UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PROTECT THE PUBLIC'S TRUST 712 H Street, N.E. Suite 1682 Washington, D.C. 20002, Plaintiff, v. U. S. FOOD AND DRUG ADMINISTRATION 10903 New Hampshire Avenue Silver Spring, MD 20993 Defendant.	)	Civil Case No. 1:23-cv-03750

COMPLAINT

1. Plaintiff Protect the Public's Trust brings this action against the U.S. Food and Drug Administration under the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA"), seeking relief to compel compliance with the requirements of FOIA.

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.

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

PARTIES

4. Plaintiff Protect the Public's Trust ("PPT") is a nonprofit corporation dedicated to restoring public trust in government by promoting the fair and equal application of the rules and standards of ethical conduct to all public servants. Consistent with Justice Brandeis's aphorism that "Sunlight is said to be the best of disinfectants; electric light the most efficient policeman," PPT seeks to promote transparency and broadly disseminate

information so that the American people can evaluate the integrity and ethical conduct of those who act in their name. Louis Brandeis, OTHER PEOPLE'S MONEY AND HOW BANKERS USE IT (1914), https://louisville.edu/law/library/special-collections/the-louis-d.-brandeis-collection/other-peoples-money-chapter-v.

5. Defendant U.S. Food and Drug Administration ("FDA") is a federal agency within the meaning of FOIA, 5 U.S.C. § 552(f)(1). FDA has possession, custody, and control of records responsive to PPT's FOIA request.

STATEMENT OF FACTS

6. On or about April 17, 2023, PPT submitted a FOIA request (attached as Exhibit A) to FDA seeking the following:

1. From September 1, 2022, through December 31, 2022, records of communications related to The Reagan-Udall Foundation Report titled *Operational Evaluation of Certain Components of FDA's Tobacco Program, regarding:*

    a. Scientific integrity concerns
    b. Scientific issues that remain unanswered
    c. Scientific analysis that can/will inform policy issues

    Search terms for this request include:

    • Scientific integrity
    • Politicization
    • Political interference
    • Logic
    • Menthol
    • e-cigarettes
    • Vaping
    • Juul
    • Flavored products
    • Combustible products
    • Electronic Nicotine Delivery Systems
    • Lifelong addiction
    • Incomplete data
    • Illegal products
    • Premarket review

- Tobacco Products Scientific Advisory Committee
- State of the science
- Application review
- Youth addiction
- Youth adoption

7. As Attorney General Garland has made clear, FOIA is "a vital tool for ensuring transparency, accessibility, and accountability in government" whose "'basic purpose . . . is to ensure an informed citizenry,' which is 'vital to the functioning of a democratic society [and] needed to check against corruption and to hold the governors accountable to the governed.'" Merrick Garland, *Memorandum for Heads of Executive Departments and Agencies: Freedom of Information Act Guidelines*, 1 (Mar. 15, 2022) (quoting *Nat'l Labor Rels. Bd. v. Robbins Tire & Rubber Co.*, 437 U.S. 214, 242 (1978)) ("Garland Memo").

8. The Reagan-Udall Foundation report provided an evaluation of the FDA and the Center for Tobacco Products' ("CTP") tobacco program. In preparing its report, the Reagan-Udall Foundation conducted stakeholder meetings and FDA interviews. *See Operational Evaluation of Certain Components of FDA's Tobacco Program* at 33, The Reagan-Udall Foundation (Dec. 2022), https://reaganudall.org/sites/default/files/2022-12/Tobacco%20report%20210pm.pdf. The Report itself noted concerns that have been raised regarding scientific integrity at FDA and CTP, including stating "CTP must do a better job of explaining how and why it weighs the evidence, explicitly quantifying the trade-offs it is willing to accept, and distinguishing policy judgments from scientific information and determinations." *Id*. at 20. The release of the documents at issue in this request is in the public interest because they will help the public understand the how the CTP and the FDA have addressed the data, analysis, and recommendations contained in the Reagan-Udall report, including how they have separated policy and science

determinations and whether FDA employees have raised scientific integrity concerns with the FDA process.

9. On April 19, 2023, PPT received an email assigning control number 2023-3164 to PPT's FOIA Request and an Acknowledgement Letter that stated in part "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 HHS components or other executive branch agencies are involved."

10. On May 10, 2023, PPT received an email from FDA claiming in part "After careful review of your FOIA request, we determined that your request is too broad in scope or did not specifically identify the records which you are seeking," asking for PPT to "provide in your response the names of the CTP program/leadership offices that you would like us to search," and to "narrow the search terms from the original list of twenty plus terms and topics provided in your request," including asking if PPT was "willing to narrow the request to only include records with the terms 'Reagan-Udall' and 'scientific' and 'evaluation'?" The email further stated, "I would like to speak with you regarding the scope of your request. Are you available today or tomorrow?"

11. On May 26, 2023, FDA reiterated its request to discuss PPT's request, asked that PPT "[p]lease identify the names of the individuals and/or offices for the search for records," and asked if PPT was "only interested in communications internal to CTP?"

12. On May 30, 2023, PPT responded by inquiring about a time to discuss the request.

13. In a July 18, 2023, email, in the midst of PPT and FDA attempting to schedule a call to discuss the scope of the request, FDA further stated, "I suggested that you only include the terms 'Reagan-Udall' and 'scientific' and 'evaluation' for the search request."

14. After additional back and forth between the FDA and PPT, on July 26, 2023, PPT provided FDA with the following clarifications:

    Names/Offices

    The following offices/officials in the Office of Center Director:
    Director Brian King
    Senior Science Advisor Priscilla Callahan-Lyon
    Deputy Director Michele Mital
    Public Health Analyst Jane Silver
    Appeals and Special Projects Coordinator Shawn Fultz
    Ombudsman Nathan Hurley

    Directors and Deputy Directors in the following divisions or offices:

    Office of Compliance and Enforcement, Division of Product Compliance
    Office of Regulations
    Office of Science

    - Science Policy Branch
    - Division of Regulatory Science Informatics
    - Division of Product Science
    - Division of Research and Knowledge Integration

    We agree with your suggestion to only include the terms "Reagan-Udall" and "scientific" and "evaluation" for the search request.

15. That same day, July 26, 2023, FDA acknowledged the clarifying email from PPT and inquired about fee related information: "Would you be interested in decreasing the number of program offices/records custodians to decrease the fees for the multiple search requests?"

16. On July 28, 2023, the FDA stated "I would like to discuss this request further with you. A rough estimate indicates the fees will exceed $1,000. Are you willing to pay that amount

or possibly more for this FOIA Request?" The FDA also recommended that PPT "limit the searches to the program offices where you provided the names for the various records custodians (i.e., OCD)," asked if PPT was "still interested in requesting searches of the multiple records types (emails, texts, WhatsApp messages, etc.)," and asked if PPT was "agreeable with informing the program offices that you consider records that are not responsive to the following issues (itemized in the original FOIA Request as a., b., and c.,) to be non-responsive to your FOIA Request?"

17. On August 22, 2023, PPT responded to the fee estimate and provided the following list of narrowed custodians to help facilitate the search process:

- Office of Compliance and Enforcement

Director- Ann Simoneau

- Division of Product Compliance

Director- Chad Burger

- Office of Regulations

Director- May Nelson
Deputy Director- Annette Marthaler

- Office of Science

Director- Matthew Farrelly

- Science Policy Branch

Director- Dale Slavin

- Division of Regulatory Science Informatics

Director- Yuan Tian
Deputy Director- Johnny Wen

- Division of Product Science

Director- Colleen Rogers
Deputy Director- Matthew Walters

- Division of Research and Knowledge Integration

Director- Robin Toblin

18. That same day, FDA responded "[i]n reviewing this issue, it has been determined that your fee waiver request is moot."

19. On August 28, 2023, PPT asked whether FDA had "status update or estimated timeline for producing records responsive to 2023-3164?"

20. That same day, FDA responded "The searches have been initiated and I expect to receive the responses next week. I will have a better idea about how much longer it will take to process this case after I have heard back from the program offices. At this time, I anticipate the estimated completion date for your case will be 11/30/2023."

21. On September 8, 2023, FDA provided a new estimate, stating: "I would like to update you on the status of your FOIA request 2023-3164. We have received responses from the program offices for our search requests. I anticipate that your FOIA request will be completed earlier than I had originally anticipated. The estimated completion date is now October 27, 2023."

22. As the Garland Memo makes clear, "Timely disclosure of records is also essential to the core purpose of FOIA." Garland Memo, at 3.

23. As the FDA's representations that the "searches have been initiated" and "[w]e have received responses from the program offices for our search requests" indicate, FDA has a valid FOIA request that sufficiently describes the records sought.

24. FDA estimated that it would provide records by October 27, 2023. October 27 has come and gone with no records provided by FDA.

25. FDA previously estimated that it would provide records by November 30, 2023. November 30 has come and gone with no records provided by FDA.

26. As the record described above indicates, more than 240 days have elapsed since the FDA acknowledged receipt of PPT's request. Even crediting time negotiating over the scope of PPT's request, over 100 days have passed since the agency "initiated" its search. This is well beyond the statutory period for federal agencies to make a determination with respect to a FOIA request. 5 U.S.C. § 552(a)(6)(A)-(B).

27. To date, the FDA has not made a determination of whether it will comply with Plaintiff's FOIA request. *See Citizens for Responsibility and Ethics in Washington v. FEC*, 711 F.3d 180 (D.C. Cir. 2013). To wit, the FDA has not produced responsive documents to PPT, has not communicated to PPT the scope of the documents it intends to produce and withhold, along with the reasons for such withholding, and has not informed PPT of its ability to appeal any adverse portion of its determination.

28. Given these facts, FDA has not met its statutory obligations to provide the requested records absent litigation.

29. Through the FDA's failure to make a determination within the time period required by law, PPT has constructively exhausted its administrative remedies and seeks immediate judicial review.

COUNT I
Violation of FOIA, 5 U.S.C. § 552
Wrongful Withholding of Non-Exempt Responsive Records

30. PPT repeats and incorporates by reference each of the foregoing paragraphs as if fully set forth herein.

31. PPT properly requested records within the possession, custody, and control of FDA.

32. FDA is an agency subject to FOIA, and therefore has an obligation to release any non-exempt records and provide a lawful reason for withholding any materials in response to a proper FOIA request.
33. FDA is wrongfully withholding non-exempt agency records requested by PPT in FOIA Request # 2023-3164 by failing to produce non-exempt records responsive to its request.
34. FDA is wrongfully withholding non-exempt agency records requested by PPT in FOIA Request # 2023-3164 by failing to segregate exempt information in otherwise non-exempt records responsive to the request.
35. FDA's failure to provide all non-exempt responsive records violates FOIA.
36. Plaintiff PPT is therefore entitled to relief requiring Defendant FDA to promptly produce all non-exempt records responsive to FOIA Request # 2023-3164 and provide indexes justifying the withholding of any responsive records withheld under claim of exemption.

REQUESTED RELIEF

Protect the Public's Trust respectfully requests this Court:

(1) Assume jurisdiction in this matter and maintain jurisdiction until the Defendant complies with the requirements of FOIA and any and all orders of this Court.

(2) Order Defendant to produce, within ten days of the Court's order, or by other such date as the Court deems appropriate, any and all non-exempt records responsive to PPT's FOIA Request # 2023-3164 and indexes justifying the withholding of all or part of any responsive records withheld under claim of exemption.

(3) Enjoin the Defendant from continuing to withhold any and all non-exempt records responsive to PPT's FOIA Request # 2023-3164.

(4) Award PPT the costs of this proceeding, including reasonable attorney's fees and other litigation costs reasonably incurred in this action, pursuant to 5 U.S.C. § 552(a)(4)(E).

(5) Grant PPT other such relief as the Court deems just and proper.

Dated: December 18, 2023

Respectfully submitted,

PROTECT THE PUBLIC'S TRUST
By Counsel:

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