UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

INFORMED CONSENT ACTION NETWORK, Plaintiff, -against- FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 1:23-cv-00219-RBW

PLAINTIFF'S RESPONSE IN OPPOSITION TO DEFENDANT'S MOTION FOR AN EIGHTEEN-MONTH STAY OF PROCEEDINGS

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INTRODUCTION

Informed Consent Action Network ("**ICAN**" or "**Plaintiff**") respectfully submits this Opposition to the Food and Drug Administration's ("**FDA**") Motion for an Eighteen-Month Stay of Proceedings (ECF No. 21). This matter concerns a Freedom of Information Act ("**FOIA**") request submitted by ICAN to FDA seeking critical records concerning Empirical Bayesian data mining ("**EB data mining**"). As described in more detail below, FDA uses EB data mining to identify disproportional adverse event reporting for vaccines. The EB data is crucial to understanding the safety profile of the Covid-19 vaccines and while federal health authorities have heavily relied upon it in their resounding claims that "the vaccines are safe!" they have refused to disclose it to the public.[1] Eleven months after Plaintiff submitted its FOIA request and almost 4 months after the instant litigation commenced, FDA represented that it had finally identified 150 responsive records (75 emails and 75 excel files) and still had more searches to run. Instead of producing those identified records – a majority of which likely contain only data which is not exempt from disclosure – and/or running additional searches, FDA has withheld all the identified records and now seeks to continue to withhold those records and to not run additional searches for at least an additional eighteen months. ICAN vehemently opposes FDA's motion.

In its motion, FDA goes to great lengths to attempt to cast Plaintiff and Plaintiff's counsel as bad actors. FDA repeatedly highlights, in accusatory fashion, the number of FOIA requests submitted and the number of FOIA cases litigated by Plaintiff's counsel in an effort to show the

[1] Notably, ICAN is not the only requester to seek the EB data. Children's Health Defense and The Epoch Times also submitted FOIAs for this data and were denied, and Senator Ron Johnson directly requested the data from both CDC and FDA and was denied. Like ICAN, Children's Health Defense also commenced litigation to obtain the EB data and, in that litigation, FDA has also sought a stay. *See Children's Health Defense v. Food and Drug Administration*, No. 1:23-cv-00220-RDM, Dkt. 17 (D.D.C. Sept. 14, 2023) (hereinafter, "**CHD EB data mining litigation"**); *see also* https://www.documentcloud.org/documents/23940343-sen-johnson-letter-to-fda-on-eb-data-mining and https://www.theepochtimes.com/article/exclusive-fda-refuses-to-provide-key-covid-19-vaccine-safety-analyses-4722586.

Court how a single law firm has crippled its Center for Biologics Evaluation and Research ("**CBER**") FOIA office. The reality is that Plaintiff, Plaintiff's counsel, and other clients represented by Plaintiff have done nothing but legally and effectively use FOIA for its intended purpose. *See Open America v. Watergate Special Prosecution Force*, 547 F.2d 605, 609 (D.C. Cir. 1976) (Freedom of Information Act does not require a party to specify the purpose for which they desire access) (hereinafter, "***Open America***"). That FDA cannot uphold its statutory obligations does not render Plaintiff or Plaintiff's counsel at fault. In fact, fatal to its argument for a stay, a majority of FDA's brief is not about this Plaintiff or its instant request; instead, it is about two unrelated litigations involving a different plaintiff and FDA's alleged lack of resources. And as the Court in one of those two unrelated litigations held only a few months ago: "[W]hile the Court recognizes the limited resources that the FDA has dedicated to FOIA requests, the number of resources an agency dedicates to such requests does not dictate the bounds of an individual's FOIA rights." *Pub. Health & Med. Pros. for Transparency v. FDA*, No. 4:22-cv-00915-P, Dkt. 31 at 4 (N.D. Tex. May 9, 2023) (hereinafter, "***PHMPT 2***").

It should be noted at the outset that FDA did not slow down the review or granting of emergency use authorization for Covid-19 vaccines due to a lack of resources. It did not slow down its approval process for those vaccines due to a lack of resources. Nor did it slow down its promotion of these products due to a lack of resources. It did whatever it needed to do to get these vaccines approved, widely promoted, and into the arms of the American public; it purportedly moved the sun and earth to do so and now it must do the same to get the relevant data to the public. FDA was not legally obligated to make every possible effort to get these vaccines out immediately, but it did. Now, where FDA *is* obligated by law to be transparent about these products and about government action related to these products, FDA wants to shirk its statutory duties. However, it

should be made to take equal if not greater steps to meet its obligations. It certainly should not be excused from doing so for a minimum of eighteen additional months, possibly more, rendering the data completely stale by the time it ever sees the light of day.

Additionally, the FOIA backlog complained of by FDA is of FDA's own making, not that of any Court, *PHMPT* or otherwise. The solution is for the agency to stop chronically underfunding its FOIA offices. Congress made billions of dollars available to FDA to address Covid-19 and an appropriate portion should have been devoted to transparency and accountability to those providing these funds: the public. FDA acknowledges that CBER began to see a dramatic increase in the number of FOIA requests being submitted and FOIA litigations being filed at the start of the pandemic. *See* ECF No. 21-2 ¶19. This was a clear sign more than three years ago that more resources should have been devoted to FOIA as increased obligations were then predictable. Instead, the agency waited until a Court ordered it to uphold its statutory obligation in January 2022. *Pub. Health & Med. Pros. for Transparency v. FDA*, Civ. A. No. 21-1058, Dkt. 35 (N.D. Tex. Jan. 6, 2022) (hereinafter, "***PHMPT I***"). That order is now almost two years old and was another clear sign that the agency had not devoted enough resources to FOIA. The situation FDA finds itself in was entirely predictable and, for most parts, completely avoidable. In any event, unless or until Congress changes the requirements of FOIA, FDA (and CBER specifically), is not excused from them, just as no citizen is excused from his or her legal obligations due to a claimed lack of resources.

For these reasons and for the reasons detailed below, FDA is not entitled to a stay as it cannot meet its burden under 5 U.S.C. § 552(a)(6)(C)(i) or *Landis v. N. Am. Co.*, 299 U.S. 248 (1936) (hereinafter, "***Landis***"). As concerns 5 U.S.C. § 522(a)(6)(C)(i) or an *Open America* stay, exceptional circumstances do not exist because FDA is not deluged with a volume of requests for

information vastly in excess of that anticipated by Congress. Moreover, as set forth herein, FDA's resources are adequate to deal with the volume of pending requests within the time limits of subsection 6(A). Finally, and perhaps most importantly, FDA cannot show that it is exercising due diligence for the request at bar. The good faith effort and due diligence of an agency to comply with all lawful demands under FOIA in as short a time as possible by assigning all requests on a first-in, first-out basis, except where exceptional need or urgency is shown, is compliance with the Act. *Open America v. Watergate Special Prosecution Force*, 547 F.2d 605, 616 (D.C. Cir. 1976). Here, however, FDA is attempting to remove ICAN from the first-in, first-out queue altogether. This fact alone renders it impossible for FDA to assert it is exercising due diligence with respect to this request. The only alternative scenario is one in which FDA does not seek to selectively remove the instant request from the queue and allow others to move forward, but instead seeks to stop the queue altogether, effectively freezing FOIA for the next eighteen or more months. Neither scenario is justified and both have far-reaching, troubling ramifications.

As concerns a stay under *Landis*, because ICAN will suffer harm and FDA is unable to show sufficient hardship and inequity by being required to produce documents pursuant to FOIA, it is not entitled to relief. Likewise, FDA has failed to offer any argument to show that a *Landis* stay would further the orderly course of justice.

Accordingly, FDA is not entitled to the relief it has requested.

BACKGROUND

ICAN is a not-for-profit news media organization whose mission is to put health information in the hands of the public to enable informed consent concerning medical decisions. ICAN actively investigates and disseminates for free scientifically based health information

regarding, among other things, vaccine safety through its website and its weekly health news and talk show.[2]

To monitor vaccine safety, federal health authorities heavily rely on the Vaccine Adverse Event Reporting System ("**VAERS**"),[3] a passive vaccine safety surveillance system to which reports of adverse events after vaccination can be submitted. VAERS is co-managed by CDC and FDA. In January 2021, CDC released the VAERS Standard Operating Procedures for Covid-19 ("**VAERS SOP**").[4]

As explained in the VAERS SOP:

> The analyses for COVID-19 vaccine safety signals will focus on identifying deviations from preliminary safety data, and possibly from other vaccines, using disproportionality analyses and comparisons of reporting rates. **Two main approaches to data mining are Proportional Reporting Ratios (PRRs) and Empirical Bayesian Geometric Means**. Both have published literature suggesting criteria for detecting "signals". **PRR will be used at CDC for potential signal detection; Empirical Bayesian data mining will be performed by FDA**.[5]

This SOP evidenced that CDC planned to conduct its own safety signal monitoring using Proportional Reporting Rations ("**PRR**") and FDA planned to conduct its own safety signal monitoring using EB data mining.

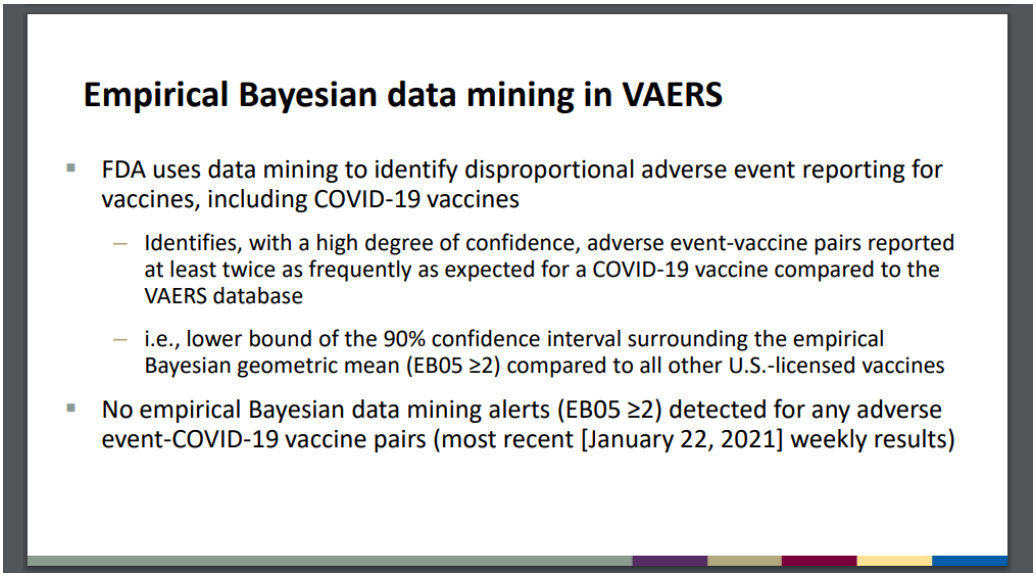
[2] https://icandecide.org/.

[3] *See* https://vaers.hhs.gov/.

[4] *See* **Exhibit A**. The SOP in its entirety is available at https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf. All exhibits referenced herein are attached to the Declaration of Elizabeth A. Brehm, filed concurrently herewith.

[5] *Id.* (emphasis added).

According to a January 27, 2021 CDC "vaccine safety update" presentation, the following is an explanation of EB data mining in CDC's own words:[6]



Throughout the Covid-19 vaccine rollout, presentations like the above were used by FDA and other health authorities to consistently reassure the American public that the Covid-19 vaccines were safe and that there were no EB data mining alerts detected. For instance, in its summary reports to CDC's vaccine advisory committee, FDA boasted that "[n]o empirical Bayesian data mining alerts [ ] were detected for any AE [adverse event]-COVID-19 vaccine pairs as of the January 22, 2021 weekly results."[7] The same statements to the public were made for February 18, 2021 weekly results and others that followed.[8] Indeed, FDA posits that, "[g]iven the strength of the EB data mining method, CDC and FDA plan to continue relying upon EB data

[6] *See* **Exhibit B** for the relevant portions of the presentation, which is available in full at https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-01/06-COVID-Shimabukuro.pdf?te=1&nl=well&emc=edit_hh_20210402 at 15.

[7] *See* **Exhibit C** for the relevant portions of the ACIP Summary Report (**Jan. 27, 2021**), which is available in full at https://stacks.cdc.gov/view/cdc/112184 at 31.

[8] *See* **Exhibit D** for the relevant portions of the CDC Covid-19 vaccine safety update, VRBPAC meeting (Feb. 26, 2021), which is available in full at https://www.fda.gov/media/146269/download ; *see also* **Exhibit E** for the relevant portions of the ACIP Summary Report (Feb 28 – Mar 1, 2021), which is available in full at https://stacks.cdc.gov/view/cdc/113294 (no empirical Bayesian data mining alerts were detected).

mining moving forward."[9] As it did for the initial Covid-19 vaccines, FDA likewise used EB data mining to monitor for disproportional reporting of adverse events for the pediatric population.[10] In an April 9, 2021 FDA review memorandum which expanded the emergency use of Pfizer's Covid-19 vaccine, FDA researchers said that the only potential signal from data mining was body temperature.[11] In October 2021, CDC authors released a pre-print study that announced that EB data mining identified no adverse health outcomes following Covid-19 vaccination.[12] And in May 2022, FDA and CDC authors published a pre-print stating that EB data mining through November 12, 2021 revealed only one signal for death reports in VAERS for the Astra Zeneca vaccine (not authorized or licensed in the U.S.).[13]

Thus, as part of its mission, and understanding the importance of the PRR and EB data mining given FDA and CDC's claims, on June 30, 2022, ICAN submitted a FOIA request to FDA for "[a]ll 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." ECF No. 1-1 at Exh. 1.

Plaintiff also submitted a FOIA request to CDC on the same date as the FDA EB data mining request seeking "All records related to Proportional Reporting Ratio (PRR) analyses performed "to identify AEs that are disproportionately reported relative to other AEs" pursuant to Sections 2.0, 2.3., and 2.3.1 of the VAERS Standard Operating Procedures for COVID-19," (the

[9] **Exhibit F** , which is available at https://www.documentcloud.org/documents/23940343-sen-johnson-letter-to-fda-on-eb-data-mining at 17.

[10] *See* **Exhibit G**, which is available at https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7031e1-H.pdf.

[11] *See* **Exhibit H** , which is available in full at https://fda.report/media/149528/nr_EUA+27034.132+Review+Memo+Pfizer-BioNTech+COVID-19+Vaccine_REVISED24May_final.pdf at 34-35.

[12] *See* **Exhibit I**, which is available in full at https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00054-8/fulltext#%20.

[13] *See* **Exhibit J**, which is available in full at https://www.medrxiv.org/content/10.1101/2022.05.05.22274695v1.

"**PRR Request**"). (*See* **Exhibit K,** CDC response to Plaintiff's PRR Request). In this way, Plaintiff could be sure it would obtain data from each of the signal detection methods being utilized by federal health authorities.

In response to the PRR Request, CDC denied the request on July 29, 2022, stating that there were no responsive documents. In the PRR denial letter, the agency highlighted the superiority of and historical use of EB data mining and stated that:

> [I]t was determined that the Proportional Reporting Ratio (PRR) analyses would not be performed. Instead, the U.S. Food and Drug Administration (FDA) performs Empirical Bayesian (EB) data mining with VAERS data. **EB data mining** is a statistical method of detecting disproportionate reporting and **is considered the "gold standard" for disproportionality analysis**. There are no written communications regarding the use of EB over PRR for purposes of signal detection. **EB has been used for years for this purpose. It is widely accepted as the choice method for detecting potential safety signals** (with passive pharmacovigilance data, at least), and thus **was assumed to be the preferred method of detecting safety signals among COVID-19 vaccines**. PRR is included in the SOP as a potential alternative or adjunct method, but **EB was always understood to be the superior method**.

(*Id.*) (emphases added).

On August 26, 2022, FDA denied ICAN's EB data mining request in its entirety on the grounds that the requested records were exempt from disclosure pursuant to FOIA 5 U.S.C. § 552 (b)(5) ("**Exemption 5**").[14] So as of late August 2022, both CDC and FDA had refused to turn over any data mining data concerning the novel vaccines that had been, at that point, injected into millions of people worldwide.

[14] Exemption 5 protects records that are (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). Data and factual information are not subject to Exemption 5 and are therefore not exempt from disclosure. *See e.g.*, *EPA v. Mink*, 410 U.S. 73, 91 (1973).

Just days later, on September 2, 2022, then-CDC Director Rochelle Walensky sent a letter to Senator Ron Johnson which made clear that CDC *had* performed the PRR analysis (contrary to its response to Plaintiff), stating in that letter: "CDC performed PRR analysis between March 25, 2022, through July 31, 2022, **to corroborate the results of EB data mining**. Notably, results from PRR analysis were generally consistent with EB data mining, revealing no additional unexpected safety signals." (**Exhibit F** at 18) (emphasis added). Not only had CDC conducted PRR, but FDA conducted EB data mining and the two agencies compared notes and were seemingly reassured because their results were "generally consistent."

Based on Walensky's letter, Plaintiff appealed CDC's response to its PRR Request on October 7, 2022 and was subsequently forced to commence litigation against CDC on March 20, 2023 after CDC failed to make a determination with respect to Plaintiff's appeal.

On October 31, 2022, ICAN appealed FDA's denial of its EB data mining request on the grounds that FDA failed to conduct an adequate search and improperly withheld responsive records under Exemption 5. ECF No. 1-1 at 1. On November 1, 2022, FDA acknowledged receipt of ICAN's appeal. ECF No. 1-2 at 1. On January 25, 2023, after having received no further communication from FDA, ICAN filed this suit on the grounds that FDA violated FOIA by failing to issue a timely final determination on its appeal, failing to establish the adequacy of its search, and improperly withholding responsive records. (*See* ECF No. 1.) FDA filed its Answer on March 1, 2023. ECF No. 13.

Until April 3, 2023, when CDC finally produced 18 pages of records and 51 Excel files containing PRR results in response to the litigation, no data mining results had been produced to Plaintiff. The 51 PRR Excel files that were eventually produced contain disturbing data. As one example, the following is a sheet showing numerous serious adverse events reported by 12-17-

year-olds following the Covid-19 vaccine as compared to all non-Covid-19 vaccines. As the top of the file shows, a signal is triggered when three criteria are met: (1) the number of reported cases is three or more; (2) the PRR is greater than or equal to 2.0; and (3) the Chi-Square (statistical analysis used to examine data) is greater than or equal to 4.0. As is clear from the one representative example below, these thresholds are met for multiple serious adverse events:

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)
For Current Week and Past Week Comparison
Following **ALL 12/14/2020-05/06/2022 COVID19 mRNA Vaccines (SERIOUS AGES 12 YEARS-17 YEARS)**
Compared to **ALL 01/01/2009-05/06/2022 NON-COVID19 Vaccines (SERIOUS AGES 12 YEARS-17 YEARS)**
SERIOUS AGES 12 YEARS-17 YEARS Excludes missing ages, Initial domestic reports only, VAERS reports as of 05/06/2022
Vaccination, Received, and Completed Date: 12/14 - 05/06 (Current Week) and 12/14 - 04/29 (Past Week)
N>=3 (Current Week), PRR>=2.00 (Ratio of Proportions), Chi-Square>=4.00
MedDRA PTs sorting based on lower confidence limit and COVID19 mRNA adverse event count from 12/14/2020-05/06/2022

MedDRA Codes ALL Reports (SERIOUS 12 Yrs-17 Yrs)	12/14/2020-05/06/2022 COVID19 mRNA N=1845	01/01/2009-05/06/2022 NON-COVID19 N=1590	12/14-05/06 Chi-Square	12/14-05/06 PRR	12/14-05/06 LCL	12/14-05/06 UCL	12/14/2020-04/29/2022 COVID19 mRNA N=1843	01/01/2009-04/29/2022 NON-COVID19 N=1587	12/14-04/29 Chi-Square	12/14-04/29 PRR
MYOCARDITIS	655	12	656.73	47.04	26.68	82.93	655	12	656.41	47.00
RESPIRATORY RATE INCREASED	147	6	113.83	21.11	9.36	47.63	147	6	113.74	21.10
PERICARDITIS	147	9	106.22	14.08	7.21	27.50	147	9	106.12	14.06
BLOOD PRESSURE INCREASED	129	14	78.42	7.94	4.59	13.73	128	14	77.47	7.87
ANTICOAGULANT THERAPY	56	4	36.95	12.07	4.38	33.20	55	4	36.06	11.84
PAINFUL RESPIRATION	88	9	53.47	8.43	4.26	16.68	88	9	53.42	8.42
CHEST PAIN	895	172	564.83	4.48	3.86	5.20	895	172	564.49	4.48
RESPIRATORY RATE DECREASED	42	3	27.20	12.07	3.75	38.85	42	3	27.17	12.06
PERICARDIAL EFFUSION	63	7	36.37	7.76	3.56	16.89	63	7	36.33	7.75
HEART RATE DECREASED	58	7	32.18	7.14	3.27	15.60	58	7	32.14	7.13
PLEURITIC PAIN	34	3	20.41	9.77	3.01	31.74	34	3	20.38	9.76
CHEST DISCOMFORT	260	61	104.82	3.67	2.80	4.81	260	61	104.69	3.67
SINUS ARRHYTHMIA	26	3	13.77	7.47	2.26	24.63	26	3	13.76	7.46
HEART RATE INCREASED	186	57	53.84	2.81	2.11	3.75	186	57	53.76	2.81
BLOOD PRESSURE DECREASED	81	22	25.52	3.17	1.99	5.06	81	22	25.48	3.17
APPENDICITIS	51	12	18.05	3.66	1.96	6.84	51	12	18.03	3.66
BODY TEMPERATURE INCREASED	79	24	21.62	2.84	1.81	4.46	79	24	21.59	2.83

5 Yrs-11 Yrs | 12 Yrs-17 Yrs | 18+ | SERIOUS 5 Yrs-11 Yrs | SERIOUS 12 Yrs-17 Yrs | SERIOUS 18+ | NON-SERIOUS 5 Yrs-11 Yrs | NON-SERIOUS 12 Yrs ...

Exhibit L.

Recall that Walensky told Senator Johnson that PRR was done to corroborate results of EB data mining and that "results from PRR analysis were generally consistent with EB data mining." If the EB data mining results are truly consistent and confirm the serious issues raised by the PRR analyses, that may explain why FDA wants to delay making that data public for as long as it

possibly can, especially given its continued push to have all Americans further vaccinated for Covid-19.[15]

About a month after CDC finally produced the PRR data, FDA informed ICAN on May 10, 2023, that it had finally identified 150 records responsive to ICAN's request and was continuing its search. ECF No. 17 ¶ 5. According to FDA, those 150 records consist of 75 emails and 75 Excel files. *Id*. It is notable that Excel files typically contain data, which is not exempt from disclosure pursuant to FOIA, and do not require numerous, if any, redactions (as can be seen from the PRR Excel files produced to Plaintiff with zero redactions – *see* Exhibit L). It seems very likely that each excel file is attached to one email and they likely all contain very similar content with only the data differing over time.

Despite ICAN pushing FDA to release these already-identified records, it has been met with only refusals and delay tactics, including a request to consolidate this case with other cases (as more than one requester has sought this information, which further evidences its importance – *see* footnote 1), the repeated claim that it must "coordinate" with other requesters, and a complete lack of due diligence. To that end, on September 14, 2023, FDA filed the instant Motion for an Eighteen-Month Stay of Proceedings. ECF No. 21. ICAN opposes FDA's Motion for an Eighteen-Month Stay of Proceedings because FDA has not and cannot satisfy the requirements of either 5 U.S.C. § 552(a)(6)(C)(i) or *Landis*, and because, as explained by this Circuit, "stale information is of little value." *Payne Enters., Inc. v. United States*, 837 F.2d 486, 494 (D.C. Cir. 1998).

[15] *See, e.g.*, https://www.fda.gov/; https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines#leaders.

LEGAL STANDARDS

I. 5 U.S.C. § 522(a)(6)(C)(i)

Congress's insistence that agencies timely respond to FOIA requests is apparent from the face of the statute. *Democracy Forward Found. v. Dep't of Just.*, 354 F. Supp. 3d 55, 58 (D.D.C. 2018)(Emphasis added). Specifically, FOIA provides that, upon receipt of a request, a responding agency must "determine within 20 days . . . whether to comply with such request and shall immediately notify [the requestor]." *Id.* (quoting 5 U.S.C. § 552 (a)(6)(A)(i)). The statute only allows an agency to grant itself an additional 10 days to respond in "unusual circumstances" so long as the agency notifies the requestor of the unusual circumstances and specifies "the date on which a determination is expected to be dispatched." *Id.* Next, upon receiving notice of an agency's unilateral extension, the requestor has the right to "limit the scope of the request so that it may be processed within" the applicable time limit. *Id.* (quoting 5 U.S.C. § 552(a)(6)(B)(ii)). Then, "[u]pon any determination by an agency to comply with a request for records, the records shall be made promptly available to such person making such request." *Id.* (quoting 5 U.S.C. § 552(a)(6)(C)(i)). Finally, in the event an agency fails to meet the statute's time limits, the statute permits the requestor to seek relief in federal court without first exhausting administrative remedies. *See Id.* 5 U.S.C. § 552(a)(4)(B), 5 U.S.C. § 552(a)(6)(C)(i). Thus, it is apparent that Congress carefully crafted FOIA to put a substantial burden on the government to justify to the courts any noncompliance within the time limit prescribed under FOIA – generally speaking, no more than 30 business days. To be sure, "Excessive delay by the agency in its response is often tantamount to denial. It is the intent of this bill that the affected agencies be required to respond to inquiries and administrative appeals within specific time limits." *Open America v. Watergate*

Special Prosecution Force, 547 F.2d 605, 617 (D.C. Cir. 1976) (Levanthal concurring) (quoting H. Rep. No. 93-876, 93d Cong., 2d Sess. (1974), U.S. Code Cong. & Ad. News, p. 6271).

While Congress provided agencies with a limited "safety valve" from the strict time limits afforded by the statute, *Id*. at 610, it nevertheless requires agencies to show that "exceptional circumstances exist and that the agency is exercising due diligence in responding to the [FOIA] request" to obtain a stay. *Democracy Forward Found.*, 354 F. Supp. 3d at 58 (quoting 5 U.S.C. § 552 (a)(6)(C)(i)). In this Circuit, such stays are commonly referred to as "*Open America* stays," so named after the leading decision on the subject. *Id.* In *Open America*, the D.C. Circuit held:

> [W]e interpret Section 552(a)(6)(C) to mean that "exceptional circumstances exist" when an agency . . . is deluged with a volume of requests for information vastly in excess of that anticipated by Congress, when the existing resources are inadequate to deal with the volume of such requests within the time limits of subsection (6)(A), and when the agency can show that it "is exercising due diligence" in processing the requests.

547 F.2d at 616 (quoting 5 U.S.C. § 552 (a)(6)(C)). When the *Open America* standard is met, FOIA's time limits become no longer mandatory but directory. *Id.; see also Democracy Forward Found.*, 354 F. Supp. 3d at 59. The *Open America* court concluded that, "The good faith effort and due diligence of the agency to comply with all lawful demands under the Freedom of Information Act in as short a time as is possible by assigning all requests on a first-in, first-out basis, except those where exceptional need or urgency is shown, is compliance with the Act." *Id.*

In 1996 Congress amended FOIA to narrow the definition of "exceptional circumstances." 5 U.S.C. § 552(a)(6)(C)(ii) provides:

> For purposes of this subparagraph, the term "exceptional circumstances" does not include a delay that results from a predictable agency workload of requests under this section, unless the agency demonstrates reasonable progress in reducing its backlog of pending requests.

Democracy Forward Found., 354 F. Supp. 3d at 59 (quoting 5 U.S.C. § 552 (a)(6)(C)(ii)). Hence, the safety valve provisions of 5 U.S.C. § 552(a)(6)(C) were carefully crafted to put a substantial burden on the government to justify to the courts any noncompliance with FOIA time limits. *Open America*, 547 F.2d 605 at 617 (Levanthal, concurring). According to the legislative history of the Act, Congress intended for this amendment to be "consistent with the holding in *Open America*," and "clarif[ied] that routine, predictable agency backlogs for FOIA requests do not constitute exceptional circumstances." *Democracy Forward Found.*, at 59 (quoting H. Rep. No. 104-795 at 24 (1996), reprinted in 1996 U.S.C.C.A.N. 3448, 3467). Therefore, to justify a stay, it is not sufficient that one component of an agency receives a high number of FOIA requests, or even that one component of an agency has a large backlog of requests. Instead, the agency as a whole must show that the number of requests received in the relevant period was truly unforeseen and remarkable. *Id.*; *See e.g. Leadership Conference on Civil Rights v. Gonzales*, 404 F. Supp. 2d 246, 259 n.4 (D.D.C. 2005) (noting that "[a]n agency must show more than a great number of requests to establish[ ] exceptional circumstances under the FOIA").

II. INHERENT AUTHORITY TO STAY PROCEEDINGS UNDER *LANDIS*

It is true that the authority to stay proceedings is "incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis,* 299 U.S. at 254. However, stays are nevertheless "an 'intrusion into the ordinary processes of administration and judicial review,'" *Huddleston v. FBI*, Civ. A. No. 20-0447, 2021 WL 1837548, at *2 (E.D. Tex. May 7, 2021) (citing *Nken v. Holder*, 556 U.S. 418, 427, 129 S. Ct. 1749, 173 L. Ed. 2d 550 (2009) (quoting *Va. Petroleum Jobbers Ass'n v. FPC*, 259 F.2d 921, 925, 104 U.S. App. D.C. 106 (D.C. Cir. 1958) (per curiam)), and they are "not a matter of right, **even if irreparable injury might otherwise result**." *Id.* (citing *Virginian R. Co. v. United States*, 272 U.S. 658, 672, (1926)) (emphasis added). Instead, stays are

"an exercise of judicial discretion, and the 'party requesting a stay bears the burden of showing that the circumstances justify an exercise of that discretion.'" *Id*. (citing *Ind. State Police Pension Tr. v. Chrysler LLC*, 556 U.S. 960, 961, (2009) (per curiam) (quoting *Nken*, 556 U.S. at 433-34); *see Exner v. FBI*, 542 F.2d 1121, 1123 (9th Cir. 1976) (explaining that the responding agency bears the burden to demonstrate its due diligence in fulfilling its FOIA-related obligations). Indeed, a court's stay order "must be supported by 'a balanced finding that such need overrides the injury to the party being stayed.'" *Belize Soc. Dev. Ltd. v. Govt. of Belize,* 668 F.3d 724, 732 (D.C. Cir. 2012) (quoting *Dellinger v. Mitchell*, 442 F.2d 782, 787, (D.C. Cir. 1971)). "[I]f there is even a fair possibility that the stay . . . will work damage to someone else," the movant "must make out a clear case of hardship or inequity in being required to go forward." *Landis*, 299 U.S. at 255.

In deciding whether to exercise that power, courts must "weigh competing interests and maintain an even balance between the court's interest in judicial economy and any possible hardship to the parties." *Belize Soc. Dev. Ltd.,* 668 F.3d at 732-33 (quoting *Landis,* 299 U.S. at 254); *Wolf Designs, Inc. v. Donald McEvoy Ltd., Inc.*, 355 F. Supp. 2d 848, 853 (N.D. Tex. 2005) (citing *Landis*, 299 U.S. at 254-55); *CMAX, Inc. v. Hall*, 300 F.2d 265, 268 (9th Cir. 1962) (It is the district court's responsibility to weigh the competing interests of the parties relating to the appropriateness of a stay). Identifying and weighing these "competing interests" of "possible hardship[s]," and "judicial economy," *id.*, requires the court to "make such determinations in the light of the particular circumstances of the case." *SEC v. Dresser Indus., Inc.*, 628 F.2d 1368, 1375, (D.C. Cir. 1980). Specifically, the Court must examine: (1) the possible damage which may result from the granting of a stay, (2) the hardship or inequity which a party may suffer in being required to go forward, and (3) the orderly course of justice measured in terms of the simplifying or

complicating of issues, proof, and questions of law which could be expected to result from a stay. *See CMAX, Inc. v. Hall,* 300 F.2d 265, 268 (9th Cir. 1962); *Landis*, 299 U.S. at 254-55.

In *Landis*, the Supreme Court instructed that a court abuses its discretion in ordering a stay "of indefinite duration in the absence of a pressing need." *Landis*, 299 U.S. at 255. A stay is "immoderate and hence unlawful unless so framed in its inception that its force will be spent within reasonable limits, so far at least as they are susceptible of prevision and description," and "an order which is to continue by its terms for an immoderate stretch of time is not to be upheld as moderate because conceivably the court that made it may be persuaded at a later time to undo what it has done." *Id*. at 257. Underlying the Court's analysis was a recognition that "[o]nly in rare circumstances will a litigant in one cause be compelled to stand aside while a litigant in another settles the rule of law that will define the rights of both." *Id*. at 255.

ARGUMENT

I. THE COURT SHOULD NOT GRANT AN EIGHTEEN-MONTH STAY UNDER 5 U.S.C. § 552(A)(6)(C)(I) BECAUSE FDA CANNOT DEMONSTRATE "EXCEPTIONAL CIRCUMSTANCES" OR "DUE DILIGENCE"

This Court should deny FDA's requested stay under 5 U.S.C. § 55 (a)(6)(C)(i) because FDA did not and cannot demonstrate "exceptional circumstances" or that the agency is exercising due diligence with respect to ICAN's specific request.[16]

[16] If the Court is inclined to grant a stay, it has the discretion to order a stay for less time than requested by the Agency. *See, e.g.*, *Elec. Frontier Found. v. DOJ*, 563 F. Supp. 2d 188, 196 (D.D.C. 2008) (granting stay until August 1, 2008, instead of February 2013); *Hendricks v. DOJ*, No. 05-05-H, slip op. at 13 (D. Mont. Aug. 18, 2005) (concluding that FBI did not demonstrate exceptional circumstances sufficient to warrant stay for full length of time requested); *Bower v. FDA*, No, 03-224, 2004 WL 2030277, at *3 (approving seven-month stay, rather than leaving FDA "to its own, unmonitored devices" for full two and-one-half-year period that it had requested); *Ruiz v. DOJ*, No. 00-0105, slip op. at 3 (D.D.C. Sept. 27, 2001) (acknowledging that agency made "a satisfactory showing that a stay . . . is warranted," but reducing the stay's length from requested thirty-three months to only seven months); *Beneville v. DOJ*, No. 98-6137, slip op. at 8 (D. Or. Dec. 17, 1998) (declining to approve full stay of proceedings requested by FBI regarding Unabomber files); *Grecco v. DOJ*, No. 97-0419, slip op. at 2 (D.D.C. Aug. 24, 1998) (granting two-year stay rather than four-year stay that was requested by FBI); *see also Peralta v. FBI*, No. 94-760, slip op. at 2 (D.D.C. June 6, 1997) (reducing *Open America* stay by four months because of enactment of Electronic FOIA amendments, and requiring that agency justify additional time needed for processing on basis of new statutory standard), *vacated & remanded on*

A. FDA Cannot Demonstrate Exceptional Circumstances

First, a claim of "exceptional circumstances" should be viewed at the agency-level, not at the individual center level. *See* 5 U.S.C. § 552 generally and 5 U.S.C. § 552 (a)(6)(C)(i)-(iii) discussing "agency." Meaning, it is FDA that must make a showing of exceptional circumstances agency-wide and not CBER, one specific center within FDA. FDA has a significant annual discretionary budget ($3.4 billion in 2022),[17] which does not even include supplemental appropriations provided to respond to Covid-19 or the $500 million provided to the Secretary for medical countermeasure activities at FDA.[18] As of 2022, FDA had 162.95 full-time FOIA staff.[19] As detailed further below, while CBER bemoans that its FOIA requests have increased over the past few years, FDA's overall FOIA numbers have decreased. FDA distracts with its CBER-specific FOIA request, budget, and staff numbers when those numbers only highlight the agency's failure to adequately allocate its plentiful resources among its components.

However, even if one were to analyze the numbers at the CBER level, the recent and current FOIA request numbers are not "vastly in excess of that anticipated by Congress . . . " *Open America*, 547 F.2d at 616. First, by FDA's own admission, the number and complexity of the FOIA requests made to CBER began increasing in 2019. ECF No. 21-1 at 9.[20] By 2021, CBER began to receive more than 500 requests each year. *Id*. However, despite CBER's knowledge in 2019 of the increased volume and complexity of requests, it did not hire additional staff until receiving the

other grounds, 136 F.3d 169 (D.C. Cir. 1998); cf. *Donham*, 192 F. Supp. 2d 877, 884 (S.D. Ill. 2002) (refusing to set processing deadline, but also refusing to grant open-ended stay of proceedings).

[17] https://www.fda.gov/media/157737/download?attachment.

[18] *See* The Food and Drug Administration (FDA) Budget: Fact Sheet, dated December 9, 2022 available at https://crsreports.congress.gov/product/pdf/R/R44576 at 7.

[19] *See* HHS Fiscal year 2022 Freedom of Information Annual Report at Table IX. FOIA Personnel and Costs, available at https://www.hhs.gov/foia/reports/annual-reports/2022/index.html.

[20] Page citations to ECF No. 21-1 are to the numbered pages of the brief itself and not to the pdf page numbers.

order for *PHMPT 1* in January 2022. *See Pub. Health & Med. Pros. for Transparency v. FDA*, Civ. A. No. 21-1058 (N.D. Tex.). Furthermore, given that FDA approved a group of novel vaccines in record time, it would be reasonable to predict that the public would seek transparency about the approval of and data underlying the safety profile of the vaccines. Since the purpose of FOIA is "to ensure an informed citizenry, vital to the functioning of a democratic society, needed to check against corruption and to hold the governors accountable to the governed," it would be reasonable to anticipate that CBER specifically would receive an increase in FOIA requests on the heels of approving the Covid-19 vaccines. *NLRB v. Robbins Tire & Rubber Co.,* 437 U.S. 214, 242 (1978).

Second, in an apparent effort to show that exceptional circumstances exist (and to claim that the agency has demonstrated due diligence), FDA highlights that it has hired additional staff in CBER's FOIA office. However, its efforts have been a day late and a dollar short. Prior to *PHMPT 1*, CBER's FOIA office was comprised of nine full-time employees ("**FTE**") and one branch chief. ECF No. 21-2 ¶ 18.[21] Despite its existing backlog and increasing FOIA requests, it was only after the *PHMPT 1* order in January 2022 when CBER hired an additional nine FTE contractors and one part-time contractor to "primarily focus on processing records" for *PHMPT 1*. *Id*. ¶ 24. This means that after those hires, CBER's FOIA office had 18.5 FTEs to handle all FOIA requests and litigations. Shortly after the January 2022 *PHMPT 1* order, FDA began producing records in March 2022. *Id*. ¶ 23. According to FDA, the 9.5 contractor FTEs hired have been the employees focused on producing those records for *PHMPT 1*, despite the fact that they have not

[21] FDA claims that CBER "was able to keep its FOIA queues relatively stable" with this staff "prior to the 2022 court-ordered production order in *PHMPT 1*." ECF No. 21-2 ¶ 18. FDA makes the clear insinuation that it was *PHMPT 1* that rendered these 9 FTEs and 1 Branch Chief insufficient, however the data it shares contradicts that. Its own charts show that the pending requests drastically increased in 2019 and again in 2020, prior to any *PHMPT* court order. ECF No. 21-2 ¶¶ 18-19. The agency should have sought to hire additional staff at this point in time, prior to any court order.

had a full two years' worth of training.[22] *Id*. ¶ 24. Following the *PHMPT 2* order, the original nine FTEs as well as the newer nine contractor FTEs all began working on producing *PHMPT 2* records in addition to their other work. ECF No. 21-1 at 13. Upon conclusion of the production of records for *PHMPT 1*, which FDA anticipates will be by November 1, 2023, before its Reply brief is filed in this matter (*Id*. ¶ 23), the 9.5 contractor FTEs should then be available to work on *PHMPT 2* and/or any other litigations or FOIA work. *Id*. ¶ 25.

Furthermore, following the *PHMPT 2* order, CBER hired six additional FTEs in Spring 2023. *Id*. ¶ 25. With the addition of these six employees, CBER will have 24.5 FTEs available to process *PHMPT* 2 records, other litigation records, and non-litigation records. Therefore, notwithstanding its delay in hiring additional staff, CBER now has sufficient resources to deal with the volume of requests it has. *Open America*, 547 F.2d at 605. But again, the appropriate analysis would consider FDA's overall resources and employee numbers, not limited to CBER, on which the Declaration of Suzann Burk is silent. ECF No. 21-2.

Moreover, FDA insinuates that Siri & Glimstad's ("**Siri**") representation of multiple plaintiffs in various FOIA-related matters is somehow helpful to its showing of "exceptional circumstances"; however, it is not. ECF No. 21-1 at 10. No plaintiff is required to specify the purpose for which they desire access to information under the Freedom of Information Act. *Id*. at 609. Nevertheless, unlike traditional requesters, Siri is a national law firm representing clients from across the country and has years of experience in FOIA, both at the administrative level and in

[22] While FDA asserts that it takes two years to fully train new CBER FOIA employees (*Id*. ¶ 30), to date only one and a half years have elapsed since FDA began producing records in *PHMPT 1* with the assistance of the contractors. *Id*. ¶ 23. Even assuming CBER hired the original 9.5 contractors immediately following the *PHMPT 1* order, those contractors would still not have the requisite two years of training FDA claims is required to process records and yet they have been producing records for close to two years. If they have been able to be additive prior to a full two years' worth of experience, certainly the more recently hired six FTEs will be as well.

litigation. Therefore, it is reasonable that Siri would represent multiple parties requesting documents pursuant to FOIA. Furthermore, of the twelve litigations involving CBER, FDA has currently only sought stays in three cases. ECF No. 21-1 at 9-10, n. 4. Notably, the plaintiffs in two of the three cases are represented by Siri (*ICAN v. FDA*, Civil Action No. 23-0219 (RBW) (D.D.C.) (Sept. 14, 2023) & *ICAN v. FDA*, Civil Action No. 23-1508 (CKK) (D.D.C.) (Jan. 25, 2023)[23]). The third case in which FDA has sought a stay also concerns the EB data mining data and had FDA not filed a stay there, it would have had to produce those records to the other requester and, therefore, they would then be public and available to Siri and Plaintiff. The decision to stay only three of twelve cases, two of which involve a party represented by Siri and the third which overlaps with a Siri request, appears retaliatory. ICAN is unaware of FDA seeking a stay in any of its non-CBER FOIA litigations. It is unclear how CBER or FDA have the resources to continue the other nine CBER litigations, some which were filed before and some which were filed after this litigation and many of which appear to have potentially voluminous records at issue.

B. FDA Has Not Exercised and Is Not Exercising Due Diligence with Respect to ICAN's Specific Request

FDA has not acted with due diligence generally, as to the increased number of FOIA requests received by CBER, or specifically, as to ICAN's instant request. While the Burk Declaration describes what steps CBER has taken to address the recent rise in such requests overall (yet ignores the decline in requests to FDA generally), such as a multi-track process for handling FOIA requests, it has done nothing to address what steps it has taken to address ICAN's specific request. ECF No. 21-2. Instead, FDA wrongly focuses on two other litigations.

[23] This matter was dismissed without prejudice on October 2, 2023 (Dkt 15).

CBER has failed to exercise due diligence with respect to ICAN's request for two reasons. First, FOIA requires an agency to exercise due diligence in responding to *the request at hand*. *See* 5 U.S.C. § 552(a)(6)(C)(i) -(iii). By requesting an eighteen-month stay, CBER is seeking to remove ICAN's request from the processing queue entirely for eighteen months. The removal of ICAN's request from the queue would eliminate CBER's claim of due diligence because it would violate the requirement that agencies process requests on a first-in-first-out basis. *See Open America*, 547 F.2d at 616. FDA does not explain what requests or how many requests are potentially ahead of ICAN's instant request and it offers no timeline within which it anticipates processing the instant request. Instead, it seeks an eighteen month stay "at the end of which FDA will file a status report advising the Court of its circumstances and *whether it needs additional time* before proceeding with this case." ECF No. 21-1 at 3. This stay, if granted, would effectively allow the agency to hand-pick with its discretion which requests it wants to take off the conveyor belt of first-in, first-out requests. It also begs the question of how the agency has resources to address other requests that remain on the conveyor belt. The Burk Declaration's only statement about the specific request at issue is that CBER "does not have the bandwidth at this time to concurrently [with *PHMPT* matters] produce records in response to the request at issue in this litigation." ECF No. 21-2 ¶ 31. The only alternative is that the agency is seeking the Court's permission, justified by CBER's claimed lack of bandwidth, to completely stop the conveyor belt since ICAN's request was "first in" and is at the front of the line. This makes more sense if one were to accept the agency's claim that it has no resources to dedicate to anything FOIA-related other than the *PHMPT 1 and 2* matters. However, the real-world ramification of stopping the conveyor belt completely via a stay means that FOIA is effectively neutered for at least eighteen months, either within CBER- or agency-wide.

Second, on May 10, 2023, FDA informed ICAN that CBER identified 150 records responsive to ICAN's request – 75 excel files and 75 emails. ECF No. 17 ¶ 5. Although these records were identified close to five months ago, CBER has not reviewed or applied redactions to the records in any effort to make a partial release of the records, even on a rolling basis. "An effective demonstration of due diligence might in turn depend on **whether the agency** . . . **has been or is now willing to allow partial release of documents rather than conditioning release on complete processing of the request**, and whether it has or will defer considering any voluntary actions of disclosure which are plainly outside the scope of FOIA, in the interest of expediting disclosure of material expressly covered by the Act." *Open America*, 547 F.2d at 618 (emphasis added). Here, expending the minimal resources to release these already-identified documents would kill at least two birds with one stone by satisfying Plaintiff's request and CHD's request (and perhaps more if other requests for this data remain at the administrative level).

However, instead of reviewing and potentially applying any necessary redactions to the 150 records CBER already located, it seeks to cease processing the records responsive to the request for at least eighteen months. Tellingly absent from its motion and supporting declaration is *any* explanation of the resources that the agency would require to produce at least these 150 records. There is no discussion of the contents of those 150 records or of the potential exemptions that might be at issue. There is no discussion of the time or cost it would take to review and process them. If the Court were to review these records *in camera*, Plaintiff believes it would be abundantly clear that the excel files contain data which is not exempt from disclosure and could be produced within minutes:[24] (1) Data sets most certainly serve as the basis from which EB data mining occurs.

[24] FDA's brief contains a Section III in its Argument titled "Sensitivity of the Records" that is not applicable or relevant to the instant request. It discusses medical records of minors/patients and was likely inadvertently included from another brief. Plaintiff does not anticipate any third-party interest in the records at issue nor did FDA object to the

The genesis of this process is likely conducted by a computer program or software that synthesizes a larger dataset into prompts or signals for agency review and analysis. Data 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 generated in the process is responsive to the request and not applicable to Exemption 5. 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. *See EPA v. Mink*, 410 U.S. 73, 91 (1973); *see also SW. Ctr. For Biological Diversity v. USDA*, 170 F. Supp. 2d 931, 941 (D. Ariz. 2000); (2) Likewise, the 75 emails (presumably attaching a single excel file each) are likely uniform, repetitive, and not exceedingly lengthy and could also be processed and produced within a short period of time with minimal resources – likely far fewer resources than the Agency has dedicated and will dedicate to its current motion.

Lastly, with respect to FOIA requests submitted to FDA generally (the most relevant data for the analysis of due diligence, as noted above), the number and complexity of the FOIA requests made to FDA as a whole have actually declined since the start of the pandemic. The available data demonstrate that FDA's current load of FOIA requests is neither unforeseen nor remarkable. *See Leadership Conference on Civil Rights v. Gonzales*, 404 F. Supp. 2d 246, 259 n.4 (D.D.C. 2005) (an agency must show more than a great number of requests, it must show the number of requests in the relevant period was truly unforeseen and remarkable). The number of FOIA requests received by FDA each year has remained relatively stable over the last few years, with 2021 and 2022 numbers being the *lowest* since at least 2015. Indeed, the number of requests declined

production of these records due to Exemption 6. Instead, FDA initially withheld the records based on Exemption 5 which, for the reasons discussed herein, also does not apply to these records.

substantially from its peak over the last three years.[25] The numbers of requests received by FDA as a whole from 2015 to 2022 are as follows:

Year	Number of Requests Received by FDA
2015	9,958
2016	10,374
2017	11,062
2018	10,256
2019	11,578
2020	9,951
2021	8,529
2022	9,333

Given the relative stability, if not decline, of FDA's inflow of requests, FDA cannot credibly claim that its current FOIA workload is unforeseen, remarkable, or unusually high. If FDA had been exercising due diligence, it could have diverted resources from other FDA FOIA offices to CBER's FOIA office to handle the increase in requests made to CBER, but it has not made an effort to do so.

C. FDA Has Not Demonstrated Reasonable Efforts in Reducing Its Backlog

Since CBER and FDA's workloads were predictable, FDA has the additional burden of demonstrating "reasonable progress on reducing its backlog of pending requests." *Open America*, 547 F.2d at 605. In the present case, even if the Court looks at CBER individually as FDA has prompted it to do, CBER has not demonstrated a reasonable effort in reducing its backlog of requests, and instead asserts that it does not need to demonstrate progress on reducing its backlog. ECF No. 21-1 at 6-7. FDA acknowledges that CBER's backlog has only consistently and drastically grown from 2015 (with 39 pending requests at year end) to 2022 (with 532 at year end). ECF No. 21-2 ¶¶ 18-19. In fact, FDA references CBER's "growing FOIA backlog" that existed at

[25] Data from Department of Health and Human Services' Freedom of Information Annual Reports, available at https://www.hhs.gov/foia/reports/annual-reports/index.html.

least at the time of briefing in *PHMPT 2* and argues that its hiring and training efforts to address the backlog, prompted only by the *PHMPT 1* Court, satisfies its due diligence requirement. ECF No. 21-2 ¶¶ 26, 30. It is too little, too late and it does not evidence due diligence – quite the opposite.

If instead the Court correctly looks at the backlog of FDA as a whole, the available data there also indicates that FDA has not been making reasonable progress in reducing its backlog of requests. To the contrary, the data indicates that FDA's backlog has stayed relatively flat and has even grown substantially in the most recent fiscal years.[26] The numbers of backlogged requests from 2015 to 2022 for FDA as a whole are as follows:

Year	**Number of Backlogged Requests at Year End**
2015	2,337
2016	2,248
2017	2,279
2018	2,666
2019	3,172
2020	2,825
2021	3,577
2022	4,188

At a minimum, neither FDA as a whole nor CBER as a component of FDA is dealing with an unforeseen level of FOIA requests nor are they making progress on their FOIA backlogs. Thus, FDA cannot show the "exceptional circumstances" required to warrant a stay. Even if "exceptional circumstances" existed, a stay would not be warranted because FDA has not shown and cannot show that it is responding to ICAN's specific request with due diligence.

[26] *Id*.

II. THE COURT SHOULD NOT EXERCISE ITS INHERENT AUTHORITY TO STAY THIS ACTION UNDER *LANDIS*

A. ICAN Will Suffer Harm if This Case is Stayed and FDA Will Not

The decision in *Landis* requires that the Court weigh the possible damage to the parties if a stay is granted. The Court first must consider the injury to the party being stayed. *Belize Soc. Dev.*, 668 F.3d at 732. As noted above, if it determines that there is a fair possibility that the stay will damage ICAN's interest, FDA's burden becomes even heavier, for it must then show "a clear case of hardship or inequity in being required to go forward." *Landis*, 299 U.S. at 255.

In the present case, ICAN will be injured if the Court grants FDA's motion for a minimum eighteen-month stay. ICAN appealed FDA's withholding of responsive records nearly a year ago, on October 31, 2022. ECF No. 1-1 at 2. Despite having identified 150 records responsive to ICAN's request nearly five months ago, FDA seeks to withhold responsive records for at least another eighteen months. ECF No. 21-1 at 4. If the Court grants the stay, ICAN's appeal will have gone unanswered for well beyond the time limits prescribed by FOIA. *See* 5 U.S.C. § 552 (a)(6)(A)(ii). More substantively, ICAN and the American public will be denied access to critical safety data about the most quickly and widely distributed vaccine product – one that continues to be pushed by the United States government, including by FDA. FDA has made clear that it will not produce this data unless or until compelled to do so by a Court; if the Court grants it a minimum of eighteen months before it has to make an effort to do so, the data will be completely stale by that time.

Contrary to FDA's assertion, these records will contribute significantly to the public's understanding of the government's vaccine safety programs, as discussed at length in the Background section, *supra*. Section 2.3 (2.3.2) of the VAERS Standard Operating Procedures for COVID-19 states that "FDA will perform data mining at least biweekly (with stratified data mining

monthly) using empirical Bayesian data mining to identify AEs reported more frequently than expected following vaccination with COVID-19 vaccines…"[27] FDA relied heavily on the EB data mining when it constantly reassured the public through presentations, articles, and studies that the vaccine is "safe" and that no unexpected signals were detected. This is why numerous requesters sought this data from FDA and why one of them is also litigating in order to obtain it.[28] The data derived from the EB data mining conducted by FDA is critical to assessing emerging adverse events following Covid-19 vaccination and being able to evaluate both FDA and CDC's vaccine safety surveillance programs. However, despite the critical nature of FDA's EB data mining data, FDA refuses to produce it. If the Court grants a stay, the American public will be left without this critical data for an additional eighteen months, rendering it stale. "Congress has long recognized that 'information is often useful only if it is timely' and that, therefore 'excessive delay by the agency in its response is often tantamount to denial.'" *Open Soc'y Just. Initiative v. CIA*, 399 F. Supp. 3d 161, 165 (S.D.N.Y. 2019) (quoting H. Rep. No. 93-876, at 6271 (1974)).

B. FDA Has Failed to Show Sufficient Hardship and Inequity Justifying a Stay

The second *Landis* factor only weighs in favor of FDA if it can show it will endure hardship and inequity if the action is not delayed. *See Landis*, 299 U.S. at 255. FDA's request to completely stop work on Siri-related matters of its choosing marks a stark departure from prior rulings in this Circuit which require the agency to continue working on requests, although potentially at a reduced rate and within an enlarged period of time. *See e.g. Elec. Frontier Found. v. DOJ*, 517 F. Supp. 2d

[27] *See* **Exhibit A**.

[28] In addition to ICAN, Children's Health Defense, The Epoch Times, and Senator Ron Johnson have also asked FDA to release this data. *See* CHD EB data mining litigation; *see* **Exhibit F**, also available at https://www.documentcloud.org/documents/23940343-sen-johnson-letter-to-fda-on-eb-data-mining at 19-20 (CDC directs Senator Johnson to FDA to obtain EB data mining) and at 1-3 (showing that Senator Johnson requested FDA to release EB data mining and the agency failed to do so citing pending FOIA litigation); **Exhibit M**, also available at https://www.theepochtimes.com/article/exclusive-fda-refuses-to-provide-key-covid-19-vaccine-safety-analyses-4722586 (evidencing that The Epoch Times submitted a FOIA request for the EB data mining and was refused same).

111, 118 (D.D.C. 2007) (explaining that "the fact that the [agency] faces obligations in other litigations is not, in and of itself, sufficient to establish exceptional circumstances"); *Energy Future Coal. v. Off. Of Mgmt. & Budget,* 200 F. Supp. 3d 154 (D.D.C. 2016); *Shapiro v. Dep't of Just.*, Civ. A. No. 12-0313, 2014 WL 12912625 (D.D.C. Dec. 8, 2014). Being required to defend a suit, without more, does not constitute a clear case of hardship or inequity. *Lockyer v. Mirant Corp*., 398 F. 3d 1098, 1112 (9th Cir. 2005).

As noted above, upon conclusion of the production of records for *PHMPT 1*, CBER should have at least nine contractor FTEs, as well as six additional FTEs, available to process records aside from the productions for *PHMPT 2*. FDA's FOIA numbers have declined over the past few years and so the agency can shift resources to CBER. Although FDA contends it will take two years to fully train the new FOIA employees, in the interim, CBER will still have nine full-time contractors available to process records outside of the productions for *PHMPT 2*. Therefore, CBER has sufficient resources to deal with the volume of requests it has. *Open America*, 547 F.2d at 605.

That the government has chosen to release some data concerning vaccine safety does not satisfy FDA's obligations under FOIA. ECF No. 21-1 at 15-16. Certainly, the United States is not a nation where its citizens are only entitled to select information culled, curated, and composed by the government. Indeed, "FOIA was enacted to 'pierce the veil of administrative secrecy and to open agency action to the light of public scrutiny.'" *Batton v. Evers*, 598 F.3d 169, 175 (5th Cir. 2010) (quoting *Dep't of the Air Force v. Rose*, 425 U.S. 352, 361 (1976)).

Deadly to FDA's necessary showing of hardship and inequity is the glaring absence from its argument as to any specifics concerning the amount of resources it would require to process this request. The agency has not even attempted to show the Court the hardship, if any, resulting from producing the records at issue. Even so, any hardship that may potentially come to CBER, or

FDA, if a stay is denied is a result of the agency's failure to exercise due diligence for the past, at least, eight years. The agency should not be rewarded for neglecting to address increased FOIA requests and failing to improve its backlog. Thus, FDA has made no showing of the hardship it alleges it would suffer should it have to continue to process Plaintiff's request pursuant to FOIA.

C. FDA Has Failed to Show a Stay Furthers the Orderly Course of Justice

The third *Landis* factor weighs in favor of granting a stay when the orderly course of justice will be advanced through the simplifying of issues, proof, and questions of law. *See Landis*, 299 U.S. at 255. Here, aside from stating that it "is not able to agree to a processing schedule," ECF No. 21-1 at 16. FDA has offered no evidence that the orderly course of justice will be advanced. Indeed, it cannot. This is because a stay will not advance judicial economy because the parties will continue to remain in litigation on this Court's docket and will have to return to the Court for the same material in the future – no issues, proof, or questions of law will have changed or been simplified in that time. A court may "find it efficient for its own docket and the fairest course for the parties to enter a stay … pending resolution of independent proceedings which bear upon the case." *Leyva v. Certified Grocers of California, Ltd*., 593 F. 2d 857, 863 (9th Cir. 1979). Thus, even though a court may stay an action to provide for a just determination of the cases pending before it, here there are no other cases that need to be addressed by the Court to enable it to rule on any matter presently before it. Simply put, there is nothing to warrant a halt to the present ongoing FOIA litigation and the only result of halting would be delay and, eventually, the production of stale data.

Therefore, a stay in this case would not promote the interest of uniform treatment of similar cases. *See*, *e.g. CMAX*, 300 F.2d at 270. To the contrary, it would advance the interest of other cases which is contrary to the claimed first in, first out process utilized by FDA.

CONCLUSION

For the foregoing reasons, the Court should deny FDA's motion for an eighteen-month stay in this case.

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