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. DEPARTMENT OF HEALTH AND HUMAN SERVICES 200 Independence Avenue, S.W. Washington, D.C. 20201, Defendant.	)	Civil Case No. 1:24-cv-00895

COMPLAINT

1. Plaintiff Protect the Public's Trust ("PPT") brings this action against the U.S. Department of Health and Human Services ("HHS" or the "Department") under the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA"), seeking declaratory and injunctive 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 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 disinfects, electric light the most efficient policemen," 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. Department of Health of Health and Human Services is a federal agency within the meaning of FOIA, 5 U.S.C. § 552(f)(1). The Department has possession, custody, and control of records responsive to Plaintiff's FOIA request.

STATEMENT OF FACTS

Introduction

6. In December 2023, PPT submitted four FOIA requests to HHS and its subdivision, the Food and Drug Administration ("FDA"), seeking records related to a proposed ban on menthol flavored cigarettes and the research supporting it.

7. HHS and its subdivision followed a similar pattern of non-response with all of PPT's requests, receiving them and failing to act on them. For all four requests, HHS and its subdivisions failed to meaningfully respond by either producing records or withholding records and providing its basis for doing so.

8. For all four requests, HHS and its subdivisions refused to fulfill HHS's statutory obligations under FOIA and appears unwilling to do so absent litigation.

PPT's First Request—Control Number 2023-10864

9. On or about December 4, 2023, PPT submitted its first FOIA request to FDA (the "First Request") (attached as Exhibit A), seeking the following records related agency communications on FDA's proposed menthol cigarette ban:

    1. From April 1, 2022, through the date this request is processed, records of communications regarding plans to enforce the menthol flavor ban related to regulations for which the public comment period ended on August 2, 2022.

       Officials to help facilitate the search:
       a) Brian King, Director
       b) Michele Mital, Deputy Director
       c) Jane Silver, Public Health Analyst
       d) Priscilla Callahan-Lyon, Senior Science Advisor
       e) Angela Hester, Management Specialist
       f) Jody Jones, Management & Operations Specialist
       g) William Loy, Executive Staff Assistant
       h) Jacqueline Andrews, Program Specialist
       i) Karin Appler, Policy Analyst
       j) Karin Rudolph, Policy Analyst
       k) Erika Campbell, Policy Analyst
       l) Megan Hicks, Public Health Analyst
       m) Beaza Yeheyes, Public Health Analyst
       n) Felincia Moore, Public Health Analyst
       o) Elise Richman, Special Assistant

10. The release of these documents is in the public interest because it will help the public understand FDA's decision-making in proposing the menthol cigarette ban and enable PPT to ensure FDA's decisions are made consistent with the law.

11. On December 5, 2023, FDA acknowledged PPT's request via email, assigning it the Control Number 2023-10864. The email had an attached acknowledgement letter. The letter stated that FDA would be unable to comply with the twenty-working day time limit for FOIA requests due to the volume of FOIA requests it had received:

> 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. Please note that requests for medical device approval records (e.g. 510K, PMA, DEN) may take up to 18 to 24 months to process.

12. About 90 days later on March 4, 2024, PPT followed up with FDA for an update on its request. FDA responded that the request had been assigned to its Center for Tobacco Products ("CTP") for processing and copied CTP's FOIA office on the email.

13. On March 5, 2024, CTP's FOIA office responded to the email thread and stated in part that there were "more than 200 FOIA requests ahead of [PPT's] request and at the moment [PPT's] request has not been assigned to an analyst for intake and processing." *Id*.

14. After this email, PPT received no further communications or response from FDA or CTP.

15. To date, PPT has received neither a further response nor any other communication from FDA or CTP regarding its First Request, Control Number 2023-10864.

PPT's Second Request—Control Number 2023-10867

16. PPT submitted its second request to FDA (the "Second Request") (attached as Exhibit B) also on or about December 4, 2023, seeking the following communication records:

> Records of communications involving the list of officials, and their respective date range, with the term "menthol".
>
> Custodians:
> a) Brian King (April 1, 2022 – present)
> b) Matthew Farrelly (March 1, 2023 – present)

17. The release of these documents is in the public interest because it will help the public better understand FDA's decision-making concerning menthol cigarette regulation and enable PPT to ensure the government makes decisions consistent with law.

18. On December 5, 2023, FDA responded to PPT's request with an email acknowledging the request and assigning it Control Number 2023-10867. The email had an attached

acknowledgement letter, which stated that FDA could not comply with FOIA's twenty-working-day time limit for requests because of an increase in request volume:

> 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. Please note that requests for medical device approval records (e.g. 510K, PMA, DEN) may take up to 18 to 24 months to process.

19. Over 110 days have passed since FDA acknowledged PPT's request, and PPT has received no further communications or responses from FDA regarding its Second Request, Control Number 2023-10867.

PPT's Third Request—Control Number 2023-11455

20. On or about December 22, 2023, PPT submitted its third request to FDA (the "Third Request) (attached as Exhibit C), seeking the following agency communication records:

> From October 1, 2023, through the date this request is processed, records of communications to, from, and including the list of officials regarding the Tobacco Product Standard for Menthol in Cigarettes or menthol ban.
>
> Officials to help facilitate the search:
> a) Brian King, Director
> b) Michele Mital, Deputy Director
> c) Jane Silver, Public Health Analyst
> d) May Nelson, Director, Office of Regulations
> e) April Burbach, Acting Director, Office of Health Communication and Education
> f) Matthew Farrelly, Director, Office of Science

The release of these documents is in the public interest because their disclosure will help the American people to understand FDA's efforts to regulate menthol cigarettes and enable PPT to ensure the government makes decisions consistent with law.

21. On December 26, 2023, FDA responded to PPT's requests by email, acknowledging receipt of the request and assigning it Control Number 2023-11455. The email had an attached acknowledgement letter, which stated that FDA could not comply with FOIA's twenty-working-day time limit for requests because of an increase in request volume:

> 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. Please note that requests for medical device approval records (e.g. 510K, PMA, DEN) may take up to 18 to 24 months to process.

22. Over 90 days have passed since FDA acknowledged PPT's request, and PPT has received no further communications or responses from FDA regarding its Third Request, Control Number 2023-11455.

PPT's Fourth Request—Tracking Number 2024-00373-FOIA-OS

23. On or about December 29, 2023, PPT submitted its fourth FOIA request to HHS (the "Fourth Request) (attached as Exhibit D), seeking the following agency communication records:

> From October 1, 2023, through the date this request is processed, records of communications to, from, and including the list of officials regarding the Tobacco Product Standard for Menthol in Cigarettes, also known as the menthol ban.
>
> Officials to help facilitate the search:
> a) Xavier Becerra, Secretary
> b) Andrea Palm, Deputy Secretary
> c) Vivek Murthy, Surgeon General
> d) Felicia Collins, Deputy Assistant Secretary for Minority Health
> e) Denise Hinton, Assistant Surgeon General

24. The release of these documents is in the public interest because it will help the public better understand FDA's decision-making concerning menthol cigarette regulation and enable PPT to ensure the government makes decisions consistent with law.

25. On December 29, 2023, HHS responded to PPT's request with an email acknowledging the request and assigning it the tracking number 2024-00373-FOIA-OS.

26. This was followed by further emails from HHS, stating that status of the request had been updated to "Received" and acknowledging that the request was received. Attached to the acknowledgement email was a letter stating that HHS would be unable to respond to the request within the normal FOIA timeframe due to "unusual circumstances:"

> Because you seek records which require a search in another office, "unusual circumstances" apply to your request, automatically extending the time limit to respond to your request for ten additional days. See 5 U.S.C. 552 § (a)(6)(B)(i)-(iii) (2012 & Supp. V. 2017). Further, we estimate needing more than 10 additional days to respond to your request and so, in the next paragraph of this letter we are offering you an opportunity to narrow your request, in case narrowing the request would enable us to respond to the request sooner. The actual time needed to process your request will depend on the complexity of our records search and on the volume and complexity of any material located. For your information, this Office assigns incoming requests to one of three tracks: simple, complex, or expedited. Each request is then handled on a first-in, first-out basis in relation to other requests in the same track. Our current workload is approximately 3000 cases.

27. On January 31, 2024, HHS sent an email to PPT stating that the request's status had been updated to "In Process."

28. On February 13, 2024, PPT followed up with HHS to ask for the tracking number for the request and information related to the search process.

29. On February 14, 2024, HHS responded, providing only the tracking number.

30. On March 1, 2024, PPT reached out to HHS for an update on the request. HHS did not respond to this email and has provided no further communications since.

31. Over 55 days have passed since HHS updated PPT's request to "In Process," and over 90 days have passed since HHS acknowledged PPT's request, yet HHS has neither produced responsive records nor withheld records alongside a justification for doing so.

HHS has violated its obligations under FOIA

32. 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), https://www.justice.gov/ag/page/file/1483516/download (quoting *NLRB v. Robbins Tire & Rubber Co*, 437 U.S. 214, 242 (1978)) ("Garland Memo").

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

34. Over 115 days have elapsed since PPT's First and Second requests, and over 90 days have elapsed since PPT's Third and Fourth requests, HHS and its subdivision FDA still have not made determinations with respect to them. *See Citizens for Responsibility and Ethics in Washington v. FEC*, 711 F.3d 180 (D.C. Cir. 2013). HHS and its subdivision have not produced responsive documents to PPT, have not communicated the scope of the documents they intend to produce or withhold—along with the reasons for any such withholding—and have not informed PPT of its ability to appeal any adverse portion of its determination.

35. Given these facts, HHS has not met its statutory obligations to provide the requested records for all four requests.

36. Through HHS' failure to either 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 – The First Request: Control Number 2023-10864

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

37. PPT repeats and incorporates by reference paragraphs 1-15 and 32-36 as if fully set forth herein.

38. PPT's First Request was a properly submitted request for records within the possession, custody, and control of HHS's subdivision FDA.

39. HHS 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.

40. HHS is wrongfully withholding non-exempt agency records requested by PPT by failing to produce non-exempt records responsive to its request.

41. HHS's failure to provide all non-exempt responsive records violates FOIA.

42. Plaintiff PPT is therefore entitled to declaratory and injunctive relief requiring HHS to promptly produce all non-exempt records responsive to its FOIA request and provide an index justifying the withholding of any responsive records withheld under claim of exemption.

COUNT II – The Second Request: Control Number 2023-10867

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

43. PPT repeats and incorporates by reference paragraphs 1-8, 16-19, and 32-36 as if fully set forth herein.

44. PPT's Second Request was a properly submitted request for records within the possession, custody, and control of HHS's subdivision FDA.

45. HHS 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.

46. HHS is wrongfully withholding non-exempt agency records requested by PPT by failing to produce non-exempt records responsive to its request.

47. HHS's failure to provide all non-exempt responsive records violates FOIA.

48. Plaintiff PPT is therefore entitled to declaratory and injunctive relief requiring HHS to promptly produce all non-exempt records responsive to its FOIA request and provide an index justifying the withholding of any responsive records withheld under claim of exemption.

COUNT III – The Third Request: Control Number 2023-11455

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

49. PPT repeats and incorporates by reference paragraphs 1-8, 20-22, and 32-36 as if fully set forth herein.

50. PPT's Third Request was a properly submitted request for records within the possession, custody, and control of HHS's subdivision FDA.

51. HHS 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.

52. HHS is wrongfully withholding non-exempt agency records requested by PPT by failing to produce non-exempt records responsive to its request.

53. HHS's failure to provide all non-exempt responsive records violates FOIA.

54. Plaintiff PPT is therefore entitled to declaratory and injunctive relief requiring HHS to promptly produce all non-exempt records responsive to its FOIA request and provide an index justifying the withholding of any responsive records withheld under claim of exemption.

COUNT IV – The Fourth Request: Tracking Number 2024-00373-FOIA-OS

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

55. PPT repeats and incorporates by reference paragraphs 1-8 and 23-36 as if fully set forth herein.

56. PPT's Fourth Request was a properly submitted request for records within the possession, custody, and control of HHS.

57. HHS 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.

58. HHS is wrongfully withholding non-exempt agency records requested by PPT by failing to produce non-exempt records responsive to its request.

59. HHS's failure to provide all non-exempt responsive records violates FOIA.

60. Plaintiff PPT is therefore entitled to declaratory and injunctive relief requiring HHS to promptly produce all non-exempt records responsive to its FOIA request and provide an index justifying the withholding of any responsive records withheld under claim of exemption.

REQUESTED RELIEF

Plaintiff PPT respectfully requests this Court:

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

(2) Order HHS 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 First, Second, Third, and Fourth Requests and an index justifying the withholding of all or part of any responsive records withheld under claim of exemption.

(3) Award PPT's 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).

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

Dated: March 28, 2024

Respectfully submitted,

PROTECT THE PUBLIC'S TRUST
By Counsel:

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