IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 4:21-cv-01058-P

MEMORANDUM IN SUPPORT OF DEFENDANT'S MOTION TO PARTIALLY MODIFY SCHEDULING ORDER

INTRODUCTION

Defendant U.S. Food and Drug Administration ("FDA") respectfully moves the Court to partially modify its January 6, 2022 Scheduling Order ("January 6 Order" or "Order"), Dkt. No. 35. As the Court itself has acknowledged, the processing rate of 55,000 pages every 30 days[1] established by the Order is "unprecedented," *id.* at 3—and FDA is, in turn, undertaking extraordinary and unprecedented steps to marshal every possible resource available to it, in its best efforts to comply, while also meeting production schedules in other FOIA litigation and continuing to process the thousands of other FOIA requests currently pending with FDA. However, as explained in detail below, and in the attached supporting declarations, the most

[1] For ease of reference, FDA will occasionally refer herein to this as the "monthly rate" established by the January 6 Order.

impactful of FDA's interventions—including, *inter alia,* the agency's plan to hire contractors, advertise agency-wide for voluntary detail assignments, and work with Pfizer-BioNTech, as appropriate, to speed the agency's review will, of necessity, require some amount of lead time to operationalize. Accordingly, FDA respectfully requests that the January 6 Order be modified to provide that—for *only* the first two 30-day periods following FDA's scheduled January 31, 2022 production—FDA's monthly quota be adjusted to 10,000 pages per month. FDA would use this period to "stand up" the extraordinary resources that will be required to bring full compliance with the Order within the realm of possibility—while still processing records at a rate on par with the most extreme processing rates that Plaintiff cited in its briefing. *See* Dkt. No. 26 p. 23 (Plaintiff's second brief in advance of the scheduling conference, listing outlier cases—the fastest of which is less than half the rate set by the January 6 Order). Under FDA's proposed modification, at the conclusion of this interim "stand up" period, *i.e.*, beginning with the FDA's production due on May 2, 2022,[2] the full 55,000-pages-per-month processing rate ordered by the Court would then apply, until production is complete.

As the below-described agency actions make clear, FDA is doing everything within its ability to attempt to comply with the January 6 Order. However, the unavoidable reality for FDA is that, until additional resources are in place, full compliance with the January 6 Order is not feasible. Even with the additional and unprecedented resources that FDA is actively marshalling, compliance with the Court's order will present extraordinary challenges. Accordingly, FDA respectfully submits that the relatively modest modification it requests is both necessary, and in

[2] Thirty days from March 31, 2022 is April 30, 2022—which, this year, falls on a Saturday. Pursuant to Fed. R. Civ. P. 6(a)(1)(C), this production will thus be due on Monday, May 2, 2022.

the public interest, in that it will afford FDA an adequate opportunity to gather, and operationalize, resources necessary to achieve compliance with the Court's Order.

ARGUMENT

I. Modification of the January 6 Order Is Necessary to Afford FDA a Period in which to "Stand Up" Unprecedented and Extraordinary Operations

A. FDA's Efforts to Channel Every Possible, Available Resource

As previewed above, FDA is not requesting additional time in order to spin its wheels, or to merely assess its options to attempt to achieve compliance with the unprecedented processing rate ordered by the Court. To the contrary, and as set forth in the Second Declaration of Suzann Burk ("Second Burk Declaration"), although FDA received the Court's January 6 Order only seven business days prior to the filing of the instant motion, the agency is already making its best efforts to comply, and is acting with maximal urgency to assemble every possible resource available to it, as well as those not yet available to it. Specifically, FDA is actively taking the following—and wholly unprecedented—steps:

- **Hiring Contractors**. FDA has initiated—at the anticipated cost of some $3 million dollars—the process of putting in place the contract and hiring a minimum of 15 full-time contractors to assist with processing responsive records. 2d Burk Decl. ¶¶ 6, 22 (APPX004, 009). FDA anticipates that, of this total, 11 contractors will assist with processing those records that do not require review for trade secret or confidential commercial information, and the remaining four contractors will have additional experience that will allow them to assist with processing more complex records. In addition to reviewing and redacting responsive records, the contractors will assist with certain administrative, but often time-consuming, steps required for final production, such as, *inter alia*, finalizing redactions and applying Bates numbers. *Id.* ¶ 6 (APPX004). FDA expects that, once these contract staff have been hired and trained, they will

significantly expand FDA's capacity to process the records at issue in this case. *Id.* ¶ 7 (APPX004).

- Although FDA is prepared to undertake the significant cost of these contractor positions—and is moving forward as expeditiously as it can to finalize and implement the relevant contract(s)—the unavoidable reality is that this process cannot occur overnight. Before the contractors can begin their work, and thus contribute to FDA's efforts to comply with the January 6 Order, FDA must first advertise for these positions, select appropriate contract staff members, and train selected workers so that they can meaningfully contribute to the review and production process. *Id.* ¶ 7 (APPX004); *see also* Declaration of Sarah B. Kotler ("Kotler Decl."), Dkt. No. No. 30, ¶ 22.

- **Details for FDA Staff.** Separately, FDA's Center for Biologics Evaluation and Research ("CBER")[3] is preparing to publish an agency-wide advertisement for eight temporary "detail" positions dedicated to processing the records at issue in this suit. 2d Burk Decl. ¶ 8 (APPX005). These details will reallocate resources currently devoted to other, important FDA work to the agency's efforts to comply with the January 6 Order. As with the contract staff described above, however, there will—of necessity—be some lag time before the detailees are able to begin contributing to this project. CBER is working to obtain the requisite approvals to publish the advertisements, and anticipates that they will post by approximately February 1, 2022. As with the contractors (and, indeed, any similar hiring or recruitment process in any workplace), CBER will need to allow time for applicants to respond to the posting, and will then need to both select detailees from the applicant pool, and provide the selected detailees with the

[3] As explained in prior filings, CBER is the FDA division that maintains the records at issue in this suit.

requisite training. CBER does not expect that agency staff selected for these details will have the requisite experience and training to immediately begin working at full capacity. *Id.* ¶ 9 (APPX005); *see also* Kotler Decl. ¶ 22.

- **Reassignment of Staff within CBER's OCOD.** Third—and in recognition that the above-described efforts will take some time to ramp up—CBER has already reallocated CBER resources and staff in order to prioritize FDA's efforts to comply with the January 6 Order. First, within CBER's Access Litigation and Freedom of Information Branch ("ALFOI"), approximately five and a half of CBER's ten "full-time equivalents" are, as of the date of this filing, dedicated to the review and redaction of records related to this litigation. 2d Burk Decl. ¶ 10 (APPX005).

Second, the Division of Disclosure and Oversight Management ("DDOM") has also already obtained the temporary reassignment of five additional staff members from other divisions of CBER's Office of Communication Outreach and Development ("OCOD")—the CBER office within which DDOM is situated—to assist ALFOI with processing Plaintiff's request, in the interim in which the above-described efforts are being ramped up. However, as with other additional personnel described above, these reassigned staff members will require training before they can work at full capacity on this project. *Id.* ¶ 11 (APPX006).

- **Assistance with Other Litigation Deadlines.** As discussed in prior filings, FDA has disclosure obligations in several other FOIA suits implicating CBER. In at least one case, where CBER had agreed to contribute 450 pages per month toward FDA's overall (and court-ordered) production quota, CBER has asked other agency components to take on extra work to allow CBER to devote more resources to this matter. Under such an arrangement, CBER would temporarily reduce its production obligation to zero in that case, so as to allow CBER ALFOI

staff that would otherwise have been working on that production to devote more time to this production. *Id.* ¶ 12 (APPX006).

- **Working with Vaccine Sponsors to Identify Records that Do Not Contain Exemption 4 Material.** FDA has also reached out to Comirnaty[4] sponsors Pfizer-BioNTech to seek its assistance, initially, in identifying sections of the biologics license application ("BLA") that do not contain any trade secret or confidential commercial information subject to FOIA Exemption 4. Once Pfizer-BioNTech has identified those sections (which FDA has requested that it do by February 1, 2022), FDA will be able to streamline its disclosure review with respect to this subset of records. Specifically, although FDA will still need to review the identified records for other types of information protected by the FOIA Exemptions (most notably, Exemption 6, which protects the privacy interests of clinical trial participants), it will not need to review this particular subset of records for the presence of trade secret or confidential commercial information. *Id.* ¶¶ 13-14 (APPX006-007).

As discussed in the earlier-filed Kotler Declaration, reviewing BLA files for trade secret and confidential commercial information requires specialized training and experience. *See* Kotler Decl. ¶ 24. Thus, by eliminating the need to review what FDA anticipates will be a large subset of the BLA for information protected under Exemption 4, FDA will be able to assign less experienced staff to work on this subset of records—thus freeing up more experienced staff to focus on the more complex portions of the records at issue. *Id.* ¶ 14 (APPX007).

In addition, FDA is actively assessing other potential ways in which it can request that the sponsors assist with streamlining the processing of the records at issue in this suit. *Id.* ¶ 15 (APPX007).

[4] Comirnaty is the product name for what is colloquially referred to as the "Pfizer vaccine."

B. FDA's Unprecedented Measures Will Take Time to Operationalize, Come at Considerable Cost to Other Critical Agency Missions, and Represent the Agency's Maximal Possible Efforts

As described above and in the Second Burk Declaration, FDA is actively and expeditiously responding to the unprecedented processing rate established by the January 6 Order by undertaking unprecedented measures, in a good faith effort to achieve full compliance. Initially, FDA is taking immediate, temporary measures to increase its processing capabilities to the maximal extent possible, in the short term. Specifically, between devoting approximately five and a half out of the ten employees currently employed by AFLOI solely to the processing of the relevant records, and temporarily re-assigning five other agency employees to assist with these efforts until additional staff can be brought on, FDA has immediately allocated the equivalent of nearly 11 full-time staff to this project. This re-allocation of resources is itself unprecedented within the agency, and will allow FDA to meet its proposed production quota of 10,000 pages per month for each of the first two months following the agency's scheduled January 31, 2022 production—a rate that is on par with the most extreme processing cited in Plaintiff's briefing. *See* First Declaration of Suzann Burk, Dkt. No. 23, ¶ 31 (estimating that if each of ALFOI's 10 staff members devoted all of their working hours solely to this production, they would be expected to produce 25,410 pages in 11 weeks, which translates to approximately 10,000 pages per month); Dkt. No. 26 p. 23 (Plaintiff's second brief in advance of the scheduling conference, collecting outlier cases).

However, in order to make compliance with the unprecedented processing rate entered by the Court even possible, FDA recognizes that it must muster additional—and extraordinary—resources. As described in detail above, FDA is moving swiftly to do so, most notably by preparing to onboard a total of 23 additional contractor and agency staff to this project, and by

requesting that Pfizer-BioNTech assist FDA by, initially, identifying those portions of the BLA that do not need to be reviewed for trade secret or confidential commercial information. *See* 2d Burk Decl. ¶¶ 6-9, 13-15 (APPX004-007). But notwithstanding that FDA is pressing forward with these efforts with maximal speed, the unavoidable reality is that some minimal threshold period of time is necessary for these endeavors to be fully operationalized, and to bear fruit. With respect to the additional staffing, FDA must advertise the positions, select qualified candidates, bring the selected candidates on board, and train them so that they can contribute to CBER's production efforts. *Id.* ¶¶ 7, 9 (APPX004-005). As a result, very few, if any, of the additional individuals needed for the FDA to achieve full compliance will be in place before the extant March 1, 2022 deadline to make a first initial production of 55,000 pages. *Id.* ¶ 19 (APPX008). Similarly, FDA expects that, once the sponsors have identified to the agency those portions of the BLA that do not need to be reviewed for Exemption 4 material, the agency will be able to streamline its review of that subset of the records. *Id.* ¶ 14 (APPX007). Further, FDA is actively assessing additional potential ways in which the agency may properly enlist and work with Pfizer-BioNTech to speed up the ultimate resolution of this matter. *Id.* ¶ 15 (APPX007). Again, however, while these efforts are actively underway, they will, unavoidably, take some time to bear tangible results.

It also bears emphasizing that, while FDA is making every possible effort to comply with the terms of the January 6 Order, the above-described measures far exceed what the agency considers tenable for the processing a single FOIA request, and, in fact, represent the absolute maximum efforts FDA can apply to this matter. *Id.* ¶ 21 (APPX009). Initially, while precise numbers are not yet available, CBER estimates that its plan to hire at least 15 contract staff will cost at least 3 million dollars—and, factoring in CBER's other above-described efforts, CBER

presently estimates that the total cost of its efforts to comply with the order will come to a cumulative total of $4 to $5 million dollars. *Id.* ¶¶ 4, 22 ((APPX003, 009) These expenditures must, necessarily, come at the expense of other crucial public health operations, such as, *inter alia*, assessing new medical products and treatments, inspecting FDA-regulated establishments, and purchasing laboratory equipment to run analytical testing. *Id.* ¶ 22 (APPX009). Further, the Court's direction for CBER to prioritize this FOIA case above all others will—again, of necessity—require FDA to allocate resources away from the processing of the hundreds of other FOIA requests that are currently pending before CBER, many of which also seek information related to COVID-19. *Id.* ¶ 23 (APPX009). While these FOIA requesters are not before this Court, the reallocation of resources away from processing their requests will be a direct consequence of the Court's Order.

Similarly, the reallocation of resources from other FDA components will also come with tradeoffs for the agency overall. As explained above, CBER has obtained the temporary reassignment of five OCOD employees, and it may in the future seek additional similar reassignments from other FDA disclosure offices in order to meet the exigencies created by the Court's Order. These diversions of resources will, necessarily, detract from the output of these other disclosure offices, as will the reallocation of eight agency employees through the detail assignments described above. For these reasons—which is to say, because the FDA has a broad public health mandate, but limited resources with which to accomplish its many crucial missions—FDA emphasizes that the extraordinary measures it is undertaking in response to the January 6 Order cannot be replicated in other FOIA cases, either presently or in the future. *See id*. ¶ 25 (APPX010).

Finally, while the agency recognizes the public interest in the public disclosure of the records here at issue, FDA must also ensure that the personal information of clinical trial participants, as well any trade secret or commercially confidential information contained within the records, is protected from disclosure. *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))). While FDA is putting every available resource at its disposal into its efforts to achieve compliance with the Court's Order, it cannot achieve speed at the expense of its competing obligation to protect the categories of information that FOIA exempts from disclosure. Ensuring that such information is fully and properly redacted will, unavoidably, limit the speed with which FDA can act. *See generally* the attached Declaration of Douglas Weinfield (explaining why FDA's FOIA reviews are often more time-intensive document reviews than those in garden-variety private commercial litigation) (APPX015-019); *id.* at ¶ 13 (APPX018-109) (noting, in particular, that "[i]dentification of commercially sensitive information in a biologics license application" … "requires … specialized expertise" not typically implicated in a private commercial dispute).

In sum, FDA is actively taking extraordinary measures to marshal every possible resource, and to make every possible effort to comply with the Court's Order. But because operationalizing these resources will require an upfront investment of time, FDA respectfully requests that the Court modify its Order, in part, so as to afford the agency a reasonable—and limited—interim period of two months to put the above-described operations in place, while still

meeting monthly production quotas of 10,000 pages. For all of the reasons set forth above, FDA respectfully submits that this modification is both necessary to afford the agency a practical opportunity to achieve compliance with the Court's Order, while simultaneously fulfilling its statutory duty to protect the sensitive personal and commercial information contained within the records here at issue.

CONCLUSION

For the foregoing reasons, FDA respectfully requests that the Court modify its January 6 Order so as to provide that, for the first two 30-day periods following FDA's scheduled January 31, 2022 production, FDA's monthly quota be adjusted to 10,000 pages per month. Following this initial two-month "stand up" period, FDA would then be required to process 55,000 pages per month, beginning with its May 2, 2022, production until such time as production is complete.

Dated: January 18, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 18, 2022, I electronically transmitted the foregoing to the parties and the clerk of court for the United States District Court for the Northern District of Texas using the CM/ECF filing system.

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