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

DECLARATION OF BETH BROCKNER RYAN

I, Beth Brockner Ryan, hereby declare as follows:

1. I am the Branch Chief of the Access Litigation and Freedom of Information Branch ("ALFOI"), Division of Disclosure and Oversight Management ("DDOM"), Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research ("CBER"), United States Food and Drug Administration ("FDA"), in Silver Spring, Maryland. CBER is the center in FDA that regulates biologics such as blood, vaccines, gene therapy, and human cells, tissues, and cellular and tissue-based products. DDOM is composed of the ALFOI, the Congressional and Oversight Branch, and the Electronic Disclosure Branch.

2. As the Branch Chief of ALFOI, I have supervisory responsibility for, among other things, the review and disclosure of CBER-maintained documents in response to Freedom of Information Act ("FOIA") requests. I have served as the Branch Chief of ALFOI for approximately twenty years. Prior to that, I was a Consumer Safety Officer in the Congressional

and Oversight Branch for three years. Before that, I was a Biologist in CBER's Office of Blood Research and Review for ten years.

3. ALFOI is primarily responsible for the review and disclosure of CBER-maintained documents in response to FOIA requests and FOIA litigation. ALFOI may also, at times, be responsible for other litigation-related document requests. Litigation-related document production covers disclosure in response to discovery requests and third-party subpoenas. ALFOI also responds to consultation requests from other federal agencies and other FDA components that are processing FOIA requests for records that contain information related to CBER. These records need to be reviewed, redacted, and returned to the original government entity for production.

4. The statements contained in this declaration are based upon my personal knowledge, and upon information I have learned in my official capacity.

5. The purpose of this declaration is to explain ALFOI's process for handling FOIA requests, to explain ALFOI's receipt and handling of the FOIA requests submitted by Plaintiffs Public Health and Medical Professionals for Transparency ("PHMPT") and Stephanie and Patrick de Garay (collectively, "Plaintiffs' requests"),[1] and to explain the basis for CBER's proposed production schedule in this matter.

6. As explained below, in recent years, CBER has experienced a dramatic increase in the volume and complexity of incoming FOIA requests, leading to a significant growth in the number of pending FOIA requests over the past five years. This surge began in 2019 and accelerated in 2021, largely due to requests related to FDA's work involving the COVID-19 pandemic. CBER has also experienced an increase in administrative appeals of FOIA

[1] As explained in the Sarah Kotler Declaration (¶ 8), these requests were assigned FOIA Control Numbers 2022-1614, 2022-5812, 2022-6129.

determinations and FOIA litigation over the last several years. Importantly, since the beginning of 2022, CBER's resources have been marshaled to comply with this Court's Order in *Pub. Health & Med. Pros. for Transparency v. FDA*, No. 4:21-CV-1058 ("*PHMPT 1*").

7. FDA's proposal to begin production after the end of *PHMPT 1* is not only consistent with what I understand Plaintiffs requested in the Complaint, but also accounts for CBER's obligation to comply with this Court's Order in *PHMPT 1* and increases in other FOIA responsibilities, including other pending FOIA litigation. FDA's proposed monthly production rate (of 16,000 pages of unpaginated data files; or 8,000 pages of Case Report Forms; or 1,000 pages of application files; or an equivalent combination, as more fully laid out below in paragraphs 37-41) accounts for differences in how quickly different types of documents can be reviewed and the need to balance the importance of Plaintiffs' requests with CBER's other important disclosure responsibilities, particularly FOIA requests from other members of the public. Plaintiffs' request to begin production in April 2023 (concurrently with continued production in *PHMPT 1*) is simply not reasonable given the number of resources that must be dedicated to *PHMPT 1* to meet the monthly production quotas. And Plaintiffs' proposal to require production of at least 55,000 pages per month in this litigation, even if imposed after the end of *PHMPT 1*, would divert significant resources away from the processing of other FOIA requests that are also in litigation and FOIA requests that are ahead of Plaintiffs' in CBER's FOIA queues. Such diversion would severely undermine the agency's ability to meet stipulated and/or court-ordered document processing deadlines and prejudice other pending requests – many of which also relate to COVID-19.

LEGAL OBLIGATIONS TO PROTECT CONFIDENTIAL INFORMATION

8. The majority of documents responsive to FOIA requests received by CBER contain information that is exempt from disclosure (for example, trade secret, confidential commercial, and/or personal privacy information). The Federal Food, Drug, and Cosmetic Act ("FDCA")

prohibits the release of trade secret information to persons other than Department of Health and Human Services employees, to Congress, or to the courts where relevant in cases brought under the FDCA. 21 U.S.C. § 331(j). The Trade Secrets Act prohibits the release of trade secret information unless otherwise authorized by law. 18 U.S.C. § 1905. In addition, FDA regulations provide, *inter alia*, that: (a) trade secret and privileged or confidential commercial information is unavailable for public disclosure; and (b) identifying information in medical or similar files, which, if disclosed, would be an unwarranted invasion of personal privacy, is unavailable for public disclosure. 21 C.F.R. §§ 20.61, 20.63, respectively.

9. Consistent with these requirements to protect confidential information, FOIA exempts several categories of information from its disclosure requirements. 5 U.S.C. § 552(b). For example, FOIA exempts from its disclosure requirements: trade secrets and confidential commercial or financial information obtained from a person, 5 U.S.C. § 552(b)(4); and personnel, medical, and similar files if disclosure would result in a clearly unwarranted invasion of personal privacy, 5 U.S.C. § 552(b)(6).

10. As a result, it is important for FDA to perform a careful line-by-line, word-by-word review of all responsive records before producing them in response to a FOIA request to ensure exempt material is not disclosed.

ALFOI'S PROCESS FOR HANDLING FOIA REQUESTS

11. FOIA requests for CBER-maintained documents are forwarded from FDA's Division of Freedom of Information ("DFOI") in the Office of the Executive Secretariat, Office of the Commissioner, FDA. ALFOI places each request in one or more of six queues of pending requests, based on the complexity and/or subject matter of the requested documents. Requests in each queue are generally assigned to reviewers for processing on a first-in, first-out basis.

ALFOI's queues consist of the Fast, Simple, 510(k), Adverse Event, Influenza, and Complex Tracks. The Adverse Event and Influenza queues have simple and complex sub-queues. Requests related to FDA's work regarding the COVID-19 pandemic could fall under any of the Fast, Simple, Adverse Event, or Complex queues.

12. When a request is assigned to a reviewer for processing, the reviewer must search for and collect potentially responsive records from various file locations, including hard copy and electronic filing systems. In addition, a reviewer may need to contact CBER personnel and direct them to search their individual files. After the reviewer collects potentially responsive records, s/he conducts an initial review to verify that the records are, in fact, responsive to the requests. Records available only in hard-copy are scanned into electronic files. Next, the reviewer conducts a line-by-line, word-by-word disclosure review of the responsive records to determine which, if any, FOIA exemptions apply, and then electronically redacts the material, as appropriate. ALFOI's review often requires research to evaluate whether certain information falls within a FOIA exemption. For example, an ALFOI reviewer may perform online research to determine whether certain information has been made public (i.e., is not "confidential"). Time devoted to such research is important as the reviewer works carefully to protect what is required by law while also working to provide the public with as much transparent content as possible. The reviewer must also ensure that redaction determinations are consistent throughout his/her review of responsive records—an exercise that grows in complexity with large volumes of responsive records.

13. ALFOI may consult with FDA's Office of the Chief Counsel to resolve questions on complex or novel disclosure issues. In recent years, this has become an increasingly necessary step, as FOIA requests received by CBER have increased in complexity and scope. ALFOI may

also consult with the submitter of requested records, particularly where required by its regulations. *See* 21 C.F.R. § 20.61(e) (outlining pre-disclosure notification process for certain records, to include review time by the submitter). After consultation or notification, as appropriate, the reviewer conducts a quality control check to ensure that the responsive records have been properly prepared for public disclosure and, finally, prepares copies of the responsive records for delivery to the requester. Throughout the process, the DDOM director or I may provide substantive input regarding the search's scope and whether portions of the records may be disclosed, including the handling of novel disclosure issues.

14. Additionally, if a document contains information belonging to other equity holders, such as other federal agencies, FDA will send that document out to the relevant federal agencies for consultation. These consultations can occur more than once in the review process and inform FDA's determination about the applicability of any FOIA exemption.

15. After the necessary review and internal and external consultations have been performed, records may be transmitted to FDA's Office of the Chief Counsel and the Department of Health and Human Services' Office of General Counsel for legal defensibility review. This process can also involve the U.S. Department of Justice counsel for matters that are in litigation. Once that legal review is completed, a senior FOIA reviewer conducts a quality control review to ensure that the responsive documents have been properly prepared for public disclosure.

16. To produce documents in response to court orders, reviewers perform all review tasks in paragraphs 12-15, plus additional steps that can increase, by at least two-fold, the time to process the request. The extra responsibilities associated with litigation-related document

production typically include Bates-stamping, preparing for creation of a *Vaughn* Index[2] or privilege log, and conducting a quality control check of the index/log to assure its accuracy and completeness. The strict timetables generally set for producing documents in response to FOIA litigation require ALFOI to shift resources away from processing other FOIA requests.

17. When estimating processing rates for disclosure of records under FOIA, the agency must account for steps listed in paragraphs 12-15 and ensure that there is adequate time for a careful review that will help ensure that all confidential information is protected while all releasable information is disclosed. ALFOI typically estimates that it will take approximately eight minutes per page to perform the review tasks listed in paragraphs 12-15 and produce records to the requester. Factors that affect the rate of production include the amount of sensitive information contained in the records and the amount of research or consultation with others outside of ALFOI needed for review. Based on ALFOI's review of comparable Biological Product File ("BPF") records in *PHMPT 1*, I estimate that (i) unpaginated data files, and (ii) case report forms ("CRFs"), which, generally, are records of the clinical trial experience for participants, may be reviewed and produced more quickly than the average estimated rate of eight minutes, while other records in the application files, which are more variable and complex (such as other submissions like Module 3 (quality) and Module 4 (nonclinical study reports) of the application), typically take at least the average rate to review.

ALFOI'S WORKLOAD

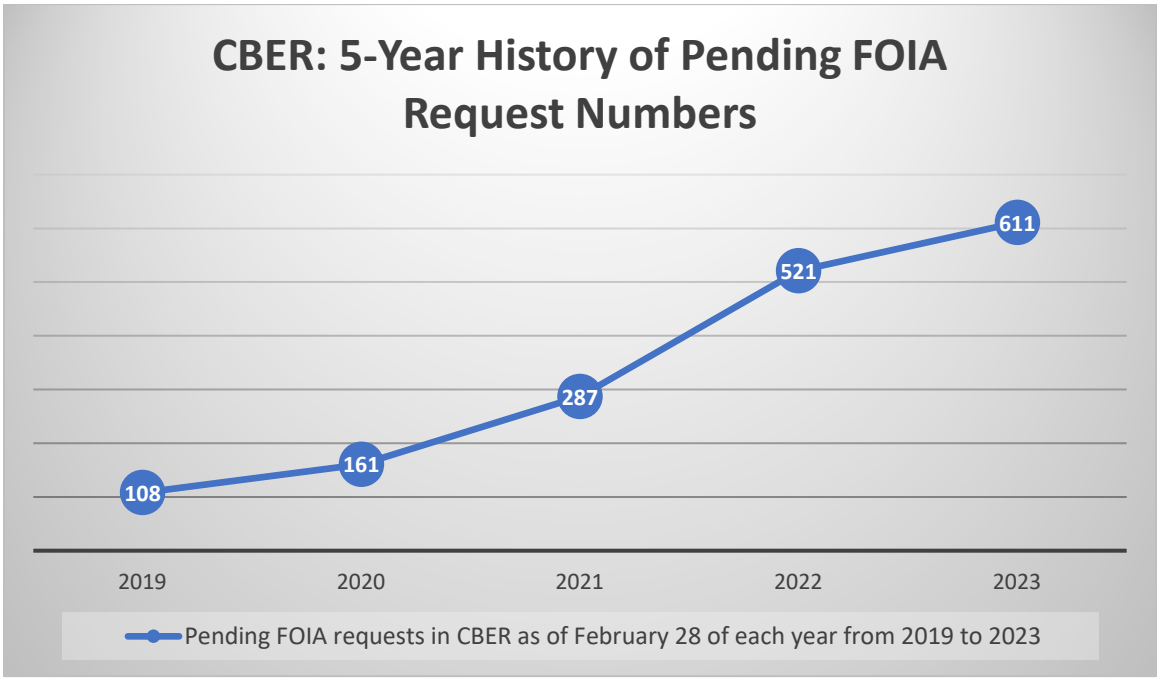
18. Prior to 2019, CBER was able to keep its FOIA queues relatively stable. From 2014 through 2018, CBER had an average of 47 pending FOIA requests at the end of each fiscal

[2] "A *Vaughn* index is a routine device through which the defendant agency describes the responsive documents withheld or redacted and indicates why the exemptions claimed apply to the withheld material." *Batton v. Evers*, 598 F.3d 169, 174 (5th Cir. 2010) (quotation omitted).

year.

19. In 2019, the number and complexity of FOIA requests received by CBER began to increase. In fiscal year 2019, CBER received 391 FOIA requests, and in fiscal year 2020, CBER received 399. By fiscal year 2021, CBER began to receive annual requests exceeding 500 (509 in fiscal year 2021 and 633 in fiscal year 2022), exacerbated by requests for records related to the COVID-19 global pandemic. Some of these more recent requests have sought unprecedented volumes of records, including the requests in *PHMPT 1* and this case, which collectively seek millions of pages of records.

20. As a result, the number of requests pending in CBER's queue has increased substantially, from 108 requests as of February 28, 2019, to 611 requests as of February 28, 2023. The following chart illustrates the increase in the number of pending FOIA requests in CBER's queue during the five previous years.



21. This litigation and *PHMPT 1* are also not the only FOIA litigation matters pending

that involve requests to which CBER is assigned. In addition to the increased volume and complexity of FOIA requests received by ALFOI, there has also been an uptick in the amount of FOIA litigation to which ALFOI has been required to respond in the last year. Some of the pending lawsuits require periodic productions pursuant to production agreements and/or court orders. Currently, there are 15 pending lawsuits regarding 20 FOIA requests received by CBER.

22. Imposing Plaintiffs' requested production schedule here would severely impact ALFOI's ability to address its now very lengthy queue of pending FOIA requests. 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. Doubtless, many of the requesters who had FOIA requests pending at CBER at the time Plaintiffs submitted their first request would insist, similarly to Plaintiffs here, that their requests are critically important and need to be processed expeditiously. As mentioned previously, many of these FOIA requests also relate to COVID-19 (but for records distinct from those at issue in the instant matter), and others relate to other biologics of importance to the public.

23. The number of pending FOIA requests 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 an equitable manner.

EFFECT OF *PHMPT 1* AND CBER'S HIRING/EFFICIENCY EFFORTS

24. In *PHMPT 1*, PHMPT (a repeat Plaintiff in the current matter) sought BPF records for Pfizer-BioNTech's Comirnaty vaccine approved for individuals 16 years of age and older. This Court ordered a production schedule of 55,000 pages every thirty days, and in February 2022, upon consideration of the agency's motion to partially modify the scheduling order to "stand up"

unprecedented and extraordinary operations to comply with the Order, the Court allowed for a graduated production schedule, which required CBER 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. To the extent CBER produced more than the required page count in any month, the Court permitted CBER to "bank" the extra pages and apply them to a later month toward its quota for that month. CBER expects that production in *PHMPT 1* will be completed by approximately November 2023.[3]

25. Since the beginning of 2022, the majority of ALFOI's resources have been devoted to reviewing the records ordered to be produced in *PHMPT 1* and managing the logistical complexities of processing records in volumes that are unprecedented for CBER. From March 2022 to December 2022, CBER produced approximately 636,000 pages in *PHMPT 1*. In January through March 2023, CBER produced another approximately 129,000 pages. These are in addition to the over 13,000 pages that CBER produced to PHMPT prior to the Court's February 2022 modified Order in *PHMPT 1*. And since ALFOI began devoting most of its resources to comply with the modified Order in *PHMPT 1*, the number of pending FOIA requests has continued to increase—indeed, the FOIA backlog increased by another 90 pending requests from the end of February 2022 to the end of February 2023.

26. CBER has worked hard to produce records as quickly as possible to the single requester in *PHMPT 1*, and it has come at significant resource costs and delay for hundreds of other requestors who are waiting to receive records related to COVID-19 or involving other biologics. Ordering similar or even greater production rates once again, to be continued for years,

[3] In *PHMPT 1*, the parties' March 2023 joint status report included this estimated date of completion. *See PHMPT 1*, No. 4:21-CV-1058, Doc. 67.

does not serve the overall goals of transparency and fairness to all. Currently, there are over 600 pending requests with more requests being received almost daily. Making progress on the FOIA backlog—or even just preventing a continuing increase in the backlog—will not be practicable under Plaintiffs' proposal. Significantly, CBER is unlikely to be able to meet its monthly production requirements in *PHMPT 1* if the Court orders FDA to immediately begin producing records in this case. In other words, complying with two significant concurrent production orders in *PHMPT 1* and this case would simply not be possible.

27. Moreover, the number of pages produced in any given month to one requester does not capture what CBER is capable of in another month for another requester—this is highly context-specific, and may be affected by the type of records being produced that month, the status of records along numerous different review tracks and at different stages of the production process, communications with the drug sponsor about those specific records, and competing constraints from other requests or litigations.

28. *PHMPT 1* has also introduced additional obligations. The broad nature of the request there (almost identically worded to the requests at issue in the 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. And because the ordered production rate in *PHMPT 1* would have been impracticable with CBER's regular staffing structure and size, CBER made immediate and aggressive efforts to recruit and train contractors and new staff, reorganize existing staff, and implement other work process changes.

29. Prior to *PHMPT 1*, ALFOI consisted of 9 regular staff (and 1 branch chief). Since this Court's production order in *PHMPT 1*, CBER has made every effort to increase its employee levels. 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. The contracts for the first set of contractors are due to expire or renew in October 2023. Additionally, CBER is still pursuing additional contractors.

30. Recently, CBER was also able to hire 4 additional full-time employee ("FTE") government staff for one-year temporary terms. Exploring all possible avenues for additional resources, CBER has additionally worked to recruit detailees from other agency components (detailees can be recruited for 120-day periods). CBER advertised for 8 detailee positions but was only able to fill 2 positions—those 2 detailees' terms recently ended in fiscal year 23 (October 2022 to September 2023).

31. Additionally, CBER was 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*. CBER has advertised and interviewed for these positions and is in the process of making initial hiring offers.

32. The re-allocation of staff was accomplished through the advertisement for and hiring of five Team Leads for temporary 2-year terms. Those temporary Team Leads were all previously part of the 9 regular staff in ALFOI.

33. Currently, CBER has assigned 9 FTEs (4 team leads, 2 regular staff, 2 one-year temporary staff, and myself, in a managing role), as well as the 9.5 contractors, to primarily focus on the processing of records for the *PHMPT 1* litigation. And currently, a team of 6 FTEs (1 team lead, 3 regular staff, and 2 one-year temporary staff) primarily handle all other FOIA requests.

34. Thus, all FOIA requests other than *PHMPT 1* are now primarily being handled by a staff of one-third the size of the *PHMPT 1* team. Moreover, the 6 remaining staff handling all non-*PHMPT 1* FOIA requests are handling a higher workload than during the years just prior to

the COVID-19 pandemic and are unavailable to transition to *PHMPT 1* work. Additionally, the numbers alone do not speak directly to capacity as the staff assigned to process these non-*PHMPT 1* FOIA requests are also generally the less experienced staff (2 of the permanent staff were hired less than 2 years ago and are in training).

35. This current declaration is being filed less than a year after ALFOI began hiring and training new contractors and staff in response to *PHMPT 1*—a resource-intensive process that remains on-going. The process of advertising, recruiting, interviewing, and administrative on-boarding alone takes several months (assuming a qualified candidate is found). After a new employee is on-boarded, this resource-intensive process continues: as disclosure review is highly technical, it takes approximately two years for the employee to become adequately trained to fully contribute to staff resources. 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. While new employees are in training, they also slow, at least initially, the efficiency of current ALFOI staff, as the current staff spends time partnering with the new contract staff to provide training and oversight. 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 lengthy ramp-up period for new employees.

36. In addition to hiring efforts, CBER continues to implement work processes to increase efficiency, including triaging FOIA requests to ensure assignment to appropriate processing tracks, posting frequently requested records on FDA's website to increase transparency, and, where appropriate, proactively contacting FOIA requesters to attempt to focus the scope of requests in order to produce documents more quickly if possible.

37. Importantly, CBER's extraordinary efforts to comply with the *PHMPT 1* Order should not be read to indicate that the production rate in *PHMPT 1* can be replicated. Setting another schedule like the one in *PHMPT 1* would adversely impact CBER's ability to reduce its growing FOIA backlog and address other COVID-19 related requests. And diverting the bulk of its resources to a single, discrete litigation would come at the expense of taxpayers, CBER's budget, and the agency's overall public health mission.

38. Indeed, CBER estimates that the cost of contractors alone for processing records in *PHMPT 1* will total approximately $3.5 million through October 2023. 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. Given that there are substantially more responsive records at issue in the instant case than those in *PHMPT 1*, CBER expects that the current records will cost even more. And this is significant, because money devoted to an unprecedented level of processing and production is then 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.

39. Thus, remaining in compliance with this Court's Order in *PHMPT 1* requires CBER to continue to prioritize the use of its resources for that litigation until production is complete. And following the conclusion of production in *PHMPT 1*, in fairness to all FOIA requesters, CBER's resources should be balanced among the other requesters in the FOIA queue as well as the Plaintiffs here. Put simply, 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. Extending this type of response beyond *PHMPT 1* would dramatically compound the

harm.

ALFOI'S HANDLING OF PLAINTIFFS' REQUESTS

40. As explained in the Sarah Kotler Declaration (¶ 22), there are three FOIA requests at issue here. On February 23, 2022, FDA received Plaintiff PHMPT's request seeking "[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']." On August 8, 2022, FDA received Plaintiff PHMPT's request seeking "[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 [PHMPT 1]." On August 22, 2022, FDA received Plaintiffs Stephanie and Patrick de Garay's request for records materially identical to those in Plaintiff PHMPT's August 8, 2022 request.[4]

41. Because the bulk of records responsive to Plaintiffs' requests should be found in portions of the Biologic License Application ("BLA") for Spikevax submitted by Moderna and portions of the Supplemental Biologic License Application ("sBLA") for Comirnaty's ages 12 through 15 years indication (hereafter, "the Comirnaty indication") submitted by Pfizer-BioNTech, ALFOI created materials outlining the records contained in the BLA and sBLA to assist the parties' negotiations. On February 6, 2023, CBER provided Plaintiffs with a

[4] The regulation cited in Plaintiffs' requests, 21 C.F.R. § 601.51(e), is not a regulation that requires immediate disclosure of any information. Rather, that regulation establishes when the specified categories of data and information in a BPF lose their across-the-board confidentiality protections and become available for public disclosure upon request (subject to review under FOIA and FDA disclosure regulations).

comprehensive index of listings and page counts for Moderna's complete BLA for Spikevax. On February 8, 2023, CBER provided Plaintiffs with a similar comprehensive index for Pfizer's complete sBLA for the Comirnaty indication.

42. ALFOI estimated that the complete BLA for Spikevax (comprised of Moderna's original BLA and subsequent amendments leading to licensure) is approximately 4 million pages. This includes over 2 million pages of Case Report Forms and approximately 1 million pages of unpaginated data files (using a 40 lines-per-page equivalency). ALFOI 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. Although the full scope of records responsive to Plaintiffs' requests cannot be estimated without opening and reviewing submissions to determine responsiveness (such as which Investigational New Drug records, if any, are incorporated into the BPF, and which portions of the BLA/sBLA fall into the categories of records specifically contemplated by 21 C.F.R. § 601.51(e), which Plaintiffs relied upon to define the scope of their requests), typically, the BLA/sBLA comprise the bulk of materials contained in a complete BPF and are thus a useful benchmark for determining which types of records are of interest to Plaintiffs.

43. Given the enormous volume of records at issue in Plaintiffs' requests, FDA provided these BLA/sBLA listings to Plaintiffs in an attempt to assist them in identifying which types of records on which they may wish to focus and potentially identifying records of lesser interest. However, Plaintiffs did not ask a single question about the BLA/sBLA listings or other explanatory materials sent by FDA. Nor did Plaintiffs answer any of FDA's questions about what types of information they are most interested in. Plaintiffs instead stated that they were unable to engage in discussions without a page count of responsive Investigational New Drug ("IND")

records (which are separate from the drug sponsors' applications for licensure or approval of an indication). But the IND page count should not prevent Plaintiffs from being able to discuss the listings of records (estimated at 4.5 million pages) provided by FDA or inquiring about the existence of records of interest and whether they reside in the BLA or IND. Moreover, as explained to Plaintiffs, FDA is legally prohibited from acknowledging the existence of portions of an IND that are not related to an approved application or supplemental application – thus, FDA is unable to 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.

44. Thus, despite FDA's good-faith efforts, Plaintiffs are unwilling to engage in negotiating a reasonable scope and production schedule. But negotiating the scope of records sought is critical here. Indeed, under *any* production schedule, production of several million pages of records would be extremely resource-intensive, lengthy, and expensive. If Plaintiffs are unwilling to engage in negotiations regarding the scope of their requests, a reasonable production rate will necessarily require that the time for full production be lengthy. Requesting higher monthly productions simply because the volume of records is so large is unfair to the many other requesters who have patiently waited for their records.

FDA'S PROPOSED PRODUCTION SCHEDULE

45. FDA maintains that it would be in the interest of all parties for Plaintiffs to narrow the scope of their FOIA requests, but provides a proposed production schedule that assumes Plaintiffs will not be adjusting the scope of their requests.

46. First, although FDA's work in *PHMPT 1* may continue after completion of production in that matter (for example, addressing objections to redactions that PHMPT may make), 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* (as noted above, currently estimated to be approximately November 2023). That should give ALFOI some time to transition from *PHMPT 1* and reorganize its resources to begin to set up the records and research that will be required to process potentially responsive records.

47. As explained above, given workload constraints, and the intricacies of line-by-line, word-by-word review to ensure compliance with applicable law and regulations, Plaintiffs' proposal that production begin concurrently with the remaining production in *PHMPT 1* would severely jeopardize the agency's ability to meet its monthly quotas in *PHMPT 1*.

48. 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 *PHMPT 1* records:

- 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).

49. These 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. These production rates also reflect an approach that more equitably balances CBER's responsibilities to other FOIA requesters/FOIA litigation matters and its consideration of the resources available to perform these specialized reviews, while allowing CBER to continue to provide a quality review that safeguards personal privacy information or confidential commercial information/trade secret information.

50. Plaintiffs' proposal that, rather than a monthly production order, this Court simply order that FDA produce the records in full by set dates is impracticable. First, as Plaintiffs acknowledge, the production rates that would likely require would be even higher than the rates in *PHMPT 1*. Moreover, it does not make sense to set a production order that works backwards—that is, that sets a deadline without even knowing the full picture of records responsive to Plaintiffs' requests. As explained in ¶ 42, determining the number of responsive records is a process that occurs in tandem with the production process (and, ideally, in this case would occur in conjunction with a requester willing to negotiate the scope of records sought).

51. FDA's proposal 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. CBER always stands willing to discuss ways to provide Plaintiffs with the information of most importance to them while also respecting the agency's limited resources. This proposal provides for reasonably prompt initiation of processing of Plaintiffs' requests at a pace that does not monopolize ALFOI's resources to the detriment of other important agency functions and other COVID-19 FOIA requests. Plaintiffs' demands that monthly productions be even faster than in *PHMPT 1* and occur concurrently with *PHMPT 1*, if granted, would create an unsustainable situation.

CONCLUSION

52. CBER is committed to continuing to comply with this Court's Order in *PHMPT 1* and is committed to processing Plaintiffs' requests in this matter as soon as practicable. FDA's proposed production schedule accounts for what is practicable—that is, rates that not only reflect the importance of the materials requested by Plaintiffs but also respect other requesters and the

agency's many constraints outlined above. Plaintiffs' proposal is not just impracticable, but impossible without severely and adversely impacting the agency's ability to respond to other record requests and production obligations, including this Court's own Order in *PHMPT 1*.

Pursuant to 28 U.S.C. § 1746, I declare under the penalty of perjury that the foregoing is true and correct.

Executed on March 31, 2023.

Beth A. Brockner Ryan -S

Digitally signed by Beth A. Brockner Ryan -S
Date: 2023.03.31 09:05:44 -04'00'

Beth Brockner Ryan
Branch Chief
Access Litigation & Freedom of Information Branch
Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
U.S. Department of Health and Human Resources