

MDP

FOIA Summons  
1/13

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

Functional Government Initiative

*Plaintiff*

v.

U.S. Department of Health and Human Services

*Defendant*

Civil Action No. 23-cv-02155-RCL

**SUMMONS IN A CIVIL ACTION**

To: *(Defendant's name and address)*

Civil Process Clerk  
United States Attorney's Office  
555 4th Street, N.W.  
Washington, DC 20530

A lawsuit has been filed against you.

Within 30 days after service of this summons on you (not counting the day you received it) you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Paul M. Bartkowski  
Bartkowski PLLC  
6803 Whittier Ave. Suite 200A  
McLean, Virginia 22101

If you fail to respond, judgment by default may be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

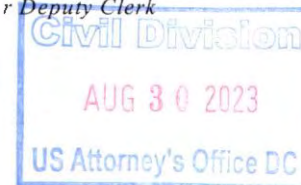
ANGELA D. CAESAR, CLERK OF COURT

Date: 07/25/2023



/s/ Luileadny J. Navas Gonzalez

Signature of Clerk or Deputy Clerk



RR

FOIA Summons (1/13) (Page 2)

Civil Action No. \_\_\_\_\_

**PROOF OF SERVICE**

*(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))*

This summons for *(name of individual and title, if any)* \_\_\_\_\_  
was received by me on *(date)* \_\_\_\_\_.

☐ I personally served the summons on the individual at *(place)* \_\_\_\_\_  
on *(date)* \_\_\_\_\_; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* \_\_\_\_\_  
\_\_\_\_\_, a person of suitable age and discretion who resides there,  
on *(date)* \_\_\_\_\_, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* \_\_\_\_\_, who is  
designated by law to accept service of process on behalf of *(name of organization)* \_\_\_\_\_  
on *(date)* \_\_\_\_\_; or

☐ I returned the summons unexecuted because \_\_\_\_\_; or

☐ Other *(specify)*: \_\_\_\_\_

My fees are \$ \_\_\_\_\_ for travel and \$ \_\_\_\_\_ for services, for a total of \$ \_\_\_\_\_ 0.00.

I declare under penalty of perjury that this information is true.

Date: \_\_\_\_\_

\_\_\_\_\_  
*Server's signature*

\_\_\_\_\_  
*Printed name and title*

\_\_\_\_\_  
*Server's address*

Additional information regarding attempted service, etc:

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

**Functional Government Initiative**

6218 Georgia Avenue NW  
Suite 1-1235  
Washington, DC 20011-5125

Plaintiff,

v.

**U.S. Department of Health and Human  
Services**

Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, D.C. 20201

Defendant.

**Civil Action No.**

**COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF**

1. This is an action under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, the Declaratory Judgment Act, and 28 U.S.C. §§ 2201 and 2202, for injunctive, declaratory, and other appropriate relief. Plaintiff Functional Government Initiative ("FGI") challenges the failure of the U.S. Department of Health and Human Services ("HHS") to disclose to FGI records that generally pertain to the Food and Drug Administration's ("FDA") tobacco regulations. The specific records sought are detailed below.

2. This case seeks declaratory relief that HHS is in violation of FOIA, 5 U.S.C. § 552(a)(6)(E), HHS's regulations, and 28 C.F.R. § 16.5(e), and for injunctive relief ordering HHS to immediately process and release to FGI the requested records in their entirety.

**Jurisdiction and Venue**

3. This Court has both subject matter jurisdiction over this action and personal jurisdiction over the parties pursuant to 5 U.S.C. §§ 552(a)(4)(B) and 552(a)(6)(c)(i). This Court

also has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 2201(a), and 2202. Venue lies in this district under 5 U.S.C. § 552(a)(4)(B).

### **Parties**

4. Plaintiff FGI is an unincorporated association of individuals dedicated to improving the American public's access to information about the officials, decisions, actions, and priorities of their government. *See* D.C. Code § 29-1102(5).

5. Defendant HHS is a cabinet-level executive branch department of the U.S. federal government created to protect the health of the U.S. people and providing essential human services. HHS has possession and control of the requested records and is responsible for fulfilling FGI's FOIA request.

### **Statutory and Regulatory Background**

6. FOIA requires agencies of the federal government to release requested records to the public unless one or more specific statutory exemptions apply.

7. An agency must notify a party making a FOIA request within 20 working days of the agency's determination and the reasons therefor and of the requester's right to appeal the determination to the agency head. 5 U.S.C. § 552(a)(6)(A)(i).

### **Factual Background**

8. In December 2019, the FDA authorized the marketing and sale of two new "reduced nicotine" tobacco products. *See* <https://www.fda.gov/news-events/press-announcements/fda-permits-sale-two-new-reduced-nicotine-cigarettes-through-premarket-tobacco-product-application> (accessed July 20, 2023).

9. In December 2021, the FDA authorized marketing of two tobacco products as "modified risk tobacco products" or MRTPs. Those two products were the first combusted

cigarettes to be authorized as MRTPs and the second tobacco products overall to receive “exposure modification” orders, which allows them to be marketed as presenting a reduced exposure to a substance. *See* <https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-tobacco-products-help-reduce-exposure-and-consumption-nicotine-smokers-who> (accessed July 20, 2023).

10. Those approvals all related to products produced by the same company, the 22<sup>nd</sup> Century Group, Inc., raising concerns that the regulatory situation is creating a monopoly.

11. On June 1, 2022, the Biden-Harris Administration published plans for regulatory actions related to tobacco and nicotine products. *See* <https://www.fda.gov/news-events/press-announcements/fda-announces-plans-proposed-rule-reduce-addictiveness-cigarettes-and-other-combusted-tobacco> (visited July 20, 2023). The plan includes a recommendation that the FDA establish a maximum nicotine level fore electronic cigarette and tobacco products.

12. On December 19, 2022, the Reagan-Udall Foundation submitted a report (hereinafter, the “Report”) containing an evaluation and resulting recommendations regarding the Food and Drug Administration’s Center for Tobacco Products (“CTP”). That Report is available on the Reagan-Udall Foundation’s website at: [Operational Evaluation of Certain Components of FDA's Tobacco Program Dec. 2022.pdf](https://reaganudall.org/wp-content/uploads/2022/12/Operational-Evaluation-of-Certain-Components-of-FDA-s-Tobacco-Program-Dec.-2022.pdf) ([reaganudall.org](https://reaganudall.org)) (accessed July 20, 2023).

13. The cover letter accompanying the Report provides that the recommendations were submitted “to strengthen the regulatory processes and operations of FDA’s tobacco program to better position it to face the future” and that the evaluation and recommendations focused on “regulations and guidance, application review, compliance and enforcement, and communication with the public and other stakeholders.” *Id.*

14. There is a clear public interest in effective regulation and approval of tobacco products, including ensuring that the regulation thereof is being conducted in a manner that allows for and promotes safety and health. In particular, the public has a specific interest in whether political considerations affect FDA's tobacco regulation through, *inter alia*, the CTP and senior officials at the Department of Health and Human Services.

**2023-00630-FOIA-OS**

15. On March 31, 2023, FGI sent the subject FOIA request<sup>1</sup> to Freedom of Information Act Office of HHS seeking all records and communication pertaining to the Report. FGI also listed Andrea Palm, Deputy Secretary, as HHS custodian to aid in the searches. *Id.*

16. The subject FOIA request stated that it requested information from December 19, 2022, to the date HHS began its search. *Id.*

17. FGI also sought a waiver of fees associated with processing its request and explained in its request that the requested records would be in the public interest and because the requested records contribute to the public's understanding of the operations or activities of the government. *Id.*

18. On April 3, 2023, FGI received a letter<sup>2</sup> from HHS acknowledging receipt of the subject FOIA and indicating it had been assigned Request Number 2023-00630-FOIA-OS and that the subject FOIA request had been assigned to the "complex track." HHS indicated that because of the "complex track" assignment, it estimated it would need more than 10 additional days to respond to the request. *Id.*

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<sup>1</sup> Attached hereto as Exhibit 1.

<sup>2</sup> Attached hereto as Exhibit 3.

19. Having not received any documents or further communication for nearly two months, on May 22, 2023, FGI asked, via email,<sup>3</sup> for an update and a completion estimate for the subject FOIA.

20. As of the filing date of this complaint, FGI has received no documents or further communication from HHS regarding 2023-00630-FOIA-OS.

21. It is apparent that, without litigation, HHS will not produce the requested documents in a timeframe that allows for timely public disclosure regarding HHS's actions. Accordingly, FGI has now exhausted all applicable administrative remedies with respect to 2023-00630-FOIA-OS.

**2023-00693-FOIA-OS**

22. On April 21, 2023, FGI sent the subject FOIA request<sup>4</sup> to the Freedom of Information Act Office of HHS seeking records and communication pertaining to tobacco and nicotine products manufactured by 22<sup>nd</sup> Century Group, Inc. with certain individuals at 22<sup>nd</sup> Century Group.

23. FGI also listed certain HHS custodians to aid in the searches.

24. The subject FOIA request stated that it requested information from January 21, 2021 through December 23, 2021. *Id.*

25. FGI also sought a waiver of fees associated with processing its request and explained in its request that the requested records would be in the public interest and because the requested records contribute to the public's understanding of the operations or activities of the government. *Id.*

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<sup>3</sup> Attached hereto as Exhibit 5 (personal telephone number redacted).

<sup>4</sup> Attached hereto as Exhibit 2.

26. On April 25, 2023, FGI received a letter<sup>5</sup> from HHS acknowledging receipt of the subject FOIA and indicating it had been assigned Request Number 2023-00693-FOIA-OS and that the subject FOIA request had been assigned to the “complex track.” HHS indicated that because of the “complex track” assignment, it estimated it would need more than 10 additional days to respond to the request. *Id.*

27. As of the filing date of this complaint, FGI has received no documents or further communication from HHS regarding 2023-00693-FOIA-OS.

28. It is apparent that, without litigation, HHS will not produce the requested documents in a timeframe that allows for timely public disclosure regarding HHS’s actions. Accordingly, FGI has now exhausted all applicable administrative remedies with respect to 2023-00693-FOIA-OS.

### **PLAINTIFF’S CLAIM FOR RELIEF**

#### **CLAIM ONE**

#### **2023-00630-FOIA-OS**

#### **(Wrongful Withholding of Non-Exempt Records In Violation of FOIA by HHS, 5 U.S.C. § 552)**

29. FGI repeats and re-alleges paragraphs 1-28.

30. FGI properly requested records within the custody and control of HHS and/or its subsidiary offices.

31. HHS failed to comply with the statutory time limits for making a determination on the FOIA request, and by withholding from disclosure records responsive to FGI’s FOIA request to HHS.

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<sup>5</sup> Attached hereto as Exhibit 3.



32. FGI is therefore entitled to injunctive and declaratory relief with respect to the immediate processing and disclosure of the requested records.

**CLAIM TWO**  
**2023-00693-FOIA-OS**  
**(Wrongful Withholding of Non-Exempt Records**  
**In Violation of FOIA by HHS, 5 U.S.C. § 552)**

33. FGI repeats and re-alleges paragraphs 1-28.

34. FGI properly requested records within the custody and control of HHS and/or its subsidiary offices.

35. HHS failed to comply with the statutory time limits for making a determination on the FOIA request, and by withholding from disclosure records responsive to FGI's FOIA request to HHS.

36. FGI is therefore entitled to injunctive and declaratory relief with respect to the immediate processing and disclosure of the requested records.

**Requested Relief**

WHEREFORE, FGI respectfully requests that this Court:

- (1) Order defendant HHS to immediately and fully process Plaintiff FGI's March 31, 2023 and April 21, 2023 FOIA requests (2023-00630-FOIA-OS and 2023-00693-FOIA-OS) and disclose all non-exempt documents immediately to FGI;
- (2) Issue a declaration that FGI is entitled to both immediate processing and disclosure of the requested records and indexes justifying the withholding of all or any portion of responsive records under claim of exemption;
- (3) Retain jurisdiction of this action to ensure no agency records are wrongfully withheld;  
and
- (4) Grant such other relief as this Court may deem just and proper.

Counsel for FGI further requests that the Court award reasonable attorneys' fees and other litigation costs incurred in this action pursuant to 5 U.S.C. § 552(a)(4)(E).

Dated: July 25, 2023

Respectfully submitted,

/s/ Paul M. Bartkowski

Paul M. Bartkowski

(D.C. Bar No. 482432)

BARTKOWSKI PLLC

6803 Whittier Ave., Suite 200A

McLean, VA 22101

Telephone: (571) 533-3581

E-Mail: [pbartkowski@bartkowskipllc.com](mailto:pbartkowski@bartkowskipllc.com)

*Counsel for Functional Government Initiative*

## CIVIL COVER SHEET

JS-44 (Rev. 11/2020 DC)

<b>I. (a) PLAINTIFFS</b> Functional Government Initiative  (b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF <u>11001</u> <small>(EXCEPT IN U.S. PLAINTIFF CASES)</small>	<b>DEFENDANTS</b> U.S. Department of Health and Human Services  COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT <u>11001</u> <small>(IN U.S. PLAINTIFF CASES ONLY)</small> <small>NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED</small>
(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER) Bartkowski PLLC 6803 Whittier Ave. Suite 200A McLean, Virginia 22101	ATTORNEYS (IF KNOWN) Paul M. Bartkowski

<b>II. BASIS OF JURISDICTION</b> <small>(PLACE AN X IN ONE BOX ONLY)</small>  <input type="radio"/> 1 U.S. Government Plaintiff <input type="radio"/> 3 Federal Question (U.S. Government Not a Party)  <input checked="" type="radio"/> 2 U.S. Government Defendant <input type="radio"/> 4 Diversity (Indicate Citizenship of Parties in item III)	<b>III. CITIZENSHIP OF PRINCIPAL PARTIES</b> <small>(PLACE AN X IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) <u>FOR DIVERSITY CASES ONLY</u></small> <table style="width: 100%; border: none;"> <tr> <th></th> <th style="text-align: center;">PTF</th> <th style="text-align: center;">DFT</th> <th></th> <th style="text-align: center;">PTF</th> <th style="text-align: center;">DFT</th> </tr> <tr> <td>Citizen of this State</td> <td style="text-align: center;"><input type="radio"/> 1</td> <td style="text-align: center;"><input type="radio"/> 1</td> <td>Incorporated or Principal Place of Business in This State</td> <td style="text-align: center;"><input type="radio"/> 4</td> <td style="text-align: center;"><input type="radio"/> 4</td> </tr> <tr> <td>Citizen of Another State</td> <td style="text-align: center;"><input type="radio"/> 2</td> <td style="text-align: center;"><input checked="" type="radio"/> 2</td> <td>Incorporated and Principal Place of Business in Another State</td> <td style="text-align: center;"><input type="radio"/> 5</td> <td style="text-align: center;"><input type="radio"/> 5</td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td style="text-align: center;"><input type="radio"/> 3</td> <td style="text-align: center;"><input type="radio"/> 3</td> <td>Foreign Nation</td> <td style="text-align: center;"><input type="radio"/> 6</td> <td style="text-align: center;"><input type="radio"/> 6</td> </tr> </table>		PTF	DFT		PTF	DFT	Citizen of this State	<input type="radio"/> 1	<input type="radio"/> 1	Incorporated or Principal Place of Business in This State	<input type="radio"/> 4	<input type="radio"/> 4	Citizen of Another State	<input type="radio"/> 2	<input checked="" type="radio"/> 2	Incorporated and Principal Place of Business in Another State	<input type="radio"/> 5	<input type="radio"/> 5	Citizen or Subject of a Foreign Country	<input type="radio"/> 3	<input type="radio"/> 3	Foreign Nation	<input type="radio"/> 6	<input type="radio"/> 6
	PTF	DFT		PTF	DFT																				
Citizen of this State	<input type="radio"/> 1	<input type="radio"/> 1	Incorporated or Principal Place of Business in This State	<input type="radio"/> 4	<input type="radio"/> 4																				
Citizen of Another State	<input type="radio"/> 2	<input checked="" type="radio"/> 2	Incorporated and Principal Place of Business in Another State	<input type="radio"/> 5	<input type="radio"/> 5																				
Citizen or Subject of a Foreign Country	<input type="radio"/> 3	<input type="radio"/> 3	Foreign Nation	<input type="radio"/> 6	<input type="radio"/> 6																				

## IV. CASE ASSIGNMENT AND NATURE OF SUIT

(Place an X in one category, A-N, that best represents your Cause of Action and one in a corresponding Nature of Suit)

<input type="radio"/> <b>A. Antitrust</b>  <input type="checkbox"/> 410 Antitrust	<input type="radio"/> <b>B. Personal Injury/Malpractice</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Medical Malpractice <input type="checkbox"/> 365 Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Product Liability	<input type="radio"/> <b>C. Administrative Agency Review</b> <input type="checkbox"/> 151 Medicare Act  <u>Social Security</u> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <u>Other Statutes</u> <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 890 Other Statutory Actions (If Administrative Agency is Involved)	<input type="radio"/> <b>D. Temporary Restraining Order/Preliminary Injunction</b>  Any nature of suit from any category may be selected for this category of case assignment.  *(If Antitrust, then A governs)*
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<input type="radio"/> <b>E. General Civil (Other)</b>		OR	<input type="radio"/> <b>F. Pro Se General Civil</b>	
<u>Real Property</u> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent, Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property  <u>Personal Property</u> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<u>Bankruptcy</u> <input type="checkbox"/> 422 Appeal 27 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157  <u>Prisoner Petitions</u> <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Conditions <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement  <u>Property Rights</u> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark <input type="checkbox"/> 880 Defend Trade Secrets Act of 2016 (DTSA)	<u>Federal Tax Suits</u> <input type="checkbox"/> 870 Taxes (US plaintiff or defendant) <input type="checkbox"/> 871 IRS-Third Party 26 USC 7609  <u>Forfeiture/Penalty</u> <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other  <u>Other Statutes</u> <input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 430 Banks & Banking <input type="checkbox"/> 450 Commerce/ICC Rates/etc <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 462 Naturalization Application	<input type="checkbox"/> 465 Other Immigration Actions <input type="checkbox"/> 470 Racketeer Influenced & Corrupt Organization <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 485 Telephone Consumer Protection Act (TCPA) <input type="checkbox"/> 490 Cable/Satellite TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes <input type="checkbox"/> 890 Other Statutory Actions (if not administrative agency review or Privacy Act)	

<input type="radio"/> <b>G. Habeas Corpus/ 2255</b>  <input type="checkbox"/> 530 Habeas Corpus – General <input type="checkbox"/> 510 Motion/Vacate Sentence <input type="checkbox"/> 463 Habeas Corpus – Alien Detainee	<input type="radio"/> <b>H. Employment Discrimination</b>  <input type="checkbox"/> 442 Civil Rights – Employment (criteria: race, gender/sex, national origin, discrimination, disability, age, religion, retaliation)  <i>*(If pro se, select this deck)*</i>	<input checked="" type="radio"/> <b>I. FOIA/Privacy Act</b>  <input checked="" type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 890 Other Statutory Actions (if Privacy Act)  <i>*(If pro se, select this deck)*</i>	<input type="radio"/> <b>J. Student Loan</b>  <input type="checkbox"/> 152 Recovery of Defaulted Student Loan (excluding veterans)
<input type="radio"/> <b>K. Labor/ERISA (non-employment)</b>  <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 740 Labor Railway Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	<input type="radio"/> <b>L. Other Civil Rights (non-employment)</b>  <input type="checkbox"/> 441 Voting (if not Voting Rights Act) <input type="checkbox"/> 443 Housing/ Accommodations <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 445 Americans w/Disabilities – Employment <input type="checkbox"/> 446 Americans w/Disabilities – Other <input type="checkbox"/> 448 Education	<input type="radio"/> <b>M. Contract</b>  <input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholder's Suits <input type="checkbox"/> 190 Other Contracts <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<input type="radio"/> <b>N. Three-Judge Court</b>  <input type="checkbox"/> 441 Civil Rights – Voting (if Voting Rights Act)

**V. ORIGIN**  
☒ 1 Original Proceeding  
 ☐ 2 Removed from State Court  
 ☐ 3 Remanded from Appellate Court  
 ☐ 4 Reinstated or Reopened  
 ☐ 5 Transferred from another district (specify)  
 ☐ 6 Multi-district Litigation  
 ☐ 7 Appeal to District Judge from Mag. Judge  
 ☐ 8 Multi-district Litigation – Direct File

**VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)**  
 5 U.S.C. Section 552 - Violation of the Freedom of Information Act

<b>VII. REQUESTED IN COMPLAINT</b>	<input type="checkbox"/> CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23	<b>DEMANDS</b> <b>JURY DEMAND:</b>	Check YES only if demanded in complaint YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>
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<b>VIII. RELATED CASE(S) IF ANY</b>	(See instruction)	YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>	If yes, please complete related case form
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DATE: July 25, 2023	SIGNATURE OF ATTORNEY OF RECORD: /s/ Paul M. Bartkowski
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**INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44**  
 Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and services of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil coversheet. These tips coincide with the Roman Numerals on the cover sheet.

- I.** COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT: (b) County of residence. Use 11001 to indicate plaintiff if resident of Washington, DC, 88888 if plaintiff is resident of United States but not Washington, DC, and 99999 if plaintiff is outside the United States.
- III.** CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.
- IV.** CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of the case.
- VI.** CAUSE OF ACTION: Cite the U.S. Civil Statute under which you are filing and write a brief statement of the primary cause.
- VIII.** RELATED CASE(S), IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.

**UNITED STATES DISTRICT AND BANKRUPTCY COURTS  
FOR THE DISTRICT OF COLUMBIA**

*ANGELA D. CAESAR*  
*Clerk of Courts*

**NOTICE OF RIGHT TO CONSENT TO TRIAL  
BEFORE A UNITED STATES MAGISTRATE JUDGE**

The substantial criminal caseload in this Court and the requirements of the criminal Speedy Trial Act frequently result in the delay in the trial of civil cases. Aware of the hardship and expense to the parties, counsel, and witnesses caused by the delays which are beyond the control of the Court, this notice is to advise you of your right to trial of your case by a United States Magistrate Judge. By statute, 28 USC §636(c), Fed.R.Civ.P. 73 and Local Civil Rule 73.1, the parties, by consent, can try their case by means of a jury trial or bench trial before a United States Magistrate Judge. Appeals from judgments and final orders are taken directly to the United States Court of Appeals for the District of Columbia Circuit, in the same manner as an appeal from a judgment of a United States District Judge in a civil case.

**WHAT IS THE PROCEDURE?**

One of the matters you are required to discuss at the meet-and-confer conference mandated by Local Civil Rule 16.3 is whether the case should be assigned to a United States Magistrate Judge for all purposes, including trial.

**All parties** must consent before the case is assigned to a Magistrate Judge for trial. You may consent at any time prior to trial. If you expressly decline to consent or simply fail to consent early in the case, you are not foreclosed from consenting later in the case. However, a prompt election to proceed before a Magistrate Judge is encouraged because it will facilitate a more orderly scheduling of the case.

Counsel for the plaintiff has been furnished a copy of the "Notice, Consent and Reference of a Civil Action to a Magistrate Judge (AO 85)" form. If and when the form is executed, your response should be made to the Clerk of the United States District Court.

**WHAT IS THE ADVANTAGE?**

The case will be resolved sooner and less expensively. The earlier the parties consent to assigning the case to a Magistrate Judge the earlier a firm and certain trial date can be established, even if the case is to be tried to a jury.

Upon the filing of the consent form the case will be randomly assigned for all purposes to a Magistrate Judge.

**HOW DO I FILE?**

Once the form is signed by **all parties**, submit the form to the Clerk's Office by mail or email, or file it electronically in CM/ECF using the event ***Consent to Proceed before Magistrate Judge for All Purposes*** (under **Other Documents**). **Do not file the form unless signed by all parties.**

# UNITED STATES DISTRICT COURT

for the

\_\_\_\_\_  
*Plaintiff*

v.

\_\_\_\_\_  
*Defendant*

)  
)  
)  
)  
)

Civil Action No.

## NOTICE, CONSENT, AND REFERENCE OF A CIVIL ACTION TO A MAGISTRATE JUDGE

*Notice of a magistrate judge's availability.* A United States magistrate judge of this court is available to conduct all proceedings in this civil action (including a jury or nonjury trial) and to order the entry of a final judgment. The judgment may then be appealed directly to the United States court of appeals like any other judgment of this court. A magistrate judge may exercise this authority only if all parties voluntarily consent.

You may consent to have your case referred to a magistrate judge, or you may withhold your consent without adverse substantive consequences. The name of any party withholding consent will not be revealed to any judge who may otherwise be involved with your case.

*Consent to a magistrate judge's authority.* The following parties consent to have a United States magistrate judge conduct all proceedings in this case including trial, the entry of final judgment, and all post-trial proceedings.

*Printed names of parties and attorneys*

*Signatures of parties or attorneys*

*Dates*


## Reference Order

**IT IS ORDERED:** This case is referred to a United States magistrate judge to conduct all proceedings and order the entry of a final judgment in accordance with 28 U.S.C. § 636(c) and Fed. R. Civ. P. 73.

Date: \_\_\_\_\_

\_\_\_\_\_  
*District Judge's signature*

\_\_\_\_\_  
*Printed name and title*

**Note:** Return this form to the clerk of court only if you are consenting to the exercise of jurisdiction by a United States magistrate judge. Do not return this form to a judge.

## Kelsey Curtis

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**From:** DCD\_ECFNotice@dcd.uscourts.gov  
**Sent:** Tuesday, July 25, 2023 3:14 PM  
**To:** DCD\_ECFNotice@dcd.uscourts.gov  
**Subject:** Activity in Case 1:23-cv-02155-RCL FUNCTIONAL GOVERNMENT INITIATIVE v. U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES Case Assigned/Reassigned

This is an automatic e-mail message generated by the CM/ECF system. Please **DO NOT RESPOND** to this e-mail because the mail box is unattended.

**\*\*\*NOTE TO PUBLIC ACCESS USERS\*\*\*** Judicial Conference of the United States policy permits attorneys of record and parties in a case (including pro se litigants) to receive one free electronic copy of all documents filed electronically, if receipt is required by law or directed by the filer. PACER access fees apply to all other users. To avoid later charges, download a copy of each document during this first viewing. However, if the referenced document is a transcript, the free copy and 30 page limit do not apply.

U.S. District Court

District of Columbia

### Notice of Electronic Filing

The following transaction was entered on 7/25/2023 at 3:14 PM and filed on 7/25/2023

**Case Name:** FUNCTIONAL GOVERNMENT INITIATIVE v. U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
**Case Number:** 1:23-cv-02155-RCL  
**Filer:**  
**Document Number:** No document attached

**Docket Text:**  
**Case Assigned to Judge Royce C. Lamberth. (zljn)**

**1:23-cv-02155-RCL Notice has been electronically mailed to:**

**1:23-cv-02155-RCL Notice will be delivered by other means to::**

**Functional Government Initiative**  
**v.**  
**U.S. Department of Health and Human Services**

**July 25, 2023 Complaint Exhibit List**

<b>Exhibit</b>	<b>Description</b>
1	FGI FOIA Request to HHS (Mar. 31, 2023)
2	FGI FOIA Request to HHS (Apr. 21, 2023)
3	HHS Acknowledgement Letter [2023-00630-FOIA-OS] (Apr. 3, 2023)
4	HHS Acknowledgement Letter [2023-00693-FOIA-OS] (Apr. 25, 2023)
5	FGI Email re Status [2023-00630-FOIA-OS] (May 22, 2023)



# **Exhibit 5**

**From:** Chris Stanley chr s@funct ona government.org  
**Subject:** Re: HHS FOIA Acknowledgement Letter -- 2023-00630-FOIA-OS  
**Date:** May 22, 2023 at 5:30 PM  
**To:** Da ey, Garfie d fo arequest@hhs.gov



May I have an update on th s request, p ease? Do you have an est mate for when t can be comp eted?

Thank you.

Chr s Stan ey  
D rector, Funct ona Government In t at ve  
chr s@funct ona government.org  
[REDACTED]

On Apr 3, 2023, at 6:58 AM, Da ey, Garfie d <fo arequest@hhs.gov> wrote:

Dear Mr.. Stanley

Please see the attached Acknowledgement Letter in response to your FOIA Request submitted to the Department of Health and Human Services (HHS) via PAL on April 3, 2023. The letter contains important information concerning your FOIA matter which has been assigned tracking number **2023-00630-FOIA-OS**.

For status updates or other inquiries, please contact our office via email at [FOIARquest@hhs.gov](mailto:FOIARquest@hhs.gov). *Please include your tracking number in the subject line of your inquiry.*

Sincerely,

OS FOIA Division Queue  
OS FOIA Division Intake  
Assistant Secretary for Public Affairs (ASPA)  
Office of the Secretary (OS)  
U.S. Department of Health and Human Services (HHS)

<Acknowledgement Letter .pdf>

# **Exhibit 4**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Public Affairs  
Washington, D.C. 20201

Refer to: Request Number **2023-00693-FOIA-OS**

**April 25, 2023**

***Sent via email:***

Mr. Chris Stanley  
Policy Director  
Functional Government Initiative  
6218 Georgia Avenue NW  
Ste 1 - 1235  
Washington, DC 20011-5125  
**[chris@functionalgovernment.org](mailto:chris@functionalgovernment.org)**

Dear Chris Stanley:

This acknowledges receipt of your April 22, 2023, Freedom of Information Act (FOIA) request, submitted to the Department of Health and Human Services (HHS), FOI/Privacy Acts Division concerning "FGI requests all records between the custodians identified and anyone with 22nd Century Group. The date range is January 21, 2021, through December 23, 2021.

This would include the following people with the company:

- James A. Mish, CEO ([Jmish@xxiicentury.com](mailto:Jmish@xxiicentury.com))
- Calvin Treat, Chief Scientific Officer ([CTreat@xxiicentury.com](mailto:CTreat@xxiicentury.com))
- John Miller, President, Tobacco Business ([JMiller@xxiicentury.com](mailto:JMiller@xxiicentury.com))
- John D. Pritchard, Vice President of Regulatory Science ([JPritchard@xxiicentury.com](mailto:JPritchard@xxiicentury.com))
- Juan Sanchez Tamburrino, Vice President of Research and Development ([JTamburrino@xxiicentury.com](mailto:JTamburrino@xxiicentury.com))
- Peter Ferola, Chief Legal Officer ([PFerola@xxiicentury.com](mailto:PFerola@xxiicentury.com))
- Lindsay Castro, Associate Corporate Counsel ([LCastro@xxiicentury.com](mailto:LCastro@xxiicentury.com))
- Shiva Vellanki, Vice President - US Federal Business Practices ([SVellanki@xxiicentury.com](mailto:SVellanki@xxiicentury.com))
- Eric Cheney, Communications Manager ([Echeney@xxiicentury.com](mailto:Echeney@xxiicentury.com))
- Brittainy Dye, Regulatory Compliance Manager ([BDye@xxiicentury.com](mailto:BDye@xxiicentury.com))
- Anyone else with an email ending with [@xxiicentury.com](mailto:@xxiicentury.com)

Custodians:

- Andrea Palm, Deputy Secretary
- Angela Botticella, Chief of Staff, Office of the Deputy Secretary
- Other staff in the immediate office of the Deputy Secretary
- The Assistant Secretary for Public Affairs
- Anyone in the office of the Assistant Secretary for Public Affairs who works on the Public Health team within the office

We received your request on April 24, 2023.

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.

Your request is assigned to the complex track. In an effort to speed up our records search, you may wish to narrow the scope of your request to limit the number of potentially responsive records or agree to an alternative time frame for processing, should records be located. You may also wish to await the completion of our records search to discuss either of these options.

I regret the necessity of this delay, but I assure you that your request will be processed as soon as possible. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the HHS FOIA office via email at [foiarequest@hhs.gov](mailto:foiarequest@hhs.gov).

If you are not satisfied with any aspect of the processing and handling of this request, you have the right to seek dispute resolution services from:

HHS FOIA/PA Public Liaison, FOI/Privacy Acts Division, Assistant Secretary for Public Affairs (ASPA) Office of the Secretary (OS) U.S. Department of Health and Human Services (HHS)  
Telephone: (202) 690-7453; E-mail: [HHS\\_FOIA\\_Public\\_Liaison@hhs.gov](mailto:HHS_FOIA_Public_Liaison@hhs.gov)

and/or:

Office of Government Information Services, National Archives and Records Administration,  
Telephone: 202- 741-5770, Toll-Free: 1-877-684-6448, E-mail: [ogis@nara.gov](mailto:ogis@nara.gov)

If you are not already submitting your requests through our Public Access Link (PAL), we recommend all future requests and appeals be submitted through PAL - <https://requests.publiclink.hhs.gov>. Submitting requests through PAL automatically logs your requests into our tracking system and provides you with a tracking number. Your PAL account will allow you to track the progress of your request, receive your documents directly through the portal, and securely submit privacy-sensitive or business-sensitive documents.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Arianne Perkins', with a stylized, cursive script.

Arianne Perkins  
Director, Initial FOIA Requests



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Office of the Secretary

Assistant Secretary for Public Affairs  
Washington, D.C. 20201

FOI/Privacy Acts Division

# **Exhibit 3**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Public Affairs  
Washington, D.C. 20201

Refer to: Request Number **2023-00630-FOIA-OS**

**April 3, 2023**

*Sent via email:*

Chris Stanley

chris@functionalgovernment.org

Dear Mr. Stanley:

This acknowledges receipt of your March 31, 2023, Freedom of Information Act (FOIA) request, submitted to the Department of Health and Human Services (HHS), FOI/Privacy Acts Division concerning "FGI requests all records from December 19, 2022, until the date the search begins pertaining to the report from the Reagan-Udall Foundation for the Food and Drug Administration about the FDA's tobacco programs, Operational Evaluation of Certain Components of FDA's Tobacco Program . This would include but not be limited to communications to anyone outside the government about the report, any analysis of the report, responses to the report, and plans to address the report.

Custodian:

Andrea Palm, Deputy Secretary

Please see the request letter for more details. (Date Range for Record Search: From 12/19/2022 To 04/07/2023)". We received your request on April 3, 2023.

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.

Your request is assigned to the complex track. In an effort to speed up our records search, you may wish to narrow the scope of your request to limit the number of potentially responsive records or agree to an alternative time frame for processing, should records be located. You may also wish to await the completion of our records search to discuss either of these options.



I regret the necessity of this delay, but I assure you that your request will be processed as soon as possible. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request, OS FOIA Division Queue at [foiarequest@hhs.gov](mailto:foiarequest@hhs.gov).

If you are not satisfied with any aspect of the processing and handling of this request, you have the right to seek dispute resolution services from:

HHS FOIA/PA Public Liaison  
FOI/Privacy Acts Division  
Assistant Secretary for Public Affairs (ASPA)  
Office of the Secretary (OS)  
U.S. Department of Health and Human Services (HHS)

Telephone: (202) 690-7453  
E-mail: [HHS\\_FOIA\\_Public\\_Liaison@hhs.gov](mailto:HHS_FOIA_Public_Liaison@hhs.gov)

and/or:

Office of Government Information Services  
National Archives and Records Administration  
Telephone: 202- 741-5770  
Toll-Free: 1-877-684-6448  
E-mail: [ogis@nara.gov](mailto:ogis@nara.gov)

If you are not already submitting your requests through our Public Access Link (PAL), we recommend all future requests and appeals be submitted through PAL - <https://requests.publiclink.hhs.gov>. Submitting requests through PAL automatically logs your requests into our tracking system and provides you with a tracking number. Your PAL account will allow you to track the progress of your request, receive your documents directly through the portal, and securely submit privacy-sensitive or business-sensitive documents.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Arianne Perkins', with a stylized, flowing script.

Arianne Perkins  
Director, Initial FOIA Requests  
FOI/Privacy Acts Division



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Office of the Secretary

Assistant Secretary for Public Affairs  
Washington, D.C. 20201

# **Exhibit 2**



April 21, 2023

Submitted online at <https://requests.publiclink.hhs.gov/>

U.S. Department of Health and Human Services  
Freedom of Information Act Office  
Hubert H. Humphrey Building, Room 729H  
200 Independence Avenue, SW  
Washington, DC 20201

Re: Communications with 22nd Century, Inc. and key officials

Dear Freedom of Information Act Officer:

The Functional Government Initiative (FGI) submits this request for records under the Freedom of Information Act, 5 U.S.C. § 552, as amended (FOIA), and the relevant implementing regulations. FGI, a non-partisan organization, engages in research, investigation, and education to promote transparency in government. Your prompt response pursuant to the requirements of FOIA, 5 U.S.C. § 522(a)(6)(A), is appreciated.

On June 1, 2022, the Biden-Harris Administration published its plans for future regulatory actions against tobacco and nicotine products.<sup>1</sup> This plan includes a recommendation to the FDA to establish a maximum nicotine level for electronic cigarette and tobacco products. The goal for establishing such regulation is to reduce the likelihood of long-term addiction, particularly for underage consumers.

In December 2021, the FDA announced it had authorized the marketing of two brands of combusted, filtered cigarettes as modified risk tobacco products (MRTPs). The FDA stated, “These are the first combusted cigarettes to be authorized as MRTPs and the second tobacco products overall to receive ‘exposure modification’ orders, which allows them to be marketed as having a reduced level of, or presenting a reduced exposure to, a substance.”<sup>2</sup> Two years earlier, FDA had authorized the marketing and sale of two new “reduced nicotine” tobacco products.<sup>3</sup> All of these products are manufactured by a single company, 22<sup>nd</sup> Century Group, Inc. The public should know whether the company was communicating directly with key officials and, if so, what was discussed about regulations that may lead to a monopoly.

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<sup>1</sup> <https://www.fda.gov/news-events/press-announcements/fda-announces-plans-proposed-rule-reduce-addictiveness-cigarettes-and-other-combusted-tobacco>

<sup>2</sup> <https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-tobacco-products-help-reduce-exposure-and-consumption-nicotine-smokers-who>

<sup>3</sup> <https://www.fda.gov/news-events/press-announcements/fda-permits-sale-two-new-reduced-nicotine-cigarettes-through-premarket-tobacco-product-application>

REQUESTED RECORDS

FGI requests all records between the custodians identified and anyone with 22<sup>nd</sup> Century Group. The date range is January 21, 2021, through December 23, 2021.

This would include the following people with the company:

- James A. Mish, CEO (Jmish@xxiicentury.com)
- Calvin Treat, Chief Scientific Officer (Ctreat@xxiicentury.com)
- John Miller, President, Tobacco Business (JMiller@xxiicentury.com)
- John D. Pritchard, Vice President of Regulatory Science (JPritchard@xxiicentury.com)
- Juan Sanchez Tamburrino, Vice President of Research and Development (JTamburrino@xxiicentury.com)
- Peter Ferola, Chief Legal Officer (PFerola@xxiicentury.com)
- Lindsay Castro, Associate Corporate Counsel (LCastro@xxiicentury.com)
- Shiva Vellanki, Vice President - US Federal Business Practices (SVellanki@xxiicentury.com)
- Eric Cheney, Communications Manager (Echeney@xxiicentury.com)
- Brittainy Dye, Regulatory Compliance Manager (BDye@xxiicentury.com)
- Anyone else with an email ending with @xxiicentury.com

Custodians:

- Andrea Palm, Deputy Secretary
- Angela Botticella, Chief of Staff, Office of the Deputy Secretary
- Other staff in the immediate office of the Deputy Secretary
- The Assistant Secretary for Public Affairs
- Anyone in the office of the Assistant Secretary for Public Affairs who works on the Public Health team within the office

The term "all records" in this request refers to emails including attachments, text messages (including messages on encrypted apps such as Signal or WhatsApp), calendars, electronic meeting invitations and replies, letters, correspondence, facsimiles, memoranda, notes from meetings and phone calls, minutes of meetings, agendas of meetings, comments, files, presentations, consultations, drawings, diagrams, graphs, charts, assessments, evaluations, telephone records and logs, virtual meeting logs (such as those produced by Microsoft Teams and Zoom), papers (published or unpublished), reports, studies, photographs and other images, databases, data, maps, or all other responsive records in draft or final form that fall within the definition of "agency records" subject to FOIA. This request is not meant to exclude any other records that, although not specifically requested, are reasonably related to the subject matter of this request.

We ask that you please provide all records in an electronic format and, to the extent practicable, in native file format or, if not practicable, with full metadata for all fields. FOIA provides that "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."<sup>4</sup> Please provide records in either a load-ready format with an index in .csv file or Excel spreadsheet, or in PDF format without any portfolios or embedded files and not in a single batched pdf file.

If you should seek to withhold or redact any responsive records, we request that you do the

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<sup>4</sup> 5 U.S.C. § 552(a)(3)(B).

following:

1. Identify each such record with specificity, including date, author, recipient, and parties copied,
2. Explain in full the basis for withholding responsive material,
3. Provide all segregable portions of the records for which you claim a specific exemption<sup>5</sup>, and
4. Correlate any redactions with specific exemptions under FOIA.

If you or your office have destroyed or decide to withhold any records that could be reasonably construed to be responsive to this request, we ask that you indicate this fact and the reasons for doing so in your response. Agencies are prohibited from denying requests for information under FOIA unless the agency reasonably believes release of the information will harm an interest that is protected by the exemption.<sup>6</sup>

Should you decide to invoke a FOIA exemption or any subsection (c) exclusions, please include sufficient information for us to assess the basis for the exemption, including any interests that would be harmed by release. Please include a detailed ledger with the following:

1. Basic factual material about each withheld record, including the originator, date, length, general subject matter, and location of each item, and
2. Complete justifications for each withheld records, including the specific exemptions 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 send the non-exempt portions to my email address below within the statutory time limit.<sup>7</sup>

FGI is willing to receive records on a rolling basis.

To facilitate our request most efficiently, we request that the FOIA office use the agency's email management system as part of the search for this request.

#### REQUEST FOR FEE WAIVER

Pursuant to 5 U.S.C. § 552 and the relevant FOIA regulations, we request a waiver of fees for searching and producing the records of this request. FOIA provides for a waiver of fees when a request is "in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester."<sup>8</sup>

Below are details explaining (1) how the disclosure of the requested records is in the public

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<sup>5</sup> See 5 U.S.C. § 552(b).

<sup>6</sup> FOIA Improvement Act of 2016 (Public Law No. 114-185), 5 U.S.C. § 552(a)(8)(A).

<sup>7</sup> 5 U.S.C. § 552(b).

<sup>8</sup> 5 U.S.C. § 552(a)(4)(A)(iii).

interest, (2) that FGI intends distribute information to a broad audience of interested persons, and (3) that FGI has no commercial interests.

In addition, FGI is a “person or entity that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience” and thus qualifies as a “representative of the news media” under 5 U.S.C. § 552(a)(4)(A)(ii). Below are details explaining (4) how FGI clearly meets these criteria.

**1. THE REQUEST IS IN THE PUBLIC INTEREST.**

Under FOIA, an agency must consider factors to determine whether a request is in the public interest. These include the following:

- A. Whether the subject of the requested records concerns “the operations or activities of the Federal government,”
- B. Whether the disclosure is “likely to contribute significantly” to an understanding of government operations or activities, and
- C. Whether the disclosure “will contribute to public understanding” of a reasonably broad audience of persons interested in the subject.

As shown below, FGI meets each of these factors.

**A. The requested records concern the operations and activities of the Federal government.**

This request seeks communications between a company regulated by the FDA, part of HHS, and HHS officials. The Department of Justice Freedom of Information Act Guide acknowledges that “in most cases records possessed by a federal agency will meet this threshold.”<sup>9</sup> The threshold is met here not only because the records sought are by nature possessed by agency staff but also because they relate to work of the federal government.

Thus, FGI meets this factor.

**B. Disclosure is “likely to contribute significantly” to an understanding of government operations or activities.**

Disclosure of the requested records is certain to contribute significantly to public understanding of the HHS. Knowing whether and, if so, what key officials are communicating with the only company to so far have its low nicotine products approved will certainly shed light on the government’s work. Once the information is made available, FGI will evaluate the information and present it to its followers and make it available to the public.

FGI is not requesting these records merely for their intrinsic informational value. The public is always well served when it knows details of what officials are communicating with interest groups. Hence, there can be no dispute that disclosure of the requested records to the public will significantly increasing the public’s understanding about the agency’s actions and whether those actions were conducted in an objective, ethical, and legal way. Thus, FGI meets this factor.

**C. Disclosure of the requested records will contribute to the understanding of a reasonably**

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<sup>9</sup> <https://www.justice.gov/sites/default/files/oip/legacy/2014/07/23/fees-feewaivers.pdf>

**broad audience.**

FGI has the ability and intention to convey this information to a broad audience (by means discussed in Section 2 below). The public does not currently have an ability to evaluate the requested records. With the wide reach of the FDA's regulatory power and the impact of its work in many different areas, a very broad audience interested in government transparency, public health policy, and ethics compliance, among other issues, would achieve a greater understanding of their government's work from the requested records.

Such public oversight of agency action is vital to our democratic system and clearly envisioned by the drafters of the FOIA. Thus, FGI meets this factor.

**2. FGI HAS THE ABILITY AND INTENT TO DISSEMINATE THE INFORMATION TO A REASONABLY BROAD AUDIENCE INTERESTED IN THE SUBJECT.**

FGI is a non-partisan organization that researches government operations and informs the public its findings. Access to information about the activities and decisions of government officials is vital to fulfilling this mission. Once the information is obtained, FGI has robust mechanisms in place, including its website, social media channels, and other platforms, to share information. FGI intends to use its channels to publish the information from these requested records, along with expert analysis. FGI also has a broad network of reporters, bloggers, and media publications with interest in its content and with durable relationships with the organization. FGI intends to use these far-reaching media outlets to publicize information obtained from this request.

Through these means, FGI's dissemination of the information will:

- Ensure that the information requested contributes significantly to the public's understanding of the government's operations or activities,
- Ensure that the information enhances the public's understanding to a greater degree than currently exists,
- Demonstrate that FGI possesses the expertise to explain the requested information to the public,
- Demonstrate that FGI possesses the ability to make the requested information accessible to the general public, and
- Demonstrate that the news media recognizes FGI as a reliable source in the relevant field.

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.<sup>10</sup> FGI need not show how it intends to distribute the information, because, as the court noted, "nothing in FOIA, the [agency] regulation, or our case law require[s] such pointless specificity."<sup>11</sup> It is sufficient for FGI to show how it distributes information to the public generally.<sup>12</sup>

**3. OBTAINING THE REQUESTED RECORDS IS OF NO COMMERCIAL INTEREST TO FGI.**

Disclosure is in no way connected with any commercial interest of the requestors. FGI is a non-

<sup>10</sup> *Carney v U.S. Dept. of Justice*, 19 F.3d 807 (2nd Cir. 1994).

<sup>11</sup> *Judicial Watch*, 326 F.3d at 1314.

<sup>12</sup> *Id.*



partisan organization. FGI has no commercial interest and will realize no commercial benefit from the release of the requested records.

#### 4. FGI IS A REPRESENTATIVE OF THE NEWS MEDIA.

Under FOIA, the term “representative of the news media” includes any person or entity that “gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience.”<sup>13</sup> In *Cause of Action v. Federal Trade Commission*, the Court of Appeals for the District of Columbia broke the test for who is a media entity into five parts: “A requester must: (1) gather information of potential interest (2) to a segment of the public; (3) use its editorial skills to turn the raw materials into a distinct work; and (4) distribute that work (5) to an audience.”<sup>14 15</sup>

In interpreting this test, the court noted “the news-media waiver . . . focuses on the nature of the requester, not its request.”<sup>16</sup> Accordingly, where a requester “satisfies the five criteria as a general matter, it does not matter whether any of the individual FOIA requests does so.”<sup>17</sup> Moreover, the media entity waiver applies to newer organizations as well as older ones: “there is no indication that Congress meant to make the lack of a prior publication record disqualifying when it enacted the statutory definition in 2007.”<sup>18</sup>

##### **A. FGI gathers information of potential interest.**

FGI’s mission is to demand transparency and promote shared values and beliefs in a thriving economy, a healthy America, a strong and equitable workforce, and a safe and clean environment. As part of this mission, FGI engages in investigations and education initiatives around important issues, including high energy prices, the government’s COVID-19 response, and government transparency. These are topics of potentially broad public interest, as evidenced by the fact that multiple news outlets have written stories on FGI’s work. You can see several FGI’s media mentions at <https://functionalgovernment.org/category/media-mentions/>.

##### **B. FGI gathers information of interest to a segment of the public.**

As demonstrated above, the information that FGI gathers is of interest to a segment of the public. This includes but is not limited to the segment of the public concerned with government transparency. The size of the segment of the public interests in any particularly information gathering project may vary, however, as the court has noted, “[a] newspaper reporter, for example, is a representative of the news media regardless of how much interest there is in the story for which he or she is requesting information.”<sup>19</sup> Moreover, as long as FGI “satisfies the five criteria as a general matter, it does not matter whether any of the individual FOIA requests does so.”<sup>20</sup>

<sup>13</sup> 5 U.S.C. § 552(a)(4)(A)(ii).

<sup>14</sup> 799 F.3d 1108, 1120 (D.C. Cir. 2015).

<sup>15</sup> The court further noted that “the news-media fee waiver applies only to records that ‘are not sought for commercial use.’” *Cause of Action*, 700 F.3d at 1120. For the reasons set forth in section 3 above, FGI is not requesting these records for commercial use.

<sup>16</sup> 799 F.3d 1108, 1120 (D.C. Cir. 2015) at 1121 (emphasis in the original).

<sup>17</sup> *Id.*

<sup>18</sup> *Id.* at 1124.

<sup>19</sup> *Cause of Action*, 799 F.3d at 1121.

<sup>20</sup> *Id.*

As set forth above, FGI believes that this request is of interest to a reasonably broad segment of the public. Even if the agency disagrees, however, there can be no doubt that other issues about which FGI gathers information, such as drivers of inflation in the United States, energy prices, government transparency and more, are of interest to a significant audience. Accordingly, FGI is an organization that gathers information of interest to a segment of the population.

**C. FGI uses its editorial skills to turn raw materials into distinct works.**

As the D.C. Circuit Court has stated, “A substantive press release or editorial comment can be a distinct work based on the underlying material, just as a newspaper article about the same documents would be — and its composition can involve ‘a significant degree of editorial discretion.’”<sup>21</sup> Furthermore, “nothing in principle prevents a journalist from producing ‘distinct work’ that is based exclusively on documents obtained through FOIA.”<sup>22</sup>

FGI is an entity that uses its editorial skills to turn raw materials into distinct works. It routinely issues substantive press releases detailing its activities, posted at [functionalgovernment.org](https://functionalgovernment.org). These press releases have included substantive analysis of the information gathered by FGI with a significant degree of editorial discretion. FGI has also prepared detailed reports, posted on its website, and FGI provides substantive editorial comment to other journalists, with many news clips posted on website, as well.

Like a newspaper or other media outlet, FGI uses its editorial skills to turn raw materials into distinct works and intends to do so for other subjects as it gathers additional information. Thus, FGI meets this test.

**D. FGI distributes its work to an audience.**

For purposes of FOIA, “posting content to a public website can qualify as a means of distributing it — notwithstanding that readers have to affirmatively access the content, rather than have it delivered to their doorsteps or beamed into their homes unbidden.”<sup>23</sup> Moreover, while “[t]here is no doubt that the requirement that a requester distribute its work to ‘an audience’ contemplates that the work is distributed to more than a single person . . . beyond requiring that a person or entity have readers (or listeners or viewers), the statute does not specify what size the audience must be.”<sup>24</sup> Additionally, “[t]he fact that [a media entity’s] readership is relatively small . . . is irrelevant.”<sup>25</sup>

Assessing whether a media entity distributes its work to an audience includes consideration of “past record, current operations, and future plans jointly.”<sup>26</sup>

In addition, the court rejected “the suggestion that a public interest advocacy organization cannot satisfy the statute’s distribution criterion because it is ‘more like a middleman for dissemination to

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<sup>21</sup> *Cause of Action*, 799 F.3d 1122 (quoting *Nat. Sec. Archive v. U.S. Dept. of Defense*, 880 F.2d 1381, 1387 (D.C. Cir. 1989)).

<sup>22</sup> *Id.*

<sup>23</sup> *Cause of Action*, 799 F.3d at 1123.

<sup>24</sup> *Id.* at 1124 (footnote omitted).

<sup>25</sup> *Id.* at 1124 (quoting *Tax Analysts v. Dept. of Justice*, 965 F.2d 1092, 1095 (D.C. Cir. 1992)).

<sup>26</sup> *Id.* at 1124.

the media than a representative of the media itself,” concluding “there is no indication that Congress meant to distinguish between those who reach their ultimate audiences directly and those who partner with others to do so, as some recognized journalistic enterprises do.”<sup>27</sup>

FGI will continue to use its website to distribute original editorial content, including press releases. FGI has email subscribers and intends to establish a greater social media presence to reach its audience directly. In addition, FGI has durable relationships with a broad network of reporters, bloggers, and media publications interested in its content and with whom FGI has partnered to distribute its distinct editorial commentary.

Accordingly, FGI distributes its work to an audience.

**E. FGI qualifies as a representative of the news media.**

Under the applicable law, a government accountability group qualifies as a media organization for purposes of FOIA when it gathers information of potential interest and uses it to create original content, which can be as simple as issuing a press release or comment to other media organizations, and distributes it, which can be as simple as posting it on a website with an audience greater than one. This is true even if an organization is new and does not have a long track record. Accordingly, under the standard set forth in FOIA and interpreted in *Cause of Action*, FGI clearly qualifies as a representative of the news media.

**FGI QUALIFIES FOR A FULL FEE WAIVER.**

For all the foregoing reasons, FGI qualifies for a full fee waiver. At minimum, FGI qualifies as a representative of the news media that is exempt from search and production costs. We anticipate that you will promptly grant our fee waiver request and begin to search and disclose the requested records without any unnecessary delays.

Thank you for your prompt attention to this request. If you have any questions, please contact me. Records and any related correspondence should be sent to my attention to the email address below.

Sincerely,

Chris Stanley  
Director  
Functional Government Initiative  
6218 Georgia Avenue NW, Ste 1 - 1235  
Washington, DC 20011-5125  
[chris@functionalgovernment.org](mailto:chris@functionalgovernment.org)

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<sup>27</sup> *Id.* at 1125 (citations omitted).

# **Exhibit 1**



March 31, 2023

Submitted online at <https://requests.publiclink.hhs.gov/>

U.S. Department of Health and Human Services  
Freedom of Information Act Office  
Hubert H. Humphrey Building, Room 729H  
200 Independence Avenue, SW  
Washington, DC 20201

Re: Communications about the Reagan-Udall report on FDA's tobacco programs

Dear Freedom of Information Act Officer:

The Functional Government Initiative (FGI) submits this request for records under the Freedom of Information Act (5 U.S.C. § 552, as amended) and the implementing regulations of the Department of Health and Human Services. FGI, a non-partisan organization, engages in research, investigation, and education to promote transparency in government.

Your prompt response pursuant to the requirements of FOIA, 5 U.S.C. § 522(a)(6)(A), is appreciated.

#### REQUESTED RECORDS

FGI requests all records from December 19, 2022, until the date the search begins pertaining to the report from the Reagan-Udall Foundation for the Food and Drug Administration about the FDA's tobacco programs, *Operational Evaluation of Certain Components of FDA's Tobacco Program*<sup>1</sup>. This would include but not be limited to communications to anyone outside the government about the report, any analysis of the report, responses to the report, and plans to address the report.

Custodian:  
Andrea Palm, Deputy Secretary

The term "all records" in this request refers to letters, correspondence, emails including attachments, calendars, electronic meeting invitations and replies, facsimiles, memoranda, text messages (including messages on encrypted apps such as Signal or WhatsApp), notes from meetings and phone calls, minutes of meetings, agendas of meetings, comments, files, presentations, consultations, drawings, diagrams, graphs, charts, assessments, evaluations, telephone records and logs, virtual meeting logs (such as those produced by Microsoft Teams and Zoom), papers (published or unpublished), reports, studies, photographs and other images, databases, data, maps, or all other responsive records in draft or final form that fall within the definition of "agency

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<sup>1</sup> Found at [https://reaganudall.org/sites/default/files/2022-12/Operational%20Evaluation%20of%20Certain%20Components%20of%20FDA%27s%20Tobacco%20Program\\_De.c.%202022.pdf](https://reaganudall.org/sites/default/files/2022-12/Operational%20Evaluation%20of%20Certain%20Components%20of%20FDA%27s%20Tobacco%20Program_De.c.%202022.pdf)



records” subject to FOIA. This request is not meant to exclude any other records that, although not specifically requested, are reasonably related to the subject matter of this request.

Please provide all records in an electronic format and, to the extent practicable, in native file format or, if not practicable, with full metadata for all fields. FOIA provides that “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.”<sup>2</sup> Please provide records in either a load-ready format with an index in .csv file or Excel spreadsheet, or in PDF format without any portfolios or embedded files and not in a single batched pdf file.

If you should seek to withhold or redact any responsive records, we request that you do the following:

1. Identify each such record with specificity, including date, author, recipient, and parties copied,
2. Explain in full the basis for withholding responsive material,
3. Provide all segregable portions of the records for which you claim a specific exemption<sup>3</sup>, and
4. Correlate any redactions with specific exemptions under FOIA.

If you or your office have destroyed or decide to withhold any records that could be reasonably construed to be responsive to this request, we ask that you indicate this fact and the reasons for doing so in your response. Agencies are prohibited from denying requests for information under FOIA unless the agency reasonably believes release of the information will harm an interest that is protected by the exemption.<sup>4</sup>

Should you decide to invoke a FOIA exemption or any subsection (c) exclusions, please include sufficient information for us to assess the basis for the exemption, including any interests that would be harmed by release. Please include a detailed ledger with the following:

1. Basic factual material about each withheld record, including the originator, date, length, general subject matter, and location of each item, and
2. Complete justifications for each withheld records, including the specific exemptions 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 send the non-exempt portions to my email address below within the statutory time limit.<sup>5</sup>

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<sup>2</sup> 5 U.S.C. § 552(a)(3)(B).

<sup>3</sup> See 5 U.S.C. § 552(b).

<sup>4</sup> FOIA Improvement Act of 2016 (Public Law No. 114-185), 5 U.S.C. § 552(a)(8)(A).

<sup>5</sup> 5 U.S.C. § 552(b).



FGI is willing to receive records on a rolling basis.

#### REQUEST FOR FEE WAIVER

Pursuant to 5 U.S.C. § 552 and the agency's FOIA regulations, we request a waiver of fees for searching and producing the requested records. FOIA provides for a waiver of fees when a request is "in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester."<sup>6</sup>

Below are details explaining (1) how the disclosure of the requested records is in the public interest, (2) that FGI intends distribute information to a broad audience of interested persons, and (3) that FGI has no commercial interests.

In addition, FGI is a "person or entity that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience" and thus qualifies as a "representative of the news media" under 5 U.S.C. § 552(a)(4)(A)(ii). Below are details explaining (4) how FGI clearly meets these criteria.

#### 1. THE REQUEST IS IN THE PUBLIC INTEREST.

Under FOIA, an agency must consider factors to determine whether a request is in the public interest. These include the following:

- A. Whether the subject of the requested records concerns "the operations or activities of the Federal government,"
- B. Whether the disclosure is "likely to contribute significantly" to an understanding of government operations or activities, and
- C. Whether the disclosure "will contribute to public understanding" of a reasonably broad audience of persons interested in the subject.

As shown below, FGI meets each of these factors.

#### **A. The requested records concern the operations and activities of the federal government.**

The subject matter of this request, communications about a report submitted to a federal agency by an organization created by Congress, clearly concerns the operations and activities of the federal government. The Department of Justice Freedom of Information Act Guide acknowledges that "in most cases records possessed by a federal agency will meet this threshold."<sup>7</sup> The threshold is met here not only because the records sought are by nature possessed by agency staff but also because they relate to work as part of the federal government. Thus, FGI meets this factor.

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<sup>6</sup> 5 U.S.C. § 552(a)(4)(A)(iii).

<sup>7</sup> <https://www.justice.gov/sites/default/files/oip/legacy/2014/07/23/fees-feewaivers.pdf>



**B. Disclosure is “likely to contribute significantly” to an understanding of government operations or activities.**

The requested information will significantly improve understanding of the operations of the HHS as it evaluates a report from the Reagan-Udall Foundation about programs the department is responsible for conducting.

FGI is not requesting these records merely for their intrinsic informational value. The public is always well served when it knows how the government conducts its activities, and the requested records would provide insight in how important decisions were made by federal officials. Hence, there can be no dispute that disclosure of the requested records to the public will significantly increase the public’s understanding about the agency’s actions and decisions and whether agency actions were conducted in an objective and legal way.

Thus, FGI meets this factor.

**C. Disclosure of the requested records will contribute to the understanding of a reasonably broad audience.**

FGI has the ability and intention to convey this information to a broad audience (by means discussed in Section 2 below). A broad audience of those who follow public health, the work of the HHS and the FDA, and the government’s tobacco programs, among other issues, would be interested in the requested records. We are unaware of these records having been released to date.

**2. FGI HAS THE ABILITY AND INTENT TO DISSEMINATE THE INFORMATION TO A REASONABLY BROAD AUDIENCE INTERESTED IN THE SUBJECT.**

FGI is a non-partisan organization that researches government operations and informs and educates the public on its findings. A key component in being able to fulfill this mission is access to information about the activities and decisions of senior government officials. Once the information is obtained, FGI has robust mechanisms in place, including its website, social media channels, and other similar platforms, to share information and analysis. FGI also has a broad network of reporters, bloggers, and media publications with interest in its content and with durable relationships with the organization. FGI intends to use these far-reaching media outlets to publicize information obtained from this request.

Through these means, FGI’s dissemination of the information will:

- Ensure that the information requested contributes significantly to the public’s understanding of the government’s operations or activities,
- Ensure that the information enhances the public’s understanding to a greater degree than currently exists,
- Demonstrate that FGI possesses the expertise to explain the requested information to the public,
- Demonstrate that FGI possesses the ability to make the requested information accessible to





- the general public, and
- Demonstrate that the news media recognizes FGI as a reliable source in the relevant field.

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.<sup>8</sup> FGI need not show how it intends to distribute the information, because, as the court said, “nothing in FOIA, the [agency] regulation, or our case law require[s] such pointless specificity.”<sup>9</sup> It is sufficient for FGI to show how it distributes information to the public generally.<sup>10</sup>

### 3. OBTAINING THE REQUESTED RECORDS IS OF NO COMMERCIAL INTEREST TO FGI.

Disclosure is in no way connected with any commercial interest of the requestors. FGI is a non-partisan organization with no commercial interest, and it will realize no commercial benefit from the release of the requested records.

### 4. FGI IS A REPRESENTATIVE OF THE NEWS MEDIA.

Under FOIA, the term “representative of the news media” includes any person or entity that “gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience.”<sup>11</sup> In *Cause of Action v. Federal Trade Commission*, the Court of Appeals for the District of Columbia broke the test for who is a media entity into five parts: “A requester must: (1) gather information of potential interest (2) to a segment of the public; (3) use its editorial skills to turn the raw materials into a distinct work; and (4) distribute that work (5) to an audience.”<sup>12 13</sup>

In interpreting this test, the court noted “the news-media waiver . . . focuses on the nature of the requester, not its request.”<sup>14</sup> Accordingly, where a requester “satisfies the five criteria as a general matter, it does not matter whether any of the individual FOIA requests does so.”<sup>15</sup> Moreover, the media entity waiver applies to newer organizations as well as older ones: “there is no indication that Congress meant to make the lack of a prior publication record disqualifying when it enacted the statutory definition in 2007.”<sup>16</sup>

#### **A. FGI gathers information of potential interest.**

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<sup>8</sup> *Carney v U.S. Dept. of Justice*, 19 F.3d 807 (2nd Cir. 1994).

<sup>9</sup> *Judicial Watch*, 326 F.3d at 1314.

<sup>10</sup> *Id.*

<sup>11</sup> 5 U.S.C. § 552(a)(4)(A)(ii).

<sup>12</sup> 799 F.3d 1108, 1120 (D.C. Cir. 2015).

<sup>13</sup> The court further noted that “the news-media fee waiver applies only to records that ‘are not sought for commercial use.’” *Cause of Action*, 700 F.3d at 1120. For the reasons set forth in section 3 above, FGI is not requesting these records for commercial use.

<sup>14</sup> 799 F.3d 1108, 1120 (D.C. Cir. 2015) at 1121 (emphasis in the original).

<sup>15</sup> *Id.*

<sup>16</sup> *Id.* at 1124.



FGI's mission is to demand transparency and promote shared values and beliefs in a thriving economy, a healthy America, a strong and equitable workforce, and a safe and clean environment. As part of this mission, FGI engages in investigations and education initiatives around important issues, including high energy prices, the government's COVID-19 response, and government transparency, among other issues. These are topics of potentially broad public interest, as evidenced by the fact that multiple other news outlets have written stories on releases issued by FGI in our short but active existence. You can see several of FGI's media mentions on our website.

**B. FGI gathers information of interest to a segment of the public.**

As demonstrated above, the information that FGI gathers is of interest to a segment of the public. This includes, but is not limited to, the segment of the public concerned with government transparency. The size of the segment of the public interests in any particularly information gathering project may vary, however, as the court has noted, "[a] newspaper reporter, for example, is a representative of the news media regardless of how much interest there is in the story for which he or she is requesting information."<sup>17</sup> Moreover, as long as FGI "satisfies the five criteria as a general matter, it does not matter whether any of the individual FOIA requests does so."<sup>18</sup>

As set forth above, FGI believes that this request is of interest to a reasonably broad segment of the public. Even if the agency disagrees, however, there can be no doubt that other issues about which FGI gathers information, such as drivers of inflation in the United States, energy prices, government transparency and more, are of interest to a significant audience.

Accordingly, FGI is an organization that gathers information of interest to a segment of the population.

**C. FGI uses its editorial skills to turn raw materials into distinct works.**

As the D.C. Circuit Court has stated, "A substantive press release or editorial comment can be a distinct work based on the underlying material, just as a newspaper article about the same documents would be — and its composition can involve 'a significant degree of editorial discretion.'"<sup>19</sup> Furthermore, "nothing in principle prevents a journalist from producing 'distinct work' that is based exclusively on documents obtained through FOIA."<sup>20</sup>

FGI is an entity that uses its editorial skills to turn raw materials into distinct works. It routinely issues substantive press releases detailing its activities. These press releases have included and will continue to include substantive analysis of the information gathered by FGI and involve a significant degree of editorial discretion. Additionally, FGI has prepared detailed reports. FGI also provides substantive editorial comment to other journalists.

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<sup>17</sup> *Cause of Action*, 799 F.3d at 1121.

<sup>18</sup> *Id.*

<sup>19</sup> *Cause of Action*, 799 F.3d 1122 (quoting *Not. Sec. Archive v. U.S. Dept. of Defense*, 880 F.2d 1381, 1387 (D.C. Cir. 1989)).

<sup>20</sup> *Id.*



Like a newspaper or other media outlet, FGI uses its editorial skills to turn raw materials into distinct works and intends to do so for other subjects as it gathers additional information. Thus, FGI meets this test.

**D. FGI distributes its work to an audience.**

For purposes of FOIA, “posting content to a public website can qualify as a means of distributing it — notwithstanding that readers have to affirmatively access the content, rather than have it delivered to their doorsteps or beamed into their homes unbidden.”<sup>21</sup> Moreover, while “[t]here is no doubt that the requirement that a requester distribute its work to ‘an audience’ contemplates that the work is distributed to more than a single person . . . beyond requiring that a person or entity have readers (or listeners or viewers), the statute does not specify what size the audience must be.”<sup>22</sup> Additionally, “[t]he fact that [a media entity’s] readership is relatively small ... is irrelevant.”<sup>23</sup>

Assessing whether a media entity distributes its work to an audience includes consideration of “past record, current operations, and future plans jointly.”<sup>24</sup>

In addition, the court rejected “the suggestion that a public interest advocacy organization cannot satisfy the statute’s distribution criterion because it is ‘more like a middleman for dissemination to the media than a representative of the media itself,’” concluding “there is no indication that Congress meant to distinguish between those who reach their ultimate audiences directly and those who partner with others to do so, as some recognized journalistic enterprises do.”<sup>25</sup>

FGI will continue to use its website to distribute original editorial content, including press releases. FGI has email subscribers and intends to establish a greater social media presence to reach its audience directly. In addition, FGI has a broad network of reporters, bloggers, and media publications with interest in its content and with durable relationships with the organization that FGI can partner with to distribute its distinct editorial commentary.

Accordingly, FGI distributes its work to an audience.

**E. FGI qualifies as a representative of the news media.**

Under the applicable law, a government accountability group qualifies as a media organization for purposes of FOIA when it gathers information of potential interest and uses it to create original content, which can be as simple as issuing a press release or comment to other media organizations, and distributes it, which can be as simple as posting it on a website with an audience greater than one. This is true even when an organization does not have a long track record.

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<sup>21</sup> *Cause of Action*, 799 F.3d at 1123.

<sup>22</sup> *Id.* at 1124 (footnote omitted).

<sup>23</sup> *Id.* at 1124 (quoting *Tax Analysts v. Dept. of Justice*, 965 F.2d 1092, 1095 (D.C. Cir. 1992)).

<sup>24</sup> *Id.* at 1124.

<sup>25</sup> *Id.* at 1125 (citations omitted).



Accordingly, under the standard set forth in FOIA, and interpreted in *Cause of Action*, FGI clearly qualifies as a representative of the news media.

FGI QUALIFIES FOR A FULL FEE WAIVER.

For all the foregoing reasons, FGI qualifies for a full fee waiver. At minimum, FGI qualifies as a representative of the news media that is exempt from search and production costs. We anticipate that the agency will promptly grant our fee waiver request and begin to search and disclose the requested records without any unnecessary delays.

Thank you for your prompt attention to this request. If you have any questions, please contact me. Records and any related correspondence should be sent to my attention to the email address below.

Sincerely,

Chris Stanley  
Director  
Functional Government Initiative  
6218 Georgia Avenue NW, Ste 1 - 1235  
Washington, DC 20011-5125  
[chris@functionalgovernment.org](mailto:chris@functionalgovernment.org)

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

Functional Government Initiative

*Plaintiff*

v.

U.S. Department of Health and Human Services

*Defendant*

Civil Action No.

**SUMMONS IN A CIVIL ACTION**

To: *(Defendant's name and address)*

Civil Process Clerk  
United States Attorney's Office  
555 4th Street, N.W.  
Washington, DC 20530

A lawsuit has been filed against you.

Within 30 days after service of this summons on you (not counting the day you received it) you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Paul M. Bartkowski  
Bartkowski PLLC  
6803 Whittier Ave. Suite 200A  
McLean, Virginia 22101

If you fail to respond, judgment by default may be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

*ANGELA D. CAESAR, CLERK OF COURT*

Date: \_\_\_\_\_

\_\_\_\_\_  
*Signature of Clerk or Deputy Clerk*

FOIA Summons (1/13) (Page 2)

Civil Action No. \_\_\_\_\_

**PROOF OF SERVICE**

*(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))*

This summons for *(name of individual and title, if any)* \_\_\_\_\_  
was received by me on *(date)* \_\_\_\_\_.

☐ I personally served the summons on the individual at *(place)* \_\_\_\_\_  
on *(date)* \_\_\_\_\_; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* \_\_\_\_\_  
\_\_\_\_\_, a person of suitable age and discretion who resides there,  
on *(date)* \_\_\_\_\_, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* \_\_\_\_\_, who is  
designated by law to accept service of process on behalf of *(name of organization)* \_\_\_\_\_  
on *(date)* \_\_\_\_\_; or

☐ I returned the summons unexecuted because \_\_\_\_\_; or

☐ Other *(specify)*: \_\_\_\_\_

My fees are \$ \_\_\_\_\_ for travel and \$ \_\_\_\_\_ for services, for a total of \$ \_\_\_\_\_ 0.00.

I declare under penalty of perjury that this information is true.

Date: \_\_\_\_\_

\_\_\_\_\_  
*Server's signature*

\_\_\_\_\_  
*Printed name and title*

\_\_\_\_\_  
*Server's address*

Additional information regarding attempted service, etc:

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

Functional Government Initiative

*Plaintiff*

v.

U.S. Department of Health and Human Services

*Defendant*

)  
)  
)  
) Civil Action No.  
)  
)  
)

**SUMMONS IN A CIVIL ACTION**

To: *(Defendant's name and address)*

United States Attorney General  
U.S. Department of Justice  
950 Pennsylvania Avenue, N.W.  
Washington, DC 20530-001

A lawsuit has been filed against you.

Within 30 days after service of this summons on you (not counting the day you received it) you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Paul M. Bartkowski  
Bartkowski PLLC  
6803 Whittier Ave. Suite 200A  
McLean, Virginia 22101

If you fail to respond, judgment by default may be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

*ANGELA D. CAESAR, CLERK OF COURT*

Date: \_\_\_\_\_

\_\_\_\_\_  
*Signature of Clerk or Deputy Clerk*

Civil Action No. \_\_\_\_\_

**PROOF OF SERVICE**

*(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))*

This summons for *(name of individual and title, if any)* \_\_\_\_\_  
was received by me on *(date)* \_\_\_\_\_.

☐ I personally served the summons on the individual at *(place)* \_\_\_\_\_  
on *(date)* \_\_\_\_\_; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* \_\_\_\_\_  
\_\_\_\_\_, a person of suitable age and discretion who resides there,  
on *(date)* \_\_\_\_\_, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* \_\_\_\_\_, who is  
designated by law to accept service of process on behalf of *(name of organization)* \_\_\_\_\_  
on *(date)* \_\_\_\_\_; or

☐ I returned the summons unexecuted because \_\_\_\_\_; or

☐ Other *(specify)*: \_\_\_\_\_

My fees are \$ \_\_\_\_\_ for travel and \$ \_\_\_\_\_ for services, for a total of \$ \_\_\_\_\_ 0.00.

I declare under penalty of perjury that this information is true.

Date: \_\_\_\_\_

\_\_\_\_\_  
*Server's signature*

\_\_\_\_\_  
*Printed name and title*

\_\_\_\_\_  
*Server's address*

Additional information regarding attempted service, etc:



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

Functional Government Initiative

*Plaintiff*

v.

U.S. Department of Health and Human Services

*Defendant*

Civil Action No.

**SUMMONS IN A CIVIL ACTION**

To: *(Defendant's name and address)*

U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, D.C. 20201

A lawsuit has been filed against you.

Within 30 days after service of this summons on you (not counting the day you received it) you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Paul M. Bartkowski  
Bartkowski PLLC  
6803 Whittier Ave. Suite 200A  
McLean, Virginia 22101

If you fail to respond, judgment by default may be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

*ANGELA D. CAESAR, CLERK OF COURT*

Date: \_\_\_\_\_

\_\_\_\_\_  
*Signature of Clerk or Deputy Clerk*

FOIA Summons (1/13) (Page 2)

Civil Action No. \_\_\_\_\_

**PROOF OF SERVICE**

*(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))*

This summons for *(name of individual and title, if any)* \_\_\_\_\_  
was received by me on *(date)* \_\_\_\_\_.

☐ I personally served the summons on the individual at *(place)* \_\_\_\_\_  
on *(date)* \_\_\_\_\_; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* \_\_\_\_\_  
\_\_\_\_\_, a person of suitable age and discretion who resides there,  
on *(date)* \_\_\_\_\_, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* \_\_\_\_\_, who is  
designated by law to accept service of process on behalf of *(name of organization)* \_\_\_\_\_  
on *(date)* \_\_\_\_\_; or

☐ I returned the summons unexecuted because \_\_\_\_\_; or

☐ Other *(specify)*: \_\_\_\_\_

My fees are \$ \_\_\_\_\_ for travel and \$ \_\_\_\_\_ for services, for a total of \$ \_\_\_\_\_ 0.00.

I declare under penalty of perjury that this information is true.

Date: \_\_\_\_\_

\_\_\_\_\_  
*Server's signature*

\_\_\_\_\_  
*Printed name and title*

\_\_\_\_\_  
*Server's address*

Additional information regarding attempted service, etc: