteed under the United States Constitution and the laws of the United States.

5. The Defendant FDA is an agency of the federal government under 5 U.S.C. § 552(f), with its headquarters at 5630 Fishers Lane, Room 1035, Rockville, MD, 20857. It has possession, custody, and control of the relevant records.

FACTS

6. On September 29, 2022, AFL sent FDA a FOIA request through the FDA FOIA Public Access Portal (“PAL”) regarding the off-label use of puberty blockers and cross-sex hormones in children. *See* Exhibit 1.

7. AFL requested all records from January 21, 2021, to the date the processing is completed, that included the following terms: “child” or “minor” *and* “Lupron,” “Leuprorelin,” “Fensolvi,” “Synarel,” “Nafarelin,” “Supprelin,” “Vantas,” “Triptodur,” “Histrelin,” “puberty blocker,” “GnRH agonist,” or “GnRH analogues.” *Id.*

8. AFL identified the following custodians: Patrizia Cavazzoni, Theresa Kehoe, Naomi Lowy, Elisabeth Hanan, LaiMing Lee, Lynne Yao, Leyla Sahin, and Lily Mulugeta. *Id.*

9. AFL received confirmation of receipt on October 4, 2022. *See* Exhibit 2.

10. As of the date of this Complaint, AFL has received no further response from the FDA about its FOIA request.

CLAIM FOR RELIEF **Violation of FOIA, 5 U.S.C. § 552**

11. AFL repeats paragraphs 1-10.

12. AFL’s FOIA request complies with all applicable statutes and regulations.

13. However, the FDA has failed to respond to this request as required by law. *See* 5 U.S.C. § 552(a)(6). Accordingly, AFL has exhausted administrative remedies. 5 U.S.C. § 552(a)(6)(C).

14. By failing to respond and release all responsive, non-exempt records, the FDA has violated FOIA. 5 U.S.C. § 552(a)(3)(A).

15. By failing to release any responsive, non-exempt records, or otherwise offer a reasonable schedule for production, Defendant FDA has violated FOIA. *See* 5 U.S.C. § 552(a)(3)(A).

16. The FOIA's purpose is to ensure an informed citizenry, vital to the functioning of a democratic society, needed to check against corruption and to hold the governors accountable to the governed. *NLRB v. Robbins Tire & Rubber Co.*, 437 U.S. 214, 242 (1978).

17. By failing to comply with the FOIA, the FDA is depriving AFL and the public of vital information needed to evaluate FDA's compliance with the law regarding the off-label use of puberty blockers and cross-sex hormones on children.

PRAYER FOR RELIEF

WHEREFORE, AFL respectfully requests that this Court:

A. Declare that the records sought by the request, as described in the foregoing paragraphs, must be disclosed pursuant to 5 U.S.C. § 552.

B. Order Defendant to conduct searches immediately for all records responsive to AFL's FOIA request and demonstrate that they employed search methods reasonably likely to lead to the discovery of responsive records.

C. Order Defendant to produce by a date certain all non-exempt records responsive to AFL's FOIA request, accompanied by a Vaughn index of any responsive records or portions of responsive records being withheld under claim of exemption.

D. Award AFL attorneys' fees and costs incurred in this action pursuant to 5 U.S.C. § 552(a)(4)(E).

E. Grant AFL such other and further relief as this Court deems proper.

February 27, 2023

Respectfully submitted,

/s/ Michael Ding

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** Application for Pro Hac Vice Forthcoming*