IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY and PATRICK AND STEPHANIE DE GARAY, Plaintiffs, v. U.S. FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 4:22-cv-915-P

DEFENDANT UNITED STATES FOOD AND DRUG ADMINISTRATION'S BRIEF REGARDING FOIA PRODUCTION SCHEDULE

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I. INTRODUCTION

The central issue in this Freedom of Information Act ("FOIA") case is what constitutes a practicable schedule for FDA's processing of responsive records. Plaintiffs Public Health and Medical Professionals for Transparency ("PHMPT") and Patrick and Stephanie De Garay's FOIA requests are for records related to the product applications of Pfizer-BioNTech's Comirnaty vaccine for COVID-19, for individuals between 12 to 15 years of age, and Moderna's Spikevax vaccine for COVID-19, for individuals 18 years of age or older. This case is not a challenge to the decision of the U.S. Food and Drug Administration ("FDA") to approve the vaccines, and it is not about the legality or the wisdom of vaccination mandates. Most of Plaintiffs' "Brief in Support of Timely Production Schedule" (hereinafter, "Plaintiffs' Br."), Doc. 24, is devoted to discussing the alleged "public concerns" regarding the COVID-19 vaccines but does not speak to the straightforward issue before the Court in this FOIA case: what rate is reasonable and feasible for the processing of records responsive to Plaintiffs' FOIA requests.

As supported below, FDA's proposed briefing schedule accounts for FDA's unprecedented and ongoing workload constraints to comply with an Order in a prior case brought by Plaintiff PHMPT in this Court, *Pub. Health & Med. Pros. for Transparency v. FDA*, No. 4:21-CV-1058 ("*PHMPT 1*"). These considerations include resource reallocation from the rest of the agency's public health priorities, the increasing and substantial FOIA backlog, and fairness to other FOIA requesters, including hundreds of requesters who filed their requests prior to Plaintiffs here. Given these considerations, this Court should reject Plaintiffs' requests for production rates at least as high as those in *PHMPT 1* as impracticable and contrary to FOIA's overall goals of transparency and FDA's public health mission.

II. LEGAL BACKGROUND

1. The Freedom of Information Act

The Freedom of Information Act ("FOIA" or the "Act") provides that any person has a right to obtain access to federal agency records, except to the extent that any portions of such records are protected from disclosure by one or more of nine exemptions or three exclusions listed in the Act. *See* 5 U.S.C. § 552 (a)(3), (b), (c). Under FOIA, a person may submit a request to a federal agency "reasonably decrib[ing]" records that s/he seeks to obtain. 5 U.S.C. § 552(a)(3)(A).

An agency that has received a FOIA request is required, as relevant here, to "determine within 20 days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of any such request whether to comply with such request." *Id*. § 552(a)(6)(A)(i). FOIA further provides that a requester "shall be deemed to have exhausted his administrative remedies with respect to such request if the agency fails to comply with the applicable time limit provisions." *Id.* § 552(a)(6)(C)(i). FOIA's 20-working-day time period does not create a deadline for production. *Citizens for Responsibility & Ethics in Wash. v. FEC*, 711 F.3d 180, 189–90 (D.C. Cir. 2013). Rather, "if the agency does not adhere to FOIA's explicit timelines, the 'penalty' is that the agency cannot rely on the administrative exhaustion requirement to keep cases from getting into court." *Id*. No other provision in FOIA creates a specific timeframe for the release of records. *See* 5 U.S.C. §§ 552(a)(3)(A) (an agency shall make records responsive to a proper request "promptly available"), (a)(6)(C)(i) (same for litigated cases).

The time required to process a FOIA request will inherently depend on the scope of the request and the nature of the information requested. Federal law generally prohibits the release of certain types of information, such as trade secrets and personal medical information. *See* 21 U.S.C. § 331(j); 18 U.S.C. § 1905; 21 C.F.R. §§ 20.61, 20.63. Consistent with these obligations to protect

sensitive information, FOIA exempts several types of information from its production requirements. 5 U.S.C. § 552(b); *see Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2366 (2019) ("FOIA expressly recognizes that 'important interests [are] served by [its] exemptions,' and '[t]hose exemptions are as much a part of [FOIA's] purpose[s and policies] as the [statute's disclosure] requirement.'") (brackets in original) (quoting *FBI v. Abramson*, 456 U.S. 615, 630–631 (1982); *Encino Motorcars, LLC v. Navarro*, 138 S. Ct. 1134, 1142 (2018)); *Flightsafety Servs. Corp. v. DOL*, 326 F.3d 607, 611 (5th Cir. 2003) (Congress created nine exemptions in FOIA "because 'it realized that legitimate governmental and private interests could be harmed by release of certain types of information.'") (quotations and citations omitted). As particularly relevant to this case, FOIA Exemption 4 permits withholding of "trade secrets and commercial or financial information obtained from a person and [that are] privileged or confidential.'" 5 U.S.C. § 552(b)(4). And Exemption 6 permits agencies to withhold or redact "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6).

To ensure protection of this information and other information that is exempt from disclosure under FOIA, government agencies must carefully review all records and redact exempt information before the records are released to the FOIA requester. *See Daily Caller v. Dep't of State*, 152 F. Supp. 3d 1, 14 (D.D.C. 2015) (stating that the government must balance the public's interest in disclosure "with equally important public and private interests in safeguarding potentially sensitive information"); *see also Gahagan v. DOJ*, No. CIV.A. 13-5526, 2014 WL 2158479, at *7 (E.D. La. May 23, 2014) ("'It must be remembered that once there is disclosure, the information belongs to the general public. There is no mechanism under FOIA for a protective order allowing only the requester to see whether the information bears out his theory, or for

proscribing its general dissemination.'") (quoting *National Archives and Records Administration v. Favish*, 541 U.S. 157, 171-175) (2004)). Indeed, government records often contain sensitive information whose disclosure may be contrary to public or private interests. *See, e.g.*, *Flightsafety Servs. Corp.*, 326 F.3d at 612 ("The document disclosure here presents a serious risk that sensitive business information could be attributed to a particular submitting business"); *Aldridge v. U.S. C.I.R.*, No. 7:00-CV-131, 2001 WL 196965, at *1 n.1 (N.D. Tex. Feb. 23, 2001) ("The sensitive information withheld consisted of IRS employees' personal information, including social security numbers, home addresses, home phone numbers, and dates of birth"); *True the Vote v. Hosemann*, 43 F. Supp. 3d 693, 736 (S.D. Miss. 2014) ("[V]arious courts have recognized in the context of FOIA litigation that birthdates are sensitive information and have construed FOIA's 'Exemption 6' to protect the disclosure of birthdates") (collecting cases).

a. Expedited Processing

Agencies ordinarily process FOIA requests for agency records on a first-in, first-out basis. In 1996, Congress amended the FOIA to provide for "expedited processing" of certain categories of requests. *See* Electronic Freedom of Information Act Amendments of 1996, Pub. L. No. 104-231, § 8, 110 Stat. 3048 (codified at 5 U.S.C. § 552(a)(6)(E)) ("EFOIA"). Expedited processing, when granted, entitles requesters to move immediately to the front of an agency processing queue, though not ahead of requests filed previously by other persons granted expedited processing themselves. As part of EFOIA, Congress directed agencies to promulgate regulations providing for expedited processing of requests for records. Specifically, Congress directed agencies to enact regulations providing for expedited processing (i) "in cases in which the person requesting the records demonstrates a compelling need," 5 U.S.C. § 552(a)(6)(E)(i)(I); and (ii) "in other cases determined by the agency." *Id*. § 552(a)(6)(E)(i)(II).

FOIA further defines "compelling need" as either (1) "that a failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual," or (2) "[w]ith respect to a request made by a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(I)-(II). And, in carrying out FOIA's instruction to further implement these standards via regulation, FDA added the specification that, with respect to the second of these tests, the "urgency" must be "demonstrated." 21 C.F.R. § 20.44(a)(2). Specifically, in order to satisfy 21 C.F.R. § 20.44(a)(2), a FOIA requester must "demonstrate" that:

> (1) The requester is primarily engaged in disseminating information to the general public and not merely to a narrow interest group;
>
> (2) There is an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly . . . and
>
> (3) The request for records specifically concerns identifiable operations or activities of the Federal Government.

Id. § 20.44(c)(1)-(3).

In enacting EFOIA, Congress specified that the expedited processing categories should be "narrowly applied." *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.C. Cir. 2001) (quoting H.R. Rep. No. 104-795, at 26, 1996 U.S.C.C.A.N. 3448, 3469 (1996)). As the D.C. Circuit has explained,[1]

> Congress' rationale for a narrow application is clear: "Given the finite resources generally available for fulfilling FOIA requests, unduly generous use of the

[1] Courts often rely on case law concerning FOIA from the D.C. Circuit, as it is "the federal appellate court with the most experience in this field." *Cameron Corp. v. Dep't of Labor*, 280 F.3d 539, 543 (5th Cir. 2002).

> expedited processing procedure would unfairly disadvantage other requestors who do not qualify for its treatment." . . . Indeed, an unduly generous approach would also disadvantage those requestors who do qualify for expedition, because prioritizing all requests would effectively prioritize none.

Id. at 307 n.7 (D.C. Cir. 2001) (quoting H.R. Rep. No. 104-795, at 26). Likewise, Department of Justice guidance advises agencies to "carefully" assess the merits of expedited processing requests "[b]ecause the granting of a request for expedition necessarily works to the direct disadvantage of other FOIA requesters." U.S. Department of Justice, FOIA Update: OIP Guidance: When to Expedite FOIA Requests (Jan. 1, 1983), https://www.justice.gov/oip/blog/foia-update-oip-guidance-when-expedite-foia-requests.

Finally, while the burden is on the agency to sustain its action in cases involving the improper withholding of records under claimed FOIA exemptions, 5 U.S.C. § 552(a)(4)(B), the requester has the burden to "demonstrate[] a compelling need" for expedited processing. 5 U.S.C. § 552(a)(6)(E)(i); *see also Wadelton v. Dep't of State*, 941 F. Supp. 2d 120, 122 (D.D.C. 2013) (explaining that "[t]he requestor bears the burden of proof" in expedited processing cases); *Al-Fayed*, 254 F.3d at 305 n.4 (same) (citing 5 U.S.C. § 552(a)(6)(E)(i)(I) and H.R. Rep. No. 104-795, at 25).

b. FOIA's Reasonableness Requirement

Even in cases of expedited FOIA processing, "[t]he statute does not assign any particular time frame to release of the records sought." *Landmark Legal Found. v. EPA*, 910 F. Supp. 2d 270, 275 (D.D.C. 2012). Rather, the statute directs an agency to "process as soon as practicable any request for records to which the agency has granted expedited processing." 5 U.S.C. § 552(a)(6)(E)(iii); *see also, e.g.*, *Muttitt v. Dep't of State*, 926 F. Supp. 2d 284, 296 (D.D.C. 2013) ("the only relief required by the FOIA with regard to expedited processing is moving an individual's request 'to the front of the agency's processing queue'"). Indeed, expedited

consideration entitles requesters to move immediately to the front of the applicable processing queue, but *not* ahead of all other requests that have already been granted expedited processing. A Senate Judiciary Committee report explained the expedited processing provisions as follows:

> Once . . . the request for expedited access is granted, the agency must then proceed to process that request "as soon as practicable." No specific number of days for compliance is imposed by the bill since, depending upon the complexity of the request, the time needed for compliance may vary. The goal is not to get the request for expedited access processed within a specific time frame, but to give the request priority for processing more quickly than otherwise would occur.

EFOIA, S. Rep. No. 104-272, at 17 (1996), *available at* 1996 WL 262861.

Thus, even in cases where expedited processing is granted, courts evaluate whether the processing schedule is reasonable in light of other expedited FOIA requests the agency was already processing, the volume of materials, the need for agency review, and competing obligations of the same agency staffers. *See Elec. Privacy Info. Ctr.* (*"EPIC"*) *v. DOJ*, 15 F. Supp. 3d 32, 43 (D.D.C. 2014).

2. Relevant Agency Regulation

The application for FDA approval of a vaccine is called a biologic license application ("BLA"). Once a vaccine is approved by FDA for specific conditions of use (including for one or more "indications"), the applicant of the vaccine may submit a supplemental BLA ("sBLA") if it seeks approval of a new indication. FDA's regulation at 21 C.F.R. § 601.51 governs the confidentiality of data and information in biological product files. Biological product files include all data and information submitted with or incorporated by reference in any BLA as well as certain other related records.[2] Section 601.51 outlines how the agency should treat the information in a

[2] Section 601.51(a) provides that "the biological product file includes all data and information submitted with or incorporated by reference in any application for a biologics license, IND's incorporated into any such application, master files, and other related submissions."

biological product file throughout the "lifecycle" of the BLA or sBLA to which the biological product file corresponds. Information related to the development of a new biological product is of great commercial sensitivity, and pursuant to this regulation, FDA does not disclose such information unless and until the biological product is approved. Thus, while a BLA/sBLA remains pending before FDA, its corresponding biological product file cannot be disclosed.[3]

After a license for a biological product has been issued, section 601.51(e) provides that several enumerated categories of information within the biological product file lose their regulatory confidentiality and become "immediately *available* for public disclosure." 21 C.F.R. § 601.51(e)(1)-(8) (listing the applicable categories of data and information) (emphasis added). Under this provision, the specified categories of data and information lose their across-the-board confidentiality protections, such that they are now *available* for public disclosure, upon request, just like any other public record within the parameters of FOIA. The provision does not, however, require the immediate *publication* of such information.

Like any other agency record within the parameters of FOIA, records that may include information and data listed in Section 601.51(e) must be carefully reviewed to determine whether one or more FOIA exemptions apply. Section 601.51(e) itself limits disclosure of several types of information if such information falls within certain categories protected by FDA's regulations. *See* 21 C.F.R. §§ 601.51(e)(2), (3), (5), (6), (7). The regulation also expressly states that certain other types of information in the biological product file for an approved BLA are not available for

[3] Specifically, prior to the approval of a given BLA, FDA will not disclose even the mere *existence* of the BLA "unless it has previously been publicly disclosed or acknowledged," nor will FDA disclose any "data or information in the biological product file." 21 C.F.R. § 601.51(b), (c); *see* Decl. of Beth Brockner Ryan ("Brockner Ryan Decl.") ¶ 37. Even where the existence of a biological product file is "publicly disclosed or acknowledged before a license has been issued," FDA will not disclose any "data or information contained in the file," outside narrow circumstances not relevant here. *Id.* § 601.51(d)(1).

public disclosure, even after an application is approved. *See* 21 C.F.R. § 601.51(f). The categories of information not available for public disclosure can be intermingled with the types of information available for disclosure under 21 C.F.R. § 601.51(e).

III. FACTUAL BACKGROUND

1. Plaintiffs' FOIA Requests

As detailed in the Declaration of Sarah B. Kotler, FDA's Director of its Division of Freedom of Information ("DFOI"), *see* Decl. of Sarah B. Kotler ("Kotler Decl."), ¶ 22, Plaintiffs collectively submitted three FOIA requests to the agency:

First Request: On February 23, 2022, Plaintiff PHMPT submitted a request seeking expedited processing of "[a]ll data and information for the Moderna Vaccine enumerated in 21 C.F.R. § 601.51(e), with the exception of publicly available reports on the Vaccine Adverse Events Reporting System ['VAERS']" (citation omitted). FDA assigned this request control number 2022-1614 (hereafter, "First Request"). Complaint, Ex. 1.

Second Request: On August 8, 2022, Plaintiff PHMPT submitted a request seeking expedited processing of "[a]ll data and information for the 12-15-Year-Old Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e), with the exception of publicly available reports on [VAERS]" and excluding "any data and information responsive to and being produced in FOIA Control # 2021-5683 (previously made on behalf of PHMPT)"[4] (citation omitted). FDA assigned this request control number 2022-5812 (hereafter, "Second Request"). Complaint, Ex. 5.

Third Request: On August 22, 2022, Plaintiffs Stephanie and Patrick de Garay submitted

[4] FOIA Control # 2021-5683 is the FOIA request at issue in the *PHMPT 1* litigation.

a request materially identical to Plaintiff PHMPT's August 8, 2022 request.[5] FDA assigned this request control number 2022-6129 (hereafter, "Third Request"). Complaint, Ex. 8.

DFOI, the office responsible for FDA's compliance with FOIA, assigned the requests to FDA's Center for Biologics Evaluation and Research ("CBER") for processing because they sought information (biological product file records) in CBER's custody (Kotler Decl. ¶¶ 8, 24). On behalf of FDA, DFOI also denied Plaintiffs' requests for expedited processing. *See* Complaint, Exs. 2, 6, and 8; Kotler Decl. ¶ 25. On June 1, 2022, Plaintiff PHMPT appealed FDA's denial of expedited processing of the First Request.[6] *See* Complaint, Ex. 3.

2. Plaintiffs' Complaint and the Parties' Negotiations

On October 11, 2022, Plaintiffs PHMPT and the de Garays filed the complaint in this action. Doc. 1. After FDA filed its answer on January 6, 2023, Doc. 17, the parties began discussions concerning the scope of the requests and the production of the non-exempt portions of the records responsive to the requests. *See* Doc. 20 (Joint Scheduling Report). Although the full scope of records responsive to Plaintiffs' requests may not be estimated without opening and reviewing submissions and related files to determine responsiveness, portions of the BLA/sBLA should comprise the majority of records responsive to Plaintiffs' requests and are useful benchmarks for determining which types of records are of interest to Plaintiffs. Brockner Ryan Decl. ¶ 41. Thus, to assist the parties' negotiations, FDA agreed to provide Plaintiffs with materials outlining all records contained in the BLA for Spikevax submitted by Moderna and the

[5] The de Garays requested "[a]ll data and information for the 12-15-Year-Old Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System" (citation omitted). Complaint, Ex. 7.

[6] Plaintiffs did not appeal the denials of expedited processing for the Second and Third FOIA requests.

sBLA for Comirnaty's ages 12 through 15 years indication (hereafter, "the Comirnaty indication") submitted by Pfizer-BioNTech. *Id*. On February 6, 2023, FDA provided Plaintiffs with a comprehensive index of listings and page counts for Moderna's complete BLA for Spikevax. *Id*. On February 8, 2023, FDA provided Plaintiffs with a similar comprehensive index for Pfizer's complete sBLA for the Comirnaty indication. *Id*.

FDA estimated that the complete BLA for Spikevax (comprised of Moderna's original BLA and subsequent amendments leading to licensure) is approximately 4 million pages, including over 2 million pages of Case Report Forms[7] and approximately 1 million pages of unpaginated data files (using a 40 lines-per-page equivalency). *Id*. ¶ 42. FDA estimated that the complete sBLA for the Comirnaty indication (comprised of Pfizer's original sBLA and subsequent amendments leading to approval of the indication) is approximately 0.5 million pages. *Id*. Given the enormous volume of records at issue in Plaintiffs' requests (potentially approximately four times the size of responsive records in *PHMPT 1*), FDA provided these BLA/sBLA listings to Plaintiffs in an attempt to assist their focusing of the scope of their requests. *Id*. ¶ 43.

However, after receiving the listings, Plaintiffs stated they were unable to engage in discussions about the BLA/sBLA and failed to ask a single substantive question about the BLA/sBLA listings or online materials about the types of records found in BLAs provided by FDA. *Id*. Nor did Plaintiffs answer any of FDA's questions about what types of information they are most interested in. *Id*. Instead, Plaintiffs stated that they needed a page count of any responsive Investigational New Drug ("IND") records, which are separate from the drug sponsors' applications for licensure or approval of an indication. FDA explained that it is legally prohibited

[7] Case Report Forms are clinical documents designed to record information on each subject in a clinical research study.

from acknowledging the existence of portions of an IND that are not related to an approved BLA or sBLA and thus cannot provide a complete page count for the INDs until it has reviewed the records to determine which portions are able to be acknowledged and which are not. *Id*.

Subsequently, Plaintiffs unilaterally declared an impasse and requested that the Court order a production rate of at least 55,000 pages per month beginning in April 2023, or alternatively, a briefing schedule for the parties to brief their proposed production schedules (Doc. 22). The Court granted Plaintiffs' request for a briefing schedule (Doc. 23). On March 8, 2023, Plaintiffs filed their brief proposing a production schedule (hereinafter, "Plaintiffs' Br."). Doc. 24.

3. FDA's Proposed Production Schedule

FDA maintains that it would be in the interest of all parties for Plaintiffs to narrow the scope of their FOIA requests, and FDA remains committed to engaging in such discussions. Nevertheless, FDA provides the following proposed production schedule that assumes Plaintiffs will not be adjusting the scope of their requests.

First, FDA proposes that production in this case begin no earlier than January 2, 2024, or 60 days after the completion of the final production in *PHMPT 1*, whichever date is later. Brockner Ryan Decl. ¶ 46. *PHMPT 1* is currently estimated to be completed in approximately November 2023. *Id*. ¶ 24. This timing would allow FDA time to transition from its substantial productions in *PHMPT 1* and reorganize its resources to begin to set up the records and research that will be required to process potentially responsive records for this action. *Id*. ¶ 46.

Second, FDA proposes monthly production rates that account for differences in how quickly different types of documents can be reviewed and are informed by CBER's experiences reviewing records in *PHMPT 1*:

- 16,000 pages of the unpaginated data files; or

- 8,000 pages of CRFs; or
- 1,000 pages of application files; or
- A combination of the three types of records that are equivalent (for example, 500 pages of application files and 8,000 pages of unpaginated data files).

Id. ¶ 48. As explained below, these proposed production rates represent a significant allocation of CBER's staff resources to Plaintiffs' requests while reasonably balancing CBER's responsibilities to other FOIA requesters and FOIA litigation matters and its consideration of the resources available to perform these specialized reviews.

IV. ARGUMENTS AND AUTHORITIES

For the reasons explained below, this Court should adopt FDA's proposed production schedule. First, Plaintiffs are not entitled to expedited processing of their requests because they have failed to demonstrate a "compelling need" under 5 U.S.C. § 552(a)(6)(E)(i)(I). Second, even if Plaintiffs are entitled to expedited processing, FOIA still mandates that a production schedule be "practicable" under 5 U.S.C. § 552(a)(6)(E)(iii). While FDA's proposed production schedule satisfies FOIA's requirement of reasonableness by balancing CBER's responsibility to other FOIA requesters (as well as Plaintiffs) and accounting for CBER's current workload constraints, Plaintiffs' proposal would severely undermine the mission and operations of CBER's FOIA-processing branch, ALFOI (Access Litigation and Freedom of Information Branch), and affect the agency's public health mission.

1. Plaintiffs' Requests are Not Entitled to Expedited Processing

As an initial matter, FDA correctly determined that Plaintiffs' requests are not entitled to expedited processing under the applicable standards established by FOIA and agency regulations. In narrowly applied and exceptional situations (*see Al-Fayed*, 254 F.3d at 310), FOIA allows

agencies to prioritize certain requests where, as relevant here, a requester establishes a "compelling need" under 5 U.S.C. § 552(a)(6)(E)(i)(I). To establish a "compelling need," a requester must either show: (1) "that a failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual," or (2) "[w]ith respect to a request made by a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(I)-(II). FDA's regulations further provide that a FOIA requester must "demonstrate" that: (1) the requester is primarily engaged in disseminating information to the general public and not merely to a narrow interest group; (2) there is an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly . . . and (3) the request for records specifically concerns identifiable operations or activities of the Federal Government. 21 C.F.R. §§ 20.44(a)(2), (c)(1)-(3). Expedited consideration entitles requesters to move to the front of the applicable processing queue, but not ahead of all other requests that have already been granted expedited processing.[8]

FDA properly found that Plaintiffs had not demonstrated an "urgency to inform" or "imminent threat" and thus did not show a "compelling need" for expedition. *See* Kotler Decl. ¶¶ 26–27. In denying expedited processing for the three requests, FDA noted, among other things, that large amounts of information about the Spikevax and Comirnaty vaccines had already been made available to the public and that information was continually updated on FDA's website, as well as the Centers for Disease Control and Prevention ("CDC") website. *See id.* ¶¶ 26, 29. The

[8] In *PHMPT 1*, the Court found that "expeditious completion of Plaintiff's request is not only practicable, but necessary," *see* 4:21-cv-1058 (Doc. 35), and its Order effectively required FDA to move the *PHMPT 1* FOIA request to the front of the FOIA queue immediately. Given that processing in *PHMPT 1* has not been completed, the instant case thus should not move ahead of *PHMPT 1* in the queue.

large amount of information related to the COVID-19 vaccines on FDA's website is described in further detail in the Kotler Declaration (¶¶ 11-21). FDA also explained that differing opinions regarding FDA-regulated products do not create an "urgency" for disclosure within the meaning of the expedited processing standard. *Id.* ¶ 30. Indeed, there are almost always persons who are administered approved products shortly after approval, but that does not itself create an urgency. *Id*. Thus, because Plaintiffs had not established an urgency to inform the public or an imminent threat to the life/physical safety of an individual, FDA determined that Plaintiffs had not demonstrated a compelling need under 5 U.S.C. § 552(a)(6)(E) for expedited processing. *Id*.

For much the same reasons set forth in the Kotler Declaration, the Court should likewise deny Plaintiffs' request for expedited processing. First, like FDA, the Court should assess this request against the backdrop of the substantial amounts of information about the Comirnaty and Spikevax vaccines that the government has already made available to the public. Among other things, FDA's website provides a variety of information explaining the bases for approving the vaccines, including the Action Packages for Comirnaty and Spikevax (composed of materials that FDA expects are the most useful to the public in understanding the approval decisions, including decision and clinical/statistical review memoranda, approval letters, and other approval history documents), webcasts of FDA's Vaccines and Related Biological Products Advisory Committee meetings, package inserts (providing information about clinical trials and adverse reaction frequency in study participants of different ages), and Fact Sheets for Healthcare Providers. Kotler Decl. ¶¶ 15-19. This information comprises the most relevant and current information about the COVID-19 vaccines. *Id*. ¶ 21. CDC also provides the public with access to its WONDER database, which continually updates adverse event report data collected through the U.S. Vaccine Adverse Event Reporting System. *Id*. ¶ 20. The amount of substantive, detailed information on

these websites on the same topics encompassed by Plaintiffs' FOIA requests thus undermine any arguable justification to put Plaintiffs' request at the front of FDA's processing queue, ahead of the many hundreds of pending requests that pre-dated it.

Second, the fact that people have received COVID-19 vaccines and may have different opinions about the vaccines does not create an urgency under FOIA or the agency's regulations. Kotler Decl. ¶ 30. FDA regularly approves medical products and such products may be the subject of substantial controversy, so public debate about an FDA-regulated product does not create an "urgency" within the meaning of the expedited processing standard.[9] *Id*. While Plaintiffs claim that continued vaccine mandates create an urgency for disclosure, *see* Plaintiffs' Br. at 16-17, these claims are largely outdated as mandates have been stayed or withdrawn.[10] Additionally, the COVID-19 national emergency and public health emergency declared by the Trump

[9] In support of Plaintiffs' urgency arguments, Plaintiffs' Brief contains allegations regarding the health status of Plaintiffs Patrick and Stephanie de Garay's minor child and FDA's alleged lack of response to inquiries involving the child's health. Plaintiffs' Br. at 6-7. Although FDA lacks knowledge about the child's current health status (and in any event, would not be able to disclose any identifying health information about an individual), FDA notes that it is currently in the process of producing COVID-19 vaccine-related records to the de Garays in another FOIA suit. *See De Garay v. HHS*, 1:22-cv-512 (S.D. Ohio), Doc. 16.

[10] For example, the COVID-19 vaccine mandate for members of the Armed Forces has been rescinded. Secretary of Defense, *Memorandum: Rescission of August 24, 2021 and November 30, 2021 Coronavirus Disease 2019 Vaccination Requirements for Members of the Armed Forces* (January 10, 2023), *available at* https://media.defense.gov/2023/Jan/10/2003143118/-1/-1/1/SECRETARY-OF-DEFENSE-MEMO-ON-RESCISSION-OF-CORONAVIRUS-DISEASE-2019-VACCINATION-REQUIREMENTS-FOR-MEMBERS-OF-THE-ARMED-FORCES.PDF. Further, the vaccine mandate for federal employees has been stayed nationwide. *See Feds for Med. Freedom v. Biden*, No. 22-40043, 2023 WL 2609247, at *16 (5th Cir. Mar. 23, 2023). And the vaccine mandate for federal contractors has been partially stayed. *See Georgia v. President of the United States*, 46 F.4th 1283, 1308 (11th Cir. 2022).

Moreover, the Supreme Court has stayed the Occupational Safety and Health Administration (OSHA) rule mandating that employers with more than 100 employees require the employees to either undergo COVID-19 vaccination or weekly testing. *Nat'l Fed'n of Indep. Bus. v. DOL, OSHA*, 142 S. Ct. 661, 666 (2022).

Administration in 2020 will expire on May 11, 2023. *See* Exec. Off. of the President, Statement of Administration Policy Re: H.R. 382 & H.J. Res. 7 (Jan. 30, 2023).

Third, while FDA agrees that the COVID-19 pandemic and its associated vaccines are of paramount importance, Plaintiffs have not established how an unfocused release of millions of pages of highly technical records here satisfies an urgency to inform the public. Indeed, Plaintiffs have not explained how the unfocused release of hundreds of thousands of pages of Comirnaty records in *PHMPT 1* (the closest corollary to this matter) has informed the public in an effective manner.

Other courts have denied requests for expedition where plaintiffs have made similar insufficient showings that they meet the applicable statutory and regulatory standard. For example, in *Treatment Action Group v. FDA*, the U.S. District Court for the District of Connecticut denied a request for expedited processing of FDA records related to the approval of a new drug for the treatment of Hepatitis C viruses whose warning labels had been changed several times to include additional side effects. *See* No. 15-CV-976, 2016 WL 5171987, at *1 (D. Conn. Sept. 20, 2016). The court acknowledged that, while millions of people in the United States were infected with Hepatitis C viruses, the plaintiff had not shown an urgency to inform the public where it presented several news or journal articles discussing the drug; neither had the plaintiff shown an imminent threat to the life or safety of an individual despite the hundreds of thousands of people who were potential recipients of the drug. *Id*. at *7-*8. The court also noted that the plaintiff had not shown how any alleged medical problems caused by the drug could be "immediately solved by access to the requested information." *Id*. at *7.

Finally, the Court should bear in mind that any grant of expedition necessarily comes at the expense of other requesters who are pushed back in the queue. Granting expedition liberally

amounts to no expedition at all. *See Al-Fayed*, 254 F.3d at 307 n.7 (noting that "an unduly generous approach" to expedition requests would "disadvantage those requestors who do qualify for expedition, because prioritizing all requests would effectively prioritize none").

Accordingly, Plaintiffs are not entitled to the expedition they seek.

2. FDA's Proposed Production Schedule Satisfies FOIA's Reasonableness Requirement and Plaintiffs' Proposed Production Schedule Does Not.

Even in cases where expedited processing is granted, courts evaluate whether the processing schedule is "practicable" or reasonable in light of other expedited FOIA requests the agency is already processing, the volume of and complexity of the records, the need for agency review, and the agency's resources. *See EPIC*, 15 F. Supp. 3d at 43. This is consistent with the spirit of expedition under the FOIA statute, which "does not assign any particular time frame to release of the records sought." *Landmark Legal Found. v. EPA*, 910 F. Supp. 2d 270, 275 (D.D.C. 2012). Rather, the statute directs an agency to "process as soon as practicable any request for records to which the agency has granted expedited processing." 5 U.S.C. § 552(a)(6)(E)(iii); *see also, e.g., Muttitt v. Dep't of State*, 926 F. Supp. 2d 284, 296 (D.D.C. 2013) ("the only relief required by the FOIA with regard to expedited processing is moving an individual's request 'to the front of the agency's processing queue'"). A Senate Judiciary Committee report explained the expedited processing provisions as follows:

> Once . . . the request for expedited access is granted, the agency must then proceed to process that request "as soon as practicable." No specific number of days for compliance is imposed by the bill since, depending upon the complexity of the request, the time needed for compliance may vary. The goal is not to get the request for expedited access processed within a specific time frame, but to give the request priority for processing more quickly than otherwise would occur.

EFOIA, S. Rep. No. 104-272, at 17 (1996), available at 1996 WL 262861.

"Courts have broad discretion to determine a reasonable processing rate for

a FOIA request." *Harrington v. FDA*, 581 F. Supp. 3d 145, 150 (D.D.C. 2022) (citing *Colbert v. FBI*, No. 16-1790, 2018 WL 6299966, at *3 (D.D.C. Sept. 3, 2018) (collecting cases)). Several factors inform that analysis. "For instance, courts have looked to the volume of requests an agency faces, how much requests to the agency have increased in recent years, the resources and capacity of the agency, other FOIA litigation in which the agency is involved, the agency's release policies, and how ordering swifter production would affect other FOIA requesters patiently waiting their turn." *Id*.; *see, e.g.*, *Colbert*, 2018 WL 6299966, at *3; *Energy Future Coalition v. Office of Mgmt. & Budget*, 200 F. Supp. 3d 154, 161 (D.D.C. 2016); *EPIC v. Dept. of Justice*, 15 F. Supp. 3d 32, 47 (D.D.C. 2014). "When determining the rate at which a federal agency must respond to FOIA requests, courts often give deference to the agency's release policies." *Colbert*, 2018 WL 6299966, at *3.

Harrington is a useful corollary to apply to this case: like the substantial resource needs of *PHMPT 1*, plaintiff Harrington's FOIA requests had effectively tied up approximately 69% of FDA's Center for Veterinary Medicine ("CVM") first-level reviewers. 581 F. Supp. 3d at 151. FDA had produced thousands of pages of records to the plaintiff in similar prior FOIA cases that he had brought against CVM, with approximately 300,000 pages remaining to review and produce in one of those cases. *Id*. FDA proposed a production schedule in which processing would pause on one of Harrington's requests in order to process records in another of his requests. *Id*. at 149. In finding that FDA's proposed production schedule was reasonable, the court looked to the "heavy FOIA-related burden that CVM is facing relative to its limited resources." *Id*. at 150. The court explained that CVM had a small FOIA staff "confronting a significant volume of both FOIA requests and litigation" and noted that CVM had a backlog of 336 FOIA requests. *Id*. Notably, the court stated that:

> As the Court has frequently mused with respect to other agencies struggling under onerous FOIA burdens, **one wonders how CVM has time to do anything other than handle FOIA requests**, particularly those from Harrington. In continuing to address FOIA, **Congress may wish to bear in mind how many hours of agency time a determined individual or entity can require**.

Id. (citing *Am. Ctr. for Law & Just. v. DHS*, No. 21-1364, 573 F. Supp. 3d 78, 81–84 (D.D.C. Nov. 10, 2021) (emphases added)).

As in *Harrington*, the processing schedule here must be "practicable" for FDA and account for CBER's FOIA backlog and resource constraints (indeed, CBER's FOIA backlog is nearly double the backlog in *Harrington*, *see* Brockner Ryan Decl. ¶ 20). For several reasons, including the expedited FOIA request in *PHMPT 1* that FDA is already processing, Plaintiffs' proposed schedule is not reasonable. And as detailed in the Declaration of Beth Brockner Ryan, the Branch Chief of CBER's ALFOI branch (¶¶ 46-51), FDA's proposed production schedule is practicable because it provides a significant allocation of resources to Plaintiffs' requests, while accounting for ALFOI's staff resource constraints (particularly its significant workload in *PHMPT 1*) and respecting other FOIA requesters in the queue who should not be prejudiced merely because Plaintiffs have the resources to file lawsuits in an effort to obtain faster processing schedules.

There has been a significant increase in the number and complexity of FOIA requests submitted to CBER in recent years. Prior to 2019, CBER was able to keep its FOIA backlog relatively low: from 2014 through 2018, CBER had an average of 47 pending FOIA requests at the end of each fiscal year. Brockner Ryan Decl. ¶ 18. Beginning in 2019, CBER began to see a dramatic increase in the number and complexity of requests it received. *Id*. ¶ 19. That increase has been exacerbated by the number of requests related to COVID-19. *Id*. Many of these new requests, including the requests at issue in this case, have sought large amounts of records that have required significant resources to process. *Id*. In 2021, CBER received 509 FOIA requests, a

73% increase from pre-2019 averages. *Id*. And in 2022, CBER received 633 FOIA requests—more than double the pre-2019 averages. *Id*.

As a result, the number of requests pending in CBER's FOIA queue has increased substantially, from 108 requests as of February 28, 2019, to 611 requests as of February 28, 2023. *Id*. ¶ 20. Indeed, around the time of Plaintiffs' first request in this litigation (FOIA Control No. 2022-1614; received February 23, 2022), CBER had over 500 pending FOIA requests. *Id*. ¶ 22. Imposing Plaintiffs' requested production schedule here would severely impact CBER's ability to reduce, or even stabilize, its lengthy queue of pending FOIA requests and allow Plaintiffs to leapfrog these hundreds of requesters who submitted their requests prior to Plaintiffs' first request (not to mention second and third requests). *Id*. The number of pending FOIA requests thus illustrates why it is particularly important that the production schedule imposed here not begin until *after* the completion of production in *PHMPT 1*, and that the schedule imposed allow CBER to substantially balance its resources among requesters in a more reasonable manner. *Id*. ¶ 23.

In addition, ALFOI has been required to respond to an increase in the number of FOIA litigation matters. *Id*. ¶ 21. Currently, there are 15 pending lawsuits regarding 20 FOIA requests received by CBER. *Id*. Some of the pending lawsuits require periodic productions pursuant to production agreements and/or court orders. *Id*. Notably, one of those cases is *PHMPT 1,* in which this Court ordered a production that, in the agency's experience, is requiring unprecedented and extraordinary resources from CBER. In *PHMPT 1*, CBER was required to produce 10,000 pages per month in March and April 2022; 80,000 pages per month in May, June, and July 2022; 70,000 pages in August 2022; and 55,000 pages per month thereafter. *Id*. ¶ 24. CBER expects that it will

complete production in *PHMPT 1* by approximately November 2023.[11] *Id.* (citing *PHMPT 1,* No. 4:21-CV-1058, Doc. 67).

Since the beginning of 2022, the majority of ALFOI's resources have been devoted to *PHMPT 1*. *Id*. ¶ 25. From March 2022 through March 2023, ALFOI produced approximately 765,000 pages of records (including application files, unpaginated data files, and case report forms).[12] *Id*. Since ALFOI began devoting most of its resources to *PHMPT 1*, the FOIA backlog increased by another 90 pending requests from the end of February 2022 to the end of February 2023. *Id*. ¶ 25. To put that number in perspective, that *increase* of 90 requests in the backlog is roughly double what the *total* backlog used to be (an average of 47 cases at the end of fiscal years 2014-2018). *Id*. ¶ 18.

FDA's efforts to comply with *PHMPT 1* come at a significant cost to CBER, taxpayers, and other FOIA requesters. Unprecedented staffing burdens have required a reorganization of regular ALFOI staff, significant hiring and training efforts, and a shifting of resources away from all other FOIA requests (which, as noted above, currently number over 600). *Id*. ¶¶ 25-26. Prior to *PHMPT 1*, ALFOI consisted of 9 regular staff (and 1 branch chief). *Id*. ¶ 29. Since this Court's production Order in *PHMPT 1*, CBER has made every effort to increase its employee levels

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[11] In an effort to backtrack from their request in the Complaint for production to begin in this case after the completion of *PHMPT 1*, Plaintiffs claim that prior to the Court's production schedule order in *PHMPT 1*, "PHMPT was misled into believing there were only around 450,000 pages to produce in *PHMPT 1*." Plaintiffs' Br. at 3. FDA maintains that it did not mislead Plaintiff PHMPT in *PHMPT 1* and, instead, was candid in explaining that there may be more responsive records than it had been able to account for at the time it was providing its initial estimates, particularly given the unknown quantity of unpaginated data files among the records to be reviewed. *See PHMPT 1,* No. 4:21-CV-1058, Doc. 67.

[12] *PHMPT 1* has also introduced obligations not captured by the monthly production quotas—the broad nature of the request there, almost identically worded to the requests in this instant matter, has required consultation with the Office of Chief Counsel about novel legal issues, such as interpretation of the regulations referenced by the request. Brockner Ryan Decl. ¶ 28.

through all possible avenues. In addition to its regular staff, CBER is currently working with 9.5 contractors (9 full-time, 1 part-time) to assist staff with *PHMPT 1* review. *Id*. The contracts for the first set of contractors are due to expire or renew in October 2023. *Id.* And CBER continues to pursue additional contractors. *Id*. Recently, CBER was able to hire 4 additional full-time employee ("FTE") government staff for one-year temporary terms. *Id*. ¶ 30. Additionally, CBER advertised for 8 detailee positions but was only able to fill 2 positions—those 2 detailees' terms recently ended. *Id*. ¶ 30. CBER was also recently approved to hire 6 additional FTE permanent staff for continued processing of *PHMPT 1* and to address its FOIA backlog due to the resources already devoted to *PHMPT 1*. *Id*. ¶ 31.

A staff that is one-third the size of the *PHMPT 1* team is now primarily handling all FOIA requests other than *PHMPT 1*. *Id*. ¶ 34. CBER has assigned 9 FTEs (4 team leads, 2 regular staff, and 2 one-year temporary staff, as well as the branch chief) and the 9.5 contractors to primarily focus on the processing of records for *PHMPT 1* litigation. *Id*. ¶ 33. By contrast, a team of 6 FTEs (one team lead, 3 regular staff, and two one-year temporary staff) primarily handle all other FOIA requests and are managing a higher workload than during the years just prior to the COVID-19 pandemic; accordingly, they are unavailable to transition to *PHMPT 1* work.[13] *Id*. ¶ 34.

Hiring and training new contractors and staff in response to *PHMPT 1* is a resource-intensive process that remains on-going. *Id*. ¶ 35. The process of advertising, recruiting, interviewing, and administrative on-boarding alone takes several months, and finding a qualified candidate is not certain. *Id*. After a new employee is on-boarded, this resource-intensive process

[13] FDA also cannot reallocate disclosure resources from components outside of CBER because, among other reasons, other FDA components' disclosure staff are already over-extended by their disclosure obligations, many of which concern products or issues similarly important to public health. *See* Kotler Decl. ¶¶ 34-49.

continues. Given that disclosure review is highly technical, it takes approximately two years for an employee to become adequately trained to fully contribute to staff resources. *Id*. In the meantime, new employees require oversight even to perform straightforward tasks and require more robust oversight to perform complex tasks, which proceed at a slow pace. *Id*. While new employees are in training, they also slow, at least initially, the efficiency of existing staff as staff spends time partnering with the new contract staff to provide training and oversight. *Id*. Thus, although CBER's continued hiring efforts represent the agency's good-faith investment to address the FOIA backlog and requests like those made by Plaintiffs, its resources for the foreseeable future remain limited by the inherent constraints of new employees.

Given the aggressive efforts needed to enable CBER to comply with the court-ordered production schedule in *PHMPT 1*, Plaintiffs' proposal that CBER meet two enormous production orders concurrently is not possible. *Id*. ¶ 26. Simply put, CBER may not be able to meet its monthly productions in *PHMPT 1* if ordered to immediately begin producing records in this case. *Id*. And making progress on the substantial FOIA backlog—or even just preventing a continuing increase in the backlog—will not be possible under Plaintiffs' proposal. *Id*.

Notably, CBER's extraordinary efforts in *PHMPT 1* should not be read to indicate that the production rate in *PHMPT 1* can be replicated. *Id*. ¶ 37. Replicating another schedule like the one in *PHMPT 1*, even if beginning after the completion of *PHMPT 1*, would adversely impact CBER's ability to reduce its growing FOIA backlog and address other COVID-19 related requests. *Id*. Diverting the bulk of its resources to a single, discrete litigation once again would come at the expense of taxpayers, CBER's budget, and the agency's overall public health mission. *Id*. Indeed, CBER estimates that the cost of contractors alone for processing records in *PHMPT 1* will total approximately $3.5 million through October 2023. *Id*. ¶ 38. The six new federal FTEs added to

ALFOI will cost an estimated $1.8 million annually, in addition to existing staff resources devoted to the case and diverted from other areas. *Id*.

As there are substantially more responsive records at issue in the instant case than those in *PHMPT 1*, and Plaintiffs appear unwilling to focus the scope of their requests, CBER expects that the current records will cost even more. *Id*. And this is significant, because money devoted once again to an unprecedented level of processing and production is then again unavailable to fund other important public health priorities, such as hiring staff to review applications for new medical products or to inspect FDA-regulated establishments, purchasing laboratory equipment to run analytical testing, or training staff on new scientific advances and technologies. *Id*. The steps CBER has taken to comply with the order in *PHMPT 1* have already placed an extraordinarily heavy burden on the agency's disclosure capability and its public health mission. *Id*. ¶ 39. Extending this type of response beyond *PHMPT 1* would dramatically compound the harm. *Id.*

Given the above considerations, FDA maintains that it would be in the interest of all parties for Plaintiffs to focus the scope of their FOIA requests. At least one court has found that "it is reasonable for FDA to ask Plaintiff to choose how he wishes his various requests to be prioritized. If that were not the case, a single requester could hobble an agency and stymie all other FOIA requesters, all without satisfying the statutory criteria for expedited processing." *Harrington*, 581 F. Supp. 3d at 151. Indeed, given the number of records already produced in *PHMPT 1* and similarity of the records at issue here, it seems fair to assume that Plaintiffs are now more knowledgeable about the types of responsive records in a BLA/sBLA and would be better-situated to meaningfully engage in discussions. Negotiating the scope of records sought is critical here because under *any* production schedule, production of several million pages of records would be extremely resource-intensive, lengthy, and expensive.

However, assuming that Plaintiffs will not be adjusting the scope of their requests, this Court should adopt FDA's proposal as "practicable": that is, it reflects what CBER believes is possible with CBER's normal staff, amplified by its recent and planned permanent hires, without diverting public funds to hiring contractors, which shifts limited resources away from the agency's public health mission. Brockner Ryan Decl. ¶ 51. FDA's proposed production rates represent a significant allocation of CBER's staff resources to Plaintiffs' requests, substantially exceeding the production rates in other FOIA cases that typically set monthly production rates at a maximum of hundreds of pages. *Id*. ¶ 49; *see, e.g.*, *Huddleston v. FBI*, No. 4:20-CV-447, 2021 WL 1837548, at *2 (E.D. Tex. May 7, 2021) (a stay of the FOIA proceedings followed by a production rate of 500 pages a month was appropriate based on the agency's strained resources and other FOIA requests); *Colbert*, 2018 WL 6299966, at *3 (the agency's "standard processing rate" of 500 pages a month was reasonable); *N.Y. Times Co. v. DOD,* No. 19-CV-9821, 2022 WL 1547989, at *2 (S.D.N.Y. Apr. 21, 2022) (a production rate of 500 pages every 60 days was practicable given the agency's FOIA resource constraints, increasing complexity of requests, increasing backlog and number of requests received, and agency's evidence of making efforts to increase its processing capacity); *Am. C.L. Union v. DHS*, No. 20-CV-10083, 2021 WL 5449733, at *2 (S.D.N.Y. Nov. 19, 2021) (the 500-page per month processing rate proposed by the government was reasonable, with production estimated to be completed within 18 months).

In *Huddleston v. FBI*, the Eastern District of Texas granted the agency's requested stay of the FOIA proceedings and production schedule of 500 pages a month, stating that "Defendants make clear that the strained resources of their departments and significant volumes of other FOIA requests should allow for production at a standardized rate of 500 pages per month" and noted that the agency had provided a timeline for production. No. 4:20-CV-447, 2021 WL 1837548, at *2

(E.D. Tex. May 7, 2021). The court emphasized that many courts had found a production rate of 500 pages "reasonable." *Id*. (collecting cases). Similarly, in a FOIA case brought against the Department of Homeland Security, the District Court for the Southern District of New York held that the government's proposed 500-page processing rate was reasonable and a 1,000-page per month processing rate would be impracticable because COVID-19 had adversely affected staffing and workload constraints and FOIA requests to DHS had increased substantially between 2017 and 2020. *Am. C.L. Union*, 2021 WL 5449733, at *1.

Like the agencies in the above cited cases, FDA has provided evidence of its resource constraints and attempts to increase processing capacity. FDA's proposal equitably balances CBER's responsibilities to other FOIA requesters and FOIA litigation matters and its consideration of the resources available to perform these specialized reviews. Brockner Ryan Decl. ¶ 51. It provides for substantial productions each month without monopolizing ALFOI's resources to the detriment of other important agency functions and other COVID-19 FOIA requests. *Id*. Ordering anything more is not sustainable for the agency, other FOIA requesters, and taxpayers. *Id*.

To the extent Plaintiffs take issue with the amount of time it may take to produce all records sought, Plaintiffs bear the sole responsibility for the enormously broad scope of their requests. Plaintiffs can still engage in substantive negotiations with FDA to determine which types of documents are of greatest importance or interest to them. *Cf. Am. Ctr. for Law & Justice v. DHS*, 573 F. Supp. 3d 78, 84 (D.D.C. 2021) (dismissing overly broad request and noting that, due to certain unintended incentives created by FOIA, requesters often, and perversely, have "everything to gain and little to lose from posing broad, complicated FOIA requests," which has, in turn, engendered substantial FOIA backlogs across the federal government). CBER always stands

willing to discuss ways to provide Plaintiffs with the information of greatest importance to them while also respecting the agency's limited resources.

V. CONCLUSION

FDA acknowledges the importance of the requests at issue here and in *PHMPT 1*. The agency is committed to continuing to comply with this Court's Order in *PHMPT 1* and to processing Plaintiffs' requests in this matter as soon as practicable. But the growing backlog of hundreds of other FOIA requesters, including many who submitted their requests prior to the requests in the instant matter, cannot be ignored. Moreover, the agency continues to make all possible efforts to increase hiring, training, and efficiency, but there is a limit to how much even these unprecedented efforts can bear. FDA's proposed production schedule accounts for what is practicable, reflecting the importance of the materials requested by Plaintiffs but also respecting other requesters and the agency's many constraints as outlined above. Plaintiffs' proposal is not just impracticable, but impossible without severely impacting the agency's ability to respond to other important obligations, including this Court's own Order in *PHMPT 1*. FDA urges this Court to adopt its proposed production schedule in full.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

On March 31, 2023, I electronically filed the above brief regarding FOIA production schedule with the clerk of court for the U.S. District Court, Northern District of Texas. I certify that I have served all parties electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/ Clay R. Mahaffey
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