PROTECT the PUBLIC'S TRUST

Freedom of Information Act April 17, 2023

FDA Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: Communications regarding the Reagan-Udall Foundation's "Operational Evaluation of Certain Components of FDA's Tobacco Program" report

Dear FOIA Officer,

This is a request under the Freedom of Information Act, 5 U.S.C. § 552, *as amended* (FOIA), from the Protect the Public's Trust (PPT), a nonpartisan organization dedicated to promoting ethics in government and restoring the public's trust in government officials.

In December of 2022, the Reagan-Udall Foundation issued a report providing evaluation of the Food and Drug Administration's (FDA's) Center for Tobacco Products (CTP) and recommendations to "strengthen the regulatory processes and operations of the FDA's tobacco program to better position it to face the future" (*Operational Evaluation of Certain Components of FDA's Tobacco Program*). When conducting the analysis, the Regan-Udall Foundation conducted stakeholder meetings and FDA interviews in an effort to address the prominent issues facing the consumers.[1]

The report's analysis and recommendations address scientific integrity concerns and questions about scientific issues that remain unanswered and scientific analysis that can inform policy issues (such as weighing the public health benefits of the percentage of adults who use ENDS that will completely quit smoking combustible products against the potential public health harms that youth who use ENDS will acquire a lifelong addiction). Further, the report's findings call on the FDA to assemble a proactive, instead of reactive, approach to addressing the ever-growing, and sometimes conflicting data involving the use of Electronic Nicotine Delivery Systems (ENDS) and tobacco products.

These are not the only questions and concerns regarding scientific integrity in the Department of Health and Human Services (HHS) and its component agencies, of which CTP and FDA are included. Several of these concerns have reached the level of sparking scientific integrity complaints to the HHS Inspector General by PPT.[2] Accordingly, Protect the Public's Trust seeks the following records to better understand how CTP and

[1] https://reaganudall.org/sites/default/files/2022-12/Tobacco%20report%20210pm.pdf
[2] https://protectpublicstrust.org/science-undermined/

the FDA have addressed the data, analysis, and recommendations contained in the Reagan-Udall report, specifically with respect to issues of scientific integrity:

Records Requested

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

The term "records" includes emails (with attachments) but also refers to other documents and items, such as text messages; invitations, communications, and chats from meeting applications such as Zoom and Microsoft Teams; encrypted apps such as Signal, WhatsApp, Wikr Me, and others; phone records; as well as communications on collaboration platforms such as Slack.

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Under the FOIA Improvement Act of 2016, agencies are prohibited from denying requests for information under the FOIA unless the agency reasonably believes release of the information will harm an interest that is protected by the exemption. FOIA Improvement Act of 2016 (Public Law No. 114-185), codified at 5 U.S.C. § 552(a)(8)(A).

Should you decide to invoke a FOIA exemption, please include sufficient information for us to assess the basis for the exemption, including any interest(s) that would be harmed by release. Please include a detailed ledger which includes:

1. Basic factual material about each withheld record, including the originator, date, length, general subject matter, and location of each item; and

2. Complete explanations and justifications for the withholding, including the specific exemption(s) under which the record (or portion thereof) was withheld and a full explanation of how each exemption applies to the withheld material. Such statements will be helpful in deciding whether to appeal an adverse determination. Your written justification may help to avoid litigation.

If you determine that portions of the records requested are exempt from disclosure, we request that you segregate the exempt portions and mail the non-exempt portions of such records to my attention at the address below within the statutory time limit. 5 U.S.C. § 552(b).

PPT is willing to receive records on a rolling basis.

To facilitate this request, we request that the FOIA office use the Agency's enterprise records management system to search and process this request.

Finally, FOIA's "frequently requested record" provision was enacted as part of the 1996 Electronic Freedom of Information Act Amendments and requires all federal agencies to give "reading room" treatment to any FOIA-processed records that, "because of the nature of their subject matter, the agency determines have become the subject of subsequent requests for substantially the same records." 5 U.S.C.§552(a)(2)(D)(ii)(I). Also, enacted as part of the 2016 FOIA Improvement Act, FOIA's Rule of 3 requires all federal agencies to proactively "make available for public inspection in an electronic format" "copies of records, regardless of form or format ... that have been released to any person ... and ... that have been requested 3 or more times." 5 U.S.C.§552(a)(2)(D)(ii)(I). Therefore, we respectfully request that you make available online any records that the agency determines will become the subject of subsequent requests for substantially the same records, and records that have been requested three or more times.

Format of Requested Records

Under FOIA, you are obligated to provide records in a readily accessible electronic format and in the format requested. See, e.g., 5 U.S.C. § 552(a)(3)(B) ("In making any record available to a person under this paragraph, an agency shall provide the record in any form or format requested by the person if the record is readily reproducible by the agency in that form or format."). "Readily accessible" means text-searchable and OCR-formatted. See 5 U.S.C. § 552(a)(3)(B). We ask that you please provide all records in an electronic format. Additionally, please provide the records either in (1) load-ready format with a CSV file index or Excel spreadsheet, or; (2) for files that are in .PDF format, without any "portfolios" or "embedded files." Portfolios and embedded files within files are not readily accessible. Please do not provide the records in a single, or "batched," .PDF file. We appreciate the inclusion of an index.

If you should seek to withhold or redact any responsive records, we request that you: (1) identify each such record with specificity (including date, author, recipient, and parties copied); (2) explain in full the basis for withholding responsive material; and (3) provide all segregable portions of the records for which you claim a specific exemption. 5 U.S.C. § 552(b). Please correlate any redactions with specific exemptions under FOIA.

Fee Waiver Request

FOIA was designed to provide citizens a broad right to access government records. FOIA's basic purpose is to "open agency action to the light of public scrutiny," with a focus on the public's "right to be informed about what their government is up to." *U.S. Dep't of Justice v. Reporters Comm. for Freedom of Press*, 489 U.S. 749, 773-74 (1989) (internal quotation and citations omitted). In order to provide public access to this information, FOIA's fee waiver provision requires that "[d]ocuments shall be furnished without any charge or at a [reduced] charge," if the request satisfies the standard. 5 U.S.C. § 552(a)(4)(A)(iii). FOIA's fee waiver requirement is "liberally construed." *Judicial Watch, Inc. v. Rossotti*, 326 F.3d 1309, 1310 (D.C. Cir. 2003); *Forest Guardians v. U.S. Dept. of Interior*, 416 F.3d 1173, 1178 (10th Cir. 2005).

The 1986 fee waiver amendments were designed specifically to provide organizations access to government records without the payment of fees. Indeed, FOIA's fee waiver provision was intended "to prevent government agencies from using high fees to discourage certain types of requesters and requests," which are "consistently associated with requests from journalists, scholars, and non-profit public interest groups." *Ettlinger v. FBI*, 596 F.Supp. 867, 872 (D. Mass. 1984) (emphasis added). As one Senator stated, "[a]gencies should not be allowed to use fees as an offensive weapon against requesters seeking access to Government information ...." 132 Cong. Rec. S. 14298 (statement of Senator Leahy).

I. PPT Qualifies for a Fee Waiver.

Under FOIA, a party is entitled to a fee waiver when "disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the [Federal] government and is not primarily in the commercial interest of the requester." 5 U.S.C. § 552(a)(4)(A)(iii). The FDA FOIA regulations at 45 CFR § 5.54(b) establish the same standard.

Thus, FDA must consider four factors to determine whether a request is in the public interest: (1) whether the subject of the requested records concerns "the operations or activities of the Federal government," (2) whether the disclosure is "likely to contribute" to an understanding of government operations or activities, (3) whether the disclosure "will contribute to public understanding" of a reasonably broad audience of persons interested in the subject, and (4) whether the disclosure is likely to contribute "significantly" to public understanding of government operations or activities. 45 CFR § 5.54(b). As shown below, PPT meets each of these factors.

A. The Subject of This Request Concerns "The Operations and Activities of the Government."

The subject matter of this request concerns the operations and activities of FDA. This request asks for: communications regarding the scientific analysis and unanswered questions conceived by the December 2022 Reagan-Udall Foundation report.

B. Disclosure is "Likely to Contribute" to an Understanding of Government Operations or Activities.

The requested records are meaningfully informative about government operations or activities and will contribute to an increased understanding of those operations and activities by the public. Disclosure of the requested records will allow PPT to convey to the public information about FDA communications involving the cost-benefit analysis of the public's use of electronic cigarettes.

After disclosing the requested records, PPT will inform the public about their findings in order to ensure decisions are being made consistent with the law. Once the information is made available, PPT will analyze it and present it to its followers and the general public in a manner that will meaningfully enhance the public's understanding of this topic.

Thus, the requested records are likely to contribute to an understanding of FDA operations and activities.

C. Disclosure of the Requested Records Will Contribute to a Reasonably Broad Audience of Interested Persons' Understanding of Operations at the FDA.

The requested records will contribute to public understanding of operations at FDA. As explained above, the records will contribute to public understanding of this topic.

Access to the requested records involving the December 2022 Regan-Udall Foundation report is of great interest to the public. Tobacco is currently the leading preventable cause of death in the United Sates. [3] Since the inception of electronic cigarettes, America's youth has been drawn toward the accessibility and convenience ENDSs have to offer. As a result, the FDA has made an effort to reduce the accessibility of electronic cigarettes, which inadvertently effects of age consumers. Mounds of conflicting data, particularly those touching on the health side effects of vape products, has made navigating the nicotine and tobacco industry confusing for consumers. Access to the requested records will shed light on what scientific analysis and unanswered questions were produced as a result of this December report. PPT will inform the public on its findings. *See W. Watersheds Proj. v. Brown*, 318 F.Supp.2d 1036, 1040 (D. Idaho 2004) ("... find[ing] that WWP adequately specified the public interest to be served, that is, educating the public about the ecological conditions of the land managed by the BLM and also how ... management strategies employed by the BLM may adversely affect the environment.").

Through PPT's synthesis and dissemination (by means discussed in Section II, below), disclosure of information contained and gleaned from the requested records will contribute to a broad audience of persons who are interested in the subject matter. *Ettlinger v. FBI*, 596 F.Supp. at 876 (benefit to a population group of some size distinct from the requester alone is sufficient); *Carney v. Dep't of Justice*, 19 F.3d 807, 815 (2d Cir. 1994), cert. denied, 513 U.S. 823 (1994) (applying "public" to require a sufficient "breadth of benefit" beyond the requester's own interests); *Cmty. Legal Servs. v. Dep't of Hous. & Urban Dev.*, 405 F.Supp.2d 553, 557 (E.D. Pa. 2005) (in granting fee waiver to community legal group, court noted that while the requester's "work by its nature is unlikely to reach a very general audience," "there is a segment of the public that is interested in its work").

Indeed, the public does not currently have an ability to easily evaluate the requested records, which concern the findings of the Regan-Udall report. We are also unaware of any previous release to the public of these or similar records. See *Cmty. Legal Servs. v. HUD*, 405 F.Supp.2d 553, 560 (D. Pa. 2005) (because requested records "clarify important facts" about agency policy, "the CLS request would likely shed light on information that is new to the interested public."). As the Ninth Circuit observed in *McClellan Ecological Seepage Situation v. Carlucci*, 835 F.2d 1282, 1286 (9th Cir. 1987), "[FOIA] legislative history suggests that information [has more potential to contribute to public understanding] to the degree that the information is new and supports public oversight of agency operations...."

Disclosure of these records is not only "likely to contribute," but is certain to contribute, to public understanding the FDA's research on the tobacco industry. The public is always

[3] https://reaganudall.org/sites/default/files/2022-12/Operational%20Evaluation%20of%20Certain%20Components%20of%20FDA%27s%20Tobacco%20Program_Dec.%202022.pdf

well served when it knows how the government conducts its activities. Hence, there can be no dispute that disclosure of the requested records to the public will educate the public.

D. Disclosure is Likely to Contribute Significantly to Public Understanding of Government Operations or Activities.

PPT is not requesting these records merely for their intrinsic informational value. Disclosure of the requested records will significantly enhance the public's understanding of the data collected from the December 2022 report. Indeed, public understanding will be significantly increased as a result of disclosure.

The records are also certain to shed light on FDA's compliance with its own mission and responsibilities. Such public oversight of agency action is vital to our democratic system and clearly envisioned by the drafters of the FOIA. Thus, PPT meets this factor as well.

II. PPT Has the Ability to Disseminate the Requested Information Broadly.

PPT is a nonpartisan organization that informs, educates, and counsels the public about the importance of government officials acting consistently with their ethics obligations. A key component of being able to fulfill this mission and educate the public about these duties is access to information that articulates the requested records. PPT intends to publish information from requested records on its website, distribute the records and expert analysis to its followers through social media channels including Twitter, Facebook, and other similar platforms. PPT also has a robust network of reporters, bloggers, and media publications interested in its content and that have durable relationships with the organization. PPT intends to use any or all of these far-reaching media outlets to share with the public information obtained as a result of this request.

Through these means, PPT will ensure: (1) that the information requested contributes significantly to the public's understanding of the government's operations or activities; (2) that the information enhances the public's understanding to a greater degree than currently exists; (3) that PPT possesses the expertise to explain the requested information to the public; (4) that PPT possesses the ability to disseminate the requested information to the general public; (5) and that the news media recognizes PPT as a reliable source in the field of government ethics and conduct.

Public oversight and enhanced understanding of FDA's duties is absolutely necessary. In determining whether disclosure of requested information will contribute significantly to public understanding, a guiding test is whether the requester will disseminate the information to a reasonably broad audience of persons interested in the subject. *Carney v U.S. Dept. of Justice*, 19 F.3d 807 (2nd Cir. 1994). PPT need not show how it intends to distribute the information, because "[n]othing in FOIA, the [agency] regulation, or our

case law require[s] such pointless specificity." *Judicial Watch*, 326 F.3d at 1314. It is sufficient for PPT to show how it distributes information to the public generally. *Id*.

III. Obtaining the Requested Records is of No Commercial Interest to PPT.

Access to government records, disclosure forms, and similar materials through FOIA requests is essential to PPT's role of educating the general public. PPT is a nonpartisan organization with supporters and members of the public who seek a transparent, ethical and impartial government that makes decisions in the best interests of all Americans, not former employers and special interests. PPT has no commercial interest and will realize no commercial benefit from the release of the requested records.

IV. Conclusion

For all of the foregoing reasons, PPT qualifies for a full fee waiver. We hope that FDA will immediately grant this fee waiver request and begin to search and disclose the requested records without any unnecessary delays.

If you have any questions, please contact me at foia@protectpublicstrust.org. All records and any related correspondence should be sent to my attention at the address below.

Sincerely,

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