UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

INFORMED CONSENT ACTION NETWORK, 2025 Guadalupe Street, Suite 260 Austin, Texas 78705 Plaintiff, -against- FOOD AND DRUG ADMINISTRATION 10903 New Hampshire Ave Silver Spring, MD 20993-0002 Defendant.	Civil Action No. 1:23-cv-219

COMPLAINT

Plaintiff Informed Consent Action Network ("**ICAN**" or "**Plaintiff**") brings this action against defendant Food and Drug Administration ("**FDA**" or "**Defendant**") to compel compliance with the Freedom of Information Act, 5 U.S.C. § 552 ("**FOIA**"). As grounds therefor, Plaintiff alleges as follows:

JURISDICTION AND VENUE

1. The Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331.

2. Venue is proper in this district pursuant to 28 U.S.C. § 1391.

PARTIES

3. Plaintiff ICAN is a not-for-profit organization with an office located at 2025 Guadalupe Street, Suite 260, Austin, Texas 78705.

4. Defendant FDA is an agency within the Executive Branch of the United States Government, organized within the U.S. Department of Health and Human Services. FDA is an agency within the meaning of 5 U.S.C. § 552(f) and has possession, custody, and control of records to which Plaintiff seeks access.

5. On June 30, 2022, Plaintiff sent a FOIA request to FDA seeking copies of the following records:

> All records concerning “Empirical Bayesian data mining” and “Empirical Bayesian Geometric Means” pursuant to Section 2.3 (2.3.2) of the VAERS Standard Operating Procedures for COVID-19.[1] This should include, but not be limited to, any communications between FDA and CDC “shar[ing] and discuss[ing] results of data mining analyses and signals.” (See Section 2.3.2)

(**Exhibit 101** at 9.) (Footnote included.)

6. On August 26, 2022, FDA issued a final response stating it was denying the entire request (FOIA #2022-4855) pursuant to 5 U.S.C. § 552(b)(5) (“Exemption 5”). (*See* **Exhibit 101** at 17.)

7. On October 31, 2022, Plaintiff appealed FDA’s final response challenging the adequacy of its search and its improper use of FOIA Exemption 5. (**Exhibit 101** at 1-7.)

8. FDA acknowledged receipt of Plaintiff’s appeal on November 1, 2022 and assigned it appeal file 22-000131AA. (**Exhibit 102**.) In FDA’s acknowledgement letter, it stated in part, the following:

> Pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 CFR 5.24(f) of the HHS FOIA regulations, your appeal falls under “unusual circumstances” in that our office will need to consult with another office that has substantial interest in the determination of the appeal. The actual

[1] *See* https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf.

> processing time will depend on the complexity of the issues presented in the appeal.

(**Exhibit 102**.)

9. In violation of the time limits prescribed by 5 U.S.C. § 552(a)(6)(A)(ii) and 5 U.S.C. § 552(a)(6)(B)(i), as of the date of this Complaint, FDA has failed to make a determination with respect to Plaintiff's appeal.

COUNT I
FAILURE TO MAKE DETERMINATION BY REQUIRED DEADLINE
(VIOLATION OF FOIA, 5 U.S.C. § 552)

10. Plaintiff realleges paragraphs 1 through 9 as if fully stated herein.

11. Defendant was required to make a determination on Plaintiff's appeal no later than December 14, 2022.

12. Defendant failed to make a determination on Plaintiff's appeal within the time limits set forth by FOIA; therefore, Plaintiff is deemed to have exhausted its administrative remedies. 5 U.S.C. § 552(a)(6)(A)(ii); 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(C)(i).

13. Defendant is in violation of FOIA.

COUNT II
FAILURE TO ESTABLISH ADEQUACY OF SEARCH
(VIOLATION OF FOIA, 5 U.S.C. § 552)

14. Plaintiff realleges paragraphs 1 through 13 as if fully stated herein.

15. For appeal file 22-000131AA, Defendant has failed to establish that it adequately searched for responsive records despite Plaintiff's challenge to same in Plaintiff's appeal.

16. Defendant is in violation of FOIA.

COUNT III
IMPROPER WITHOLDING OF RECORDS
(VIOLATION OF FOIA, 5 U.S.C. § 552)

17. Plaintiff realleges paragraphs 1 through 16 as if fully stated herein.

18. For appeal file 22-000131AA, Defendant has failed to establish the validity of its claimed exemption despite Plaintiff challenging the same in Plaintiff's appeal.

19. Defendant is in violation of FOIA.

REQUESTED RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court:

a. Declare that Defendant's continued delay in processing Plaintiff's FOIA appeal is unlawful under FOIA;

b. Declare that Defendant has failed to conduct an adequate search for responsive records as required by FOIA;

c. Declare that Defendant improperly withheld responsive records under Exemption 5;

d. Order Defendant to conduct searches for any and all records responsive to Plaintiff's FOIA request and demonstrate that it employed search methods reasonably likely to lead to the discovery of records responsive to a broad interpretation of Plaintiff's FOIA request;

e. Order Defendant to produce, by a date certain, any and all non-exempt records responsive to Plaintiff's FOIA request and a *Vaughn* index of any responsive records withheld under any claimed exemption;

f. Enjoin Defendant from continuing to withhold any and all non-exempt records responsive to Plaintiff's FOIA request;

g. Maintain jurisdiction over this action until Defendant complies with FOIA and all orders of this Court;

h. Grant Plaintiff an award of attorneys' fees and other litigation costs reasonably incurred in this action pursuant to 5 U.S.C. § 552(a)(4)(E); and

i. Grant Plaintiff such other relief as the Court deems just and proper.

Dated: January 25, 2022

SIRI & GLIMSTAD LLP

/s/ Colin M. Farnsworth

Aaron Siri, Bar No. 4321790
(*pro hac vice* to be filed)
Elizabeth A. Brehm, NY Bar No. 4660353
(*pro hac vice* to be filed)
Colin M. Farnsworth, DC Bar ID OR0022
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Exhibit 101

Siri | Glimstad

NEW YORK | LOS ANGELES | MIAMI
PHOENIX | DETROIT | DENVER | AUSTIN

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FDA FREEDOM OF INFORMATION ACT APPEAL

SUBMITTED VIA EMAIL October 31, 2022

Director, Office of the Executive Secretariat
US Food & Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
FDAFOIA@fda.hhs.gov

Re: Appeal of FDA Control # 2022-4855 (IR#0802M)

Dear Sir or Madam:

This firm represents Informed Consent Action Network ("**ICAN**"). On behalf of ICAN, on June 30, 2022, we submitted a request for records from the files of Food and Drug Administration ("**FDA**") pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("**FOIA**"). The FDA designated the request as FOIA Control # 2022-4855 (the "**FOIA Request**"). On August 26, 2022, the FDA issued a final response to the FOIA Request (the "**Final Response**"). ICAN writes now to appeal the Final Response.

A. FOIA Control # 2022-1455 (IR#0802M)

On June 30, 2022, ICAN submitted a request to the FDA for the following documents:

> **All records concerning "Empirical Bayesian data mining" and "Empirical Bayesian Geometric Means" pursuant to Section 2.3 (2.3.2) of the VAERS Standard Operating Procedures for COVID-19.[1] This should include, but not be limited to, any communications between FDA and CDC "shar[ing] and 'discuss[ing] results of data mining analyses and signals." (See Section 2.3.2)**

[1] *See* https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf.

> **Information helpful to fulfilling the request: The FDA's Center for Biologics Evaluation and Research is the likely custodian of responsive records.**

(**Exhibit 1**.)[2]

On July 5, 2022, FDA acknowledged the FOIA request and assigned FOIA case # 2022 4855. (**Exhibit 2**.)

B. FDA's Final Response

On August 26, 2022, the FDA issued a final response letter. The letter stated in part,

> **We are denying your entire request. Specifically, we are denying records concerning "Empirical Bayesian data mining" and "Empirical Bayesian Geometric Means."**
>
> **The following exemption(s) of FOIA, 5 U.S.C. 552, is the authority for denying you access to the non-disclosable material: Exemption (b)5 Certain interagency and intra-agency communications. We have included citations to the FOIA and FDA's regulations for your information.**
>
> **Section 5.31 (e) of the implementing regulations of the Department of Health and Human Services (DHHS) is applicable to this denial. The regulations are contained in the Code of Federal Regulations (CFR), Title 45.**
>
> **The following sections of the implementing regulations of FDA and reason(s) applicable to this denial are contained in the CFR, Title 21**
>
> **• Section 20.62 Intra-agency memoranda consisting of opinions, recommendations, and policy discussions within the deliberative process of FDA, from which factual information is not reasonably segregable.**

(**Exhibit 3**.)

C. Argument

FDA has improperly withheld records under FOIA Exemption 5 and has failed to conduct an adequate search. For the reasons set forth below, ICAN appeals FDA's Final Response.

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[2] All "Exhibits" referenced herein are appended to this letter.

1. The FDA Improperly Withheld Records Under FOIA Exemption 5

FDA has not properly demonstrated that the withheld records fall under the scope of Exemption 5. "An agency withholding responsive documents from a [FOIA] release bears the burden of proving the applicability of the claimed exemptions." *American Civil Liberties Union v. DOD*, 628 F.3d 612, 619 (D.C. Cir. 2011). "Exemption 5 claims must be supported with specificity and detail." *Judge Rotenberng Educ. Ctr., Inc. v. United States FDA*, 376 F. Supp. 3d 47, 65 (D.D.C. 2019) (citations omitted). The document must be: (1) an inter-agency or intra-agency document; (2) "predecisional"; and (3) deliberative. *Tigue v. United States DOJ*, 312 F.3d 70, 76 (2nd Cir. 2002). The Supreme Court has defined 'predecisional' records as those records "prepared in order to assist an agency decision maker in arriving at his decision." *Renegotiation Bd. v. Grumman Aircraft Eng'g Corp*., 421 U.S. 168, 184 (1975). Whereas 'deliberative' has been defined by the courts as records "actually . . . related to the process by which policies are formulated." *Jordan v. United States DOJ*, 591 F.2d 753, 774 (D.C. Cir. 1978). "This standard requires the agency to explain (i) "the nature of the specific deliberative process involved," (ii) "the function and significance of the documents in that process," and (iii) "the nature of the decision making authority vested in the document's author and recipient." *Brennan Ctr. for Justice at NY Univ. Sch. of Law v. Dep't. of Homeland Sec*., 331 F. Supp. 3d 74, 93-94 (S.D.N.Y. 2018).

Additionally, to carry its burden, the agency "must demonstrate that (A) the materials at issue are covered by the deliberative process privilege, and (B) it is reasonably foreseeable that release of those materials *would cause harm* to an interest protected by that privilege." (emphasis added) *Reporters Comm. for Freedom of the Press v. FBI,* 3 F.4th 350, 361 (D.C. Cir. 2021) (citing *Machado Amadis v. U.S. Dep't of State*, 971 F.3d 364, 370 (D.C. Cir. 2020); 5 U.S.C. § 552(a)(8)(A)(i)(I)). "In the context of withholdings made under the deliberative process privilege, the foreseeability requirement means that agencies must concretely explain how disclosure 'would'–not 'could'– adversely impair internal deliberations." *Reporters Comm. for Freedom of the Press,* 3 F.4th. at 369-70 (quoting *Machado Amadis*, 971 F.3d at 371).

Even if the deliberative process privilege applies, it "does not protect documents in their entirety; if the government can segregate and disclose non-privileged factual information within a document, it must." *Nat'l Day Laborer Org. Network v. United States Immigration & Customs Enf't*, 486 F. Supp. 3d 669, 689 (S.D.N.Y. 2020) (quoting *Loving v. Dep't of Def*., 550 F.3d 32, 38 (D.C. Cir. 2008)). "Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under this subsection." 5 U.S.C. § 552(b). Only factual material that is "inextricably intertwined with exempted portions" of the documents need not be disclosed. *Johnson v. Exec. Office for U.S. Attorneys*, 310 F.3d 771, 776 (D.C. Cir. 2002). The government has the "burden of demonstrating that no reasonably segregable information exists within . . . documents withheld." *Loving v. Dep't of Defense*, 550 F.3d 32, 41(D.C. Cir. 2008). "[T]he ultimate objective of exemption 5 is to safeguard the deliberative process of agencies, not the paperwork generated in the course of that process." *Nat'l Wildlife Fed'n v. U.S. Forest Serv*., 861 F.2d 1114, 1119 (9th Cir. 1988).

There are three reasons why FDA's application of Exemption 5 was improper. First, FDA has not provided the specificity and detail required to withhold records under Exemption 5. *Judge Rotenberng Educ. Ctr., Inc.*, 376 F. Supp. 3d at 65. For example, FDA's Final Response does not explain specifically how the redacted documents qualify as (1) inter-agency or intra-agency; (2) predecisional; and (3) deliberative. Moreover, the agency did not explain the nature of the deliberative process involved, the function and significance of the documents withheld under the deliberative process, or the nature of the decision-making authority vested in the documents author and recipient. *Brennan Ctr. for Justice at NY Univ. Sch. of Law*, 331 F. Supp. 3d at 93-94. Instead, FDA only broadly cites Exemption 5 and its corresponding Federal Regulations, despite "denying [ICAN's] entire request." (**Exhibit 3**.) Thus, the applicability of Exemption 5 has not been adequately proven. *American Civil Liberties Union*, 628 F.3d at 619; *Tigue*, 312 F.3d at 76. Because FDA's Final Response provides no explanation as to how specifically the requested information – in its entirety – falls under the scope of Exemption 5, ICAN, like the courts cannot presume the exemption is applicable. *Id*.

Second, FDA's Final Response did not provide any specific information as to how it is reasonably foreseeable that the release of the withheld materials *would* cause harm. *Reporters*. Thus, FDA has not concretely explained how the disclosure 'would'–not 'could'– adversely impair internal deliberations as FOIA requires. *Comm. for Freedom of the Press,* 3 F.4th. at 369-70. This analysis is especially true for the segregable factual information found in the withheld records. The request sought heavily factual and data driven records: "all records concerning 'Empirical Bayesian data mining' and 'Empirical Bayesian Geometric Means." (**Exhibit 1**.) All the records concerning the data and factual information of this request have great potential to provide invaluable information to the public, in line with the purposes of FOIA. Therefore, ICAN, like the courts cannot presume the release of this information would be harmful to the agency's internal deliberations, until it is concretely explained. *Comm. for Freedom of the Press,* 3 F.4th. at 369-70

Third, it remains unclear whether FDA attempted to segregate disclosable records as required by law. *Elec. Privacy Info. Ctr.,* 910 F.3d at 1237. FDA's Final Response alludes to the fact that factual information was not reasonably segregable, but it does not explicitly declare it, nor explain why. FDA merely states:

> **The following sections of the implementing regulations of FDA and reason(s) applicable to this denial are contained in the CFR, Title 21**
>
> **• Section 20.62 Intra-agency memoranda consisting of opinions, recommendations, and policy discussions within the deliberative process of FDA, from which factual information is not reasonably segregable.**

(**Exhibit 3**.)

Data sets and factual information most certainly serve as the basis from which "Empirical Bayesian data mining" and "Empirical Bayesian Geometric Means" occur. Furthermore, the genesis of this process is likely conducted by a computer program or software that synthesizes a larger data set into prompts or signals for agency review and analysis. The underlying data or factual information that serves as the signal, or the basis for further review and analysis by agency personnel, is not subject to Exemption 5. *Nat'l Wildlife Fed'n*, 861 F.2d at 1119. Data or factual information that is synthesized or automatically generated and produced through a computer program or algorithm are not deliberative materials. Computers and their programs don't deliberate, nor could their processes be harmed by the disclosure of the material. All data or factual information generated in the process is responsive to the request and not applicable to Exemption 5. *Hemenway v. Hughes*, 601 F. Supp. 1002, 1005 (D.D.C. 1985) (It has been long established that an agency has a duty to construe FOIA requests liberally).

Therefore, for these reasons, FDA has not met its burden of proving the applicability of Exemption 5, and the withheld records should be immediately released. *American Civil Liberties Union*, 628 F.3d at 619.

2. The FDA Failed to Conduct an Adequate Search

FDA has failed to conduct an adequate search of the requested records. An agency's search is adequate only if it is "reasonably calculated to uncover all relevant documents." *Zemansky v. E.P.A.*, 767 F.2d 569, 571 (9th Cir. 1985) (quoting *Weisberg v. U.S. Dep't. of Justice*, 745 F.2d 1476, 1485 (D.C. Cir. 1984)) (internal quotation marks omitted). "An agency fulfills its obligations under FOIA if it can demonstrate *beyond material doubt* that its search was reasonably calculated to uncover all relevant documents." *Defs. of Wildlife v. United States Border Patrol,* 623 F. Supp. 2d 83, 91 (D.D.C. 2009) (quoting *Valencia-Lucena v. U.S. Coast Guard,* 180 F.3d 321, 325 (D.C. Cir. 1999)) (emphasis added). To satisfy its FOIA obligations, an agency needs to adequately describe the scope and methods of its searches, which can reasonably be expected to uncover the records sought and demonstrate that the places most likely to contain responsive materials were searched. *Davidson v. E.P.A.*, 121 F. Supp. 2d 38, 39 (D.D.C. 2000). At minimum, the agency must specify "what records were searched, by whom, and through what process." *Steinberg v. U.S. Dep't. of Justice*, 23 F.3d 548, 552 (D.C. Cir. 1994).

Furthermore, in order to determine whether a search for responsive records was adequate, a court must first determine the scope of the documents the plaintiff requested. *Wallick v. Agric. Mktg. Serv*., 281 F. Supp. 3d 56, 66 (D.D.C. 2017). It has been long established that an agency has a duty to construe FOIA requests liberally. *Hemenway v. Hughes*, 601 F. Supp. 1002, 1005 (D.D.C. 1985); *Conservation Force v. Ashe*, 979 F. Supp. 2d 90, 100-104 (D.D.C. 2013); *Rodriguez v. DOD*, 236 F. Supp. 3d 26, 36-38 (D.D.C. 2017). This means an agency is compelled to interpret requests broadly, even if a narrower reading is also reasonable. *Id*. An agency has a duty under the FOIA to select the interpretation that would likely yield the greatest number of responsive documents. *Conservation Force*, 979 F. Supp. 2d at 102; *Nat'l Sec. Counselors v. CIA*, 849 F. Supp. 2d 6, 12 (D.D.C. 2012). Technical precision is not required in FOIA requests, and a request certainly should not fail where the agency knew or should have known what the requester was seeking all along. *Institute for Justice v. Internal Revenue Service,* 941 F.3d 567, 572 (D.C. Cir. 2019). FOIA obligates agencies to conduct searches in good faith. *Steinberg*, 23 F.3d at 551 (quoting *Weisberg*, 745 F.2d at 1485). A court can conclude a search is inadequate when the facts reveal a "positive indication of overlooked materials." *Valencia-Lucena v. United States Coast Guard*, 180 F.3d 321, 326 (D.C. Cir. 1999).

FDA's Final Response provided no information regarding the adequacy of its search. Without specifying what records were searched, by whom, and through what process, like the courts, ICAN cannot assume FDA's search was adequate. *Steinberg*, 23 F.3d 552. Moreover, the lack of detail in FDA's Final Response regarding its search suggest it likely could not demonstrate beyond material doubt that its search was reasonably calculated to uncover all relevant documents. *Valencia-Lucena*, 180 F.3d at 325. ICAN respectfully requests the agency review its search methods to assure it could meet its FOIA obligations in litigation.

Additionally, due to the inadequate description of its search, it is unclear whether FDA liberally construed the FOIA Request as FOIA requires. *Hemenway*, 601 F. Supp. at 1005. The FOIA Request sought,

> **All records concerning "Empirical Bayesian data mining" and "Empirical Bayesian Geometric Means" pursuant to Section 2.3 (2.3.2) of the VAERS Standard Operating Procedures for COVID-19.[3] This should include, but not be limited to, any communications between FDA and CDC "shar[ing] and 'discuss[ing] results of data mining analyses and signals." (See Section 2.3.2)**

(**Exhibit 1**.)

Based on FDA's Final Response which denied the entire request under Exemption 5, it is likely FDA improperly interpreted the request narrowly. For example, a liberal interpretation of the request would include the data sets and factual information used to prompt or signal the agency's further review and analysis. However, as explained above, none of this factual information or data was produced. Therefore, there is a positive indication of overlooked materials. *Valencia-Lucena,* 180 F.3d at 326. Additionally, if there are any communications that indicate that Empirical Bayesian data mining was conducted, those communications may evidence the date it was conducted and by whom it was conducted – this is factual information that is not deliberative and should be segregated within the records and produced.

For these reasons above, FDA has not demonstrated beyond a material doubt that its search was reasonably calculated to uncover all relevant documents. *Valencia-Lucena,* 180 F.3d at 325.

D. Appellate Request

Given the foregoing, ICAN hereby appeals and requests that the documents responsive to the FOIA Requests be produced within 20 days of this appeal. Thank you for your time and

[3] *See* https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf.

attention to this matter. If you require any additional information, please contact us at **(212) 532-1091** or through email at **foia@sirillp.com**.

Very truly yours,

/s/ Aaron Siri
Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Colin Farnsworth, Esq.

Enclosures

Exhibit 1

Siri | Glimstad

NEW YORK | LOS ANGELES | MIAMI
PHOENIX | DETROIT | DENVER | AUSTIN

200 Park Avenue, 17th Floor, New York, NY 10166
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FDA FREEDOM OF INFORMATION ACT REQUEST

VIA ONLINE PORTAL June 30, 2022

Food and Drug Administration
Division of Freedom of Information
Office of the Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: "Empirical Bayesian" – VAERS Standard Operating Procedures for COVID-19 (IR#0802M)

Dear Sir or Madam:

This firm represents the Informed Consent Action Network ("**ICAN**"). On behalf of ICAN, please provide the following records to foia@sirillp.com in electronic form:

> **All records concerning "Empirical Bayesian data mining" and "Empirical Bayesian Geometric Means" pursuant to Section 2.3 (2.3.2) of the VAERS Standard Operating Procedures for COVID-19.[1] This should include, but not be limited to, any communications between FDA and CDC "shar[ing] and 'discuss[ing] results of data mining analyses and signals." (See Section 2.3.2)**
>
> **Information helpful to fulfilling the request: The FDA's Center for Biologics Evaluation and Research is the likely custodian of responsive records.**

We ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii). ICAN is a not-for-profit news media organization whose mission is to raise public awareness about vaccine safety and to provide the public with information to give informed consent. (**Exhibit A**.) As part of its mission, ICAN actively investigates and disseminates information regarding vaccine

[1] *See* https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf.

safety issues for free, including through its website,[2] a weekly health news and talk show,[3] and through press events and releases. ICAN is seeking the information in this FOIA request to allow it to contribute to the public understanding of the government's vaccine safety programs, including the government's efforts to promote vaccine safety. The information ICAN is requesting will not contribute to any commercial activities. Therefore, ICAN should be properly categorized as a media requester, and it is entitled to the search and processing privileges associated with such a category designation. Accordingly, ICAN will be forced to challenge any agency decision that categorizes it as any other category of requester.

Please note that the FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable. We further request that you describe any deleted or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. ICAN reserves all rights to appeal the withholding or deletion of any information.

Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and ICAN may immediately take further administrative or legal action.

Furthermore, we specifically request that the agency provide us with an estimated date of completion for this request.

If you would like to discuss our request or any issues raised in this letter, please feel free to contact us at (212) 532-1091 or foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

/s/ Aaron Siri
Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Colin M. Farnsworth Esq.

[2] https://www.icandecide.org/.

[3] https://thehighwire.com/.

Exhibit A

DECLARATION OF CATHARINE LAYTON

STATE OF TEXAS

COUNTY OF Hays

I, Catharine Layton, being duly sworn on oath do say:

1. I am the Chief Operating Officer of the Informed Consent Action Network (ICAN), a not-for-profit 501(c)(3) organization whose mission is to disseminate scientific health information to the public.

2. I have been an officer of ICAN since its founding in 2016. I oversee all day-to-day operations of the organization and all ICAN's programs. Together with our CEO and Board, I ensure that all efforts are focused on our mission statement and ensure that ICAN stays in compliance with all required rules and regulations.

3. In pursuit of its mission, ICAN relies primarily on its own investigative reporting. ICAN is both instrumental in orchestrating cutting edge investigations into the safety of various medical products, as well as widely disseminating its findings through various media channels. Most notably, ICAN's popular website hosts the organization's largest education program, The HighWire with Del Bigtree. Utilizing its media teams' 40+ years of experience in TV production and investigative journalism, The HighWire provides hours of new video content to the public each week for free.

4. The HighWire website has approximately 3.4 million weekly visitors. On Twitter, The HighWire has approximately 140,000 followers and 1 to 2.5 million impressions in a 28-day period. Between Rumble and Bitchute, The HighWire has approximately 60,000 followers and growing. Additionally, ICAN has 29,000 text subscribers and 194,245 email subscribers.

5. The size of ICAN's audience and subscribers continues to grow and is illustrative of the wide public interest in the subject of health and medical safety. Moreover, critical to ICAN's mission is its proven ability to find and review critical scientific and governmental records and meaningfully report about their social impacts.

6. One of the tools ICAN uses to gather the raw material it uses in its popular investigative reporting is the Freedom of Information Act (FOIA).

7. ICAN uses records it obtains from its FOIA requests to carry out its public mission and support its role as a non-profit news-media organization in the field of health and medical safety, but as a non-profit, ICAN does not have a commercial interest in the records it seeks through FOIA.

8. Based on what I know as the Chief Operating Officer, as well what has been demonstrated by ICAN's past and current investigative reporting, for purposes of FOIA's Fee Waiver provisions, ICAN certainly qualifies as a "representative of the news media."

Signed 3 day of May 2022

Signature of Catharine Layton

I, Amy Blackwell Notary public for the state of Texas witnessed said Catharine Layton sign the above statement this 3 day of May (month), 2022

Notary Public for

AMY MARIE BLACKWELL
Notary ID #132597493
My Commission Expires
July 30, 2024
NOTARY PUBLIC STATE OF TEXAS

Exhibit 2

U.S. FOOD & DRUG
ADMINISTRATION

July 05, 2022

In Reply refer to
FOIA Control #:
2022-4855

Requester reference:
IR#0802M

SIRI & GLIMSTAD LLP
AARON SIRI
200 PARK AVE STE 3300
NEW YORK NY 10166

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

All records concerning "Empirical Bayesian data mining" and "Empirical Bayesian Geometric Means" pursuant to Section 2.3 (2.3.2) of the VAERS Standard Operating Procedures for COVID-19. This should include, but not be limited to, any communications between FDA and CDC "shar[ing] and 'discuss[ing] results of data mining analyses and signals." (See Section 2.3.2)

We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm.

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved. Please note that requests for medical device approval records (e.g. 510K, PMA, DEN) may take up to 18 to 24 months to process.

If you have any questions about your request, please call Wilson M. Russ, Freedom Of Information Specialist, at (301) 796-8981 or write to us at:
Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

If you call or write, use the FOIA control number provided above which will help us to answer your questions more quickly.

You also have the right to seek dispute resolution services from:

Office of Government Information Services
National Archives and Administration
8601 Adelphi Road – OGIS
College Park, MD 20740-6001
Telephone:202-741-5770
Toll-Free: 1-877-684-6448
Email:ogis@nara.gov
Fax: 202-741-5769

and/or

FDA FOIA Public Liaison
Office of the Executive Secretariat
US Food Administration
5630 Fishers Lane, Room 1050
Email: FDAFOIA@fda.hhs.gov

Sincerely,

SARAH KOTLER
Director

Exhibit 3

Annalise Beube

From: Kotler, Sarah <Sarah.Kotler@fda.hhs.gov>
Sent: Friday, August 26, 2022 6:16 AM
To: S&G Information Request Staff
Subject: FDA 2022-4855

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Requester:

The Food and Drug Administration (FDA) has completed processing your request for records under the Freedom of Information Act (FOIA).

We are denying your entire request. Specifically, we are denying records concerning "Empirical Bayesian data mining" and "Empirical Bayesian Geometric Means."

The following exemption(s) of FOIA, 5 U.S.C. 552, is the authority for denying you access to the non-disclosable material: Exemption (b)5 Certain interagency and intra-agency communications. We have included citations to the FOIA and FDA's regulations for your information.

Section 5.31 (e) of the implementing regulations of the Department of Health and Human Services (DHHS) is applicable to this denial. The regulations are contained in the Code of Federal Regulations (CFR), Title 45.

The following sections of the implementing regulations of FDA and reason(s) applicable to this denial are contained in the CFR, Title 21

- Section 20.62 Intra-agency memoranda consisting of opinions, recommendations, and policy discussions within the deliberative process of FDA, from which factual information is not reasonably segregable.

FDA's Regulations at CFR Part 20 are available at:
http:www.access.gpo.gov/nara/cfr/waisidx_04/21cfr20_04.html

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision. Your appeal must be mailed within 90 days from the date of this response, to: Director, Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: FDAFOIA@fda.hhs.gov. Please clearly mark both the envelope and your letter "FDA Freedom of Information Act Appeal."

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact Sarah Kotler at 301-796-8976. You may also contact the FDA FOIA Public Liaison for assistance at: Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: FDAFOIA@fda.hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road–OGIS, College Park, MD 20740-6001; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769; e-mail at ogis@nara.gov.

Sincerely yours,

Sarah Kotler
Director
Division of Freedom of

Information

Sarah B. Kotler, J.D.
Director, Division of Freedom of Information
US FDA
301-796-8976

Sarah B. Kotler, J.D.
Director, Division of Freedom of Information
US FDA
301-796-8976

Exhibit 102

Annalise Beube

From: FDA FOIA <FDAFOIA@fda.hhs.gov>
Sent: Tuesday, November 1, 2022 7:37 AM
To: S&G Information Request Staff; FDA FOIA
Cc: Colin Farnsworth
Subject: RE: [EXTERNAL] Appeal of FDA Control # 2022-4855 (IR#0802M)

Follow Up Flag: Follow up
Flag Status: Flagged

Appeal file: 22-000131AA

November 1, 2022

Sending via Email: foia@sirillp.com

This letter acknowledges receipt of your Freedom of Information Act (FOIA) appeal, submitted to the Food and Drug Administration (FDA). We received your appeal on November 1, 2022. Your appeal challenges the *Food and Drug Administration (FDA's)* response to your original request ***#2022-4855***. Your appeal has been assigned the above-stated case number based on when it was received in this office. Please reference this number on your correspondence.

Your appeal is summarized below:
Full Denial

Pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 CFR 5.24(f) of the HHS FOIA regulations, your appeal falls under "unusual circumstances" in that our office will need to consult with another office that has substantial interest in the determination of the appeal. The actual processing time will depend on the complexity of the issues presented in the appeal. For more information about how your appeal will be processed please refer to the HHS FOIA regulations https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations).

The FOIA and the HHS FOIA regulations are available at the following web addresses: https://www.justice.gov/oip/freedom-information-act-5-usc-552 and https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations.

If you have any questions, please call (301)796-8975, or email us at fdafoia@fda.hhs.gov.

Sincerely yours,

Sarah Kotler
FDA FOIA

Sarah B. Kotler, J.D.

Director, Division of Freedom of Information
US FDA
301-796-8976

From: S&G Information Request Staff <foia@sirillp.com>
Sent: Monday, October 31, 2022 2:16 PM
To: FDA FOIA <FDAFOIA@fda.hhs.gov>
Cc: Colin Farnsworth <cfarnsworth@sirillp.com>
Subject: [EXTERNAL] Appeal of FDA Control # 2022-4855 (IR#0802M)

Dear Sir or Madam,

Attached please find our client's appeal.

Thank you,

Annalise Beube, Law Clerk
Siri | Glimstad
20200 West Dixie Highway
Suite 902
Aventura, FL 33180
Main: 786-244-5660
Facsimile: 646-417-5967
www.sirillp.com