EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

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

SECOND DECLARATION OF SUZANN BURK

I, Suzann Burk, hereby declare as follows:

1. I am the Director of the Division of Disclosure and Oversight Management ("DDOM"), Office of Communication Outreach and Development ("OCOD"), Center for Biologics Evaluation and Research ("CBER"), United States Food and Drug Administration ("FDA"), in Silver Spring, Maryland. A summary of my work experience and current job responsibilities is included in my December 6, 2021, declaration (ECF No. 23).

2. FDA is committed to transparency both in general and specifically with respect to records related to the Comirnaty biologics license application ("BLA"). As explained in more detail in the Declaration of Sarah B. Kotler ("Kotler Decl.") (ECF No. 30), from the time the Comirnaty BLA was approved, FDA endeavored to publish on its website information relevant to the public's interest in the Comirnaty vaccine. Kotler Decl. ¶¶ 11-14. FDA's transparency efforts began the day after the BLA was approved when it posted the "Summary Basis for Regulatory Action" on its website. *Id.* ¶ 13. Those efforts continued when FDA posted numerous FDA discipline review memos, including clinical, statistical, and toxicology reviews

as part of the "Action Package" 25 days after approval. *Id.* That information, along with the other information on FDA's website, provides the public with substantial information that it can use to evaluate FDA's determination approving the Comirnaty vaccine for use in individuals 16 years and older.

3. FDA has reaffirmed its commitment to transparency by providing copious information to Plaintiff in response to its FOIA request, number 2021-5683 (Plaintiff's "FOIA Request"). FDA has already produced to Plaintiff over 7,000 pages of responsive records plus several unpaginated data files, and expects—and is on track—to have produced over 12,000 pages of responsive records by January 31, 2022. Declaration of Suzann Burk ("First Burk Decl."), ECF No. 23, ¶¶ 27-28.

4. As discussed in more detail below, FDA has begun to take dramatic, and indeed unprecedented, actions in an effort to comply with this Court's January 6, 2022, order requiring production of 55,000 pages every thirty days beginning on March 1, 2022. These efforts include working to hire at least fifteen outside contract staff to help process these records; creating "details" to allow current FDA staff from other parts of the agency to work on matters related to this case; obtaining help from staff members from other parts of OCOD and CBER; temporarily receiving assistance from other FDA disclosure offices to meet production deadlines in other FOIA litigation; and reaching out to the vaccine sponsors for assistance identifying information that they consider confidential. Once fully implemented, these steps will dramatically increase the agency's ability to produce records to Plaintiff at a greatly accelerated rate, but they come at significant cost (estimated to be at least $4 to 5 million) to FDA's other disclosure work—and to its public health mission. The agency hopes that these efforts will allow it to achieve the

production rate required by the Court's order, but even with these maximal and unprecedented efforts, it is not possible to guarantee that FDA will be able to fully comply.

Actions Taken Following January 6, 2022, Order

5. After receiving this Court's January 6, 2022, Order (ECF No. 35) requiring FDA to produce 55,000 pages of records every thirty days beginning on March 1, 2022, FDA has taken extraordinary and unprecedented measures to increase its capacity to review and produce responsive records.

Hiring of Contractors

6. FDA has initiated the process of hiring at least fifteen full-time contract staff to help process records responsive to Plaintiff's FOIA Request. FDA anticipates that eleven of those contract staff will be able to assist with processing records that do not require review for trade secret or confidential commercial information; the remaining four contract staff would have the background necessary (with training and oversight from the current FOIA staff at CBER) to help process more complex records. In addition to reviewing and redacting responsive records, these contract staff members would assist with administrative steps required to prepare records for production (finalizing redactions, applying Bates numbers, etc.).

7. Although FDA anticipates that these contract staff will help expand FDA's processing capacity significantly once they are in place, it will take time to 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. Notably, this would likely slow, at least initially, the efficiency of the current ALFOI staff working on the litigation as they will need to spend time partnering with the new contract staff to provide training and oversight. *See* Declaration of Sarah B. Kotler ("Kotler Decl."), Dec. 13, 2021, ECF No. 30, ¶ 22.

Details for Agency Staff

8. CBER is going to publish an agency-wide advertisement for eight "detail" positions to work on reviewing and producing materials responsive to Plaintiff's FOIA Request. These details would allow agency staff who work in other parts of FDA to be selected for the opportunity to temporarily work on this matter in CBER.

9. As with the contract staff described above, there will be some lag before these detailees are able to begin working on this project. CBER plans to start publishing advertisements for these details by approximately February 1, 2022. Once the detail opportunities are posted, CBER will need to allow a period of time for submitting applications, and then CBER will need to select candidates from the applications received. Once detailees are selected, they will need to be trained to perform work on these files. CBER does not expect that agency staff selected for these details will have the requisite experience and training to immediately begin working at full strength. Notably, this would likely slow, at least initially, the efficiency of the current ALFOI staff working on the litigation as they will need to spend time partnering with the new detailed staff to provide training and oversight. *See* Kotler Decl. ¶ 22.

Reassignment of Staff within CBER's OCOD

10. Recognizing that efforts to bring on contractors and detailees will take time, CBER has already reallocated center resources and staff to prioritize the processing of this FOIA request to attempt to address this matter as quickly as possible. Prior to entry of this Court's January 6 order, CBER's Access Litigation and Freedom of Information Branch ("ALFOI") had dedicated approximately three "full time equivalents" to the processing of this request. Now, approximately five and a half of ALFOI's ten "full-time equivalents" are being dedicated to reviewing and redacting records related to this litigation.

11. Further, CBER has also already temporarily reassigned five additional staff members from other divisions of OCOD to assist ALFOI with processing this request for the interim in which some of the other efforts described in this declaration are being ramped up. These reassigned staff members will require training in order to complete the tasks necessary to accelerate production in this matter.

Receiving Assistance with Other Litigation Deadlines

12. FDA has disclosure obligations in several other FOIA litigations that involve CBER. In at least one case, where CBER had agreed to contribute 450 pages toward FDA's overall monthly 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 rate to zero in that case, while other agency components would take on the work that CBER is not able to do. Doing so would allow CBER ALFOI staff that would otherwise have been working on that production to devote more time to this production, while CBER ramps up its production capacity.

Working with Vaccine Sponsors to Identify Records that Do Not Contain Exemption 4 Material

13. FDA has also contacted Comirnaty sponsors Pfizer-BioNTech to seek their assistance, initially, in identifying sections of the BLA that do not contain any trade secret or confidential commercial information subject to FOIA Exemption 4. FDA has requested the sponsors to provide this information to it by February 1, 2022.

14. By knowing which records the sponsors believe do not contain information protected by FOIA Exemption 4, FDA will be able to streamline its disclosure review. Although FDA will still need to review these records for other types of information protected by the FOIA Exemptions (most notably, Exemption 6, which protects the privacy interests of clinical

participants) it will be able to move more quickly through the records if it does not need to search for Exemption 4 material. Further, it would allow FDA to assign less experienced staff or staff from other parts of the agency to work on these records. As discussed in the Kotler Declaration, reviewing files like BLAs requires specialized training and experience – especially for identifying trade secret and confidential commercial information. *See* Kotler Decl. ¶ 24. By eliminating the need to search these records for information protected under Exemption 4, less training will be required for staff outside of ALFOI to review the affected subset of documents.

15. In addition, FDA is actively assessing other potential ways in which it may properly enlist Pfizer-BioNTech to assist with streamlining the processing of the records at issue in this suit.

Overall Increase in Production Capacity

16. Once fully implemented, these dramatic efforts will greatly increase FDA's capacity for responding to Plaintiff's FOIA Request. Between contract staff and detailees, CBER will be adding approximately 23 new individuals to help ALFOI's efforts. *See*, *supra*, ¶¶ 6, 8. When those 23 individuals are fully added to CBER's existing efforts (*see*, *supra*, ¶ 10, 11), ALFOI expects that its capacity will be approximately tripled from the time the new individuals are fully trained through the end of this production.

17. Other actions – temporarily reassigning staff from other parts of OCOD and CBER and asking other FDA components to take on CBER's other litigation obligations in the short term – will provide additional resources in the short term that will help CBER bridge the gap while it awaits the contractors and detailees to arrive and be trained. And, as described above, efforts to work with the vaccine sponsors may help to streamline CBER's review by

limiting the amount of time it needs to spend searching for trade secret and confidential commercial information.

18. But even with these efforts, it is impossible to guarantee that FDA will be able to produce 55,000 pages every thirty days beginning March 1, 2022, as required by this Court's January 6, 2022, Order. In my first declaration, I estimated that if each of ALFOI's 10 staff members devoted all of their working hours to this production, they would be expected to be able to produce 25,410 pages in 11 weeks (or approximately 10,000 pages per month). *See* First Burk Decl. ¶ 31.

19. As discussed above, FDA's most far-reaching efforts to increase production capacity – hiring contractors and bringing on detailees – necessarily take time to implement. The agency has to 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. As a result, very few, if any, of those additional individuals will be in place before the March 1, 2022 deadline. The temporary measures CBER has implemented will increase production capacity, but it is not certain that the combination of the temporary additional staffing and current staff's tireless efforts will be sufficient to more than quintuple ALFOI's estimated maximum production capacity in the time before the new hiring is completed.

20. Even once the new hires fully take effect, meeting the production burden of 55,000 pages per month will pose a challenge to the agency. As discussed above, FDA is making every effort to comply with this Court's order in good faith. But in months where the agency is processing especially challenging records or may be dealing with staff reductions due to illness, attrition, or other reasons beyond FDA's control, the enormity of a 55,000 page per month obligation could still prove to be too much.

Adverse Impact of Actions on FDA's Disclosure and Public Health Work

21. The actions described above exceed what the agency considers feasible for processing a single FOIA request and, in fact, represent the maximum efforts FDA can apply to this matter. FDA cannot expand its efforts beyond what it has already committed to do. The dramatic efforts FDA has undertaken to attempt to comply with the Order have already severely impacted agency functions, and they will continue to do so for the foreseeable future.

22. First, FDA's plan to hire at least fifteen contract staff to assist with the review requires a significant financial commitment from the agency. Although exact figures are not yet available, FDA expects that the expense of hiring these contractors will cost at least three million dollars. Money spent on contractors to review Plaintiff's FOIA Request 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.

23. Further, within ALFOI, the fact that about 55 percent of the branch's full-time equivalents are devoted to this matter means that other ALFOI disclosure work, including hundreds of other FOIA requests, many of which also seek information related to COVID-19, are, of necessity created by the Court's Order, being sidelined. In my December 6, 2021, declaration, I showed the dramatic increase in FOIA backlog that CBER had suffered in recent years. First Burk Decl., ¶ 21. I copy that chart again here.

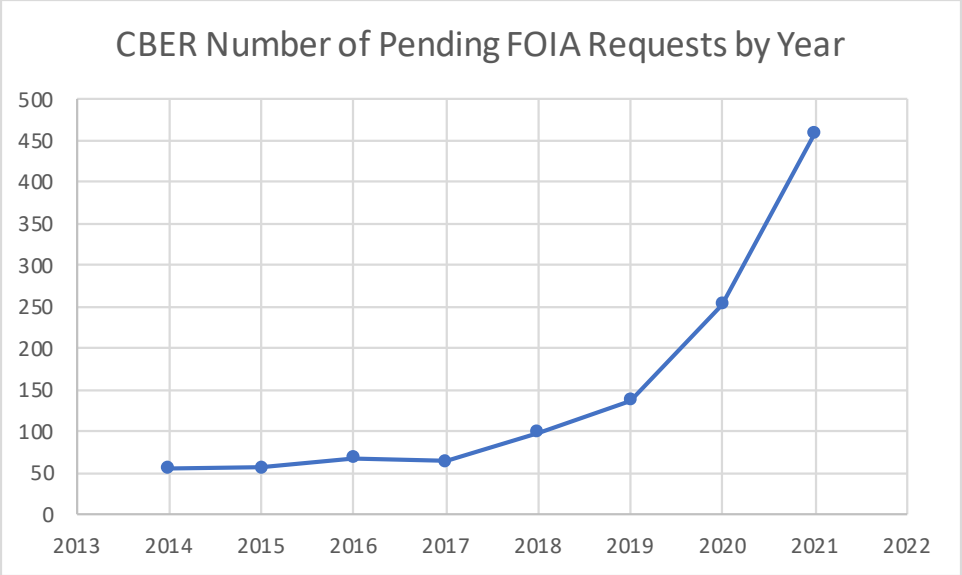

Figure 1: *Number of pending FOIA requests pending in CBER at the end of each calendar year. (2018 value was taken from end of January 2019 because December 2018 data were unavailable due to government shutdown. 2021 value was current as of November 26, 2021.)*

Further, FDA has no control over the number of new FOIA requests that it may receive, and that number can be expected to be substantial, especially if new vaccines or other biological products related to COVID-19 are approved. With the resources that FDA is allocating to fulfilling Plaintiff's request, I expect that CBER's backlog will continue to increase – likely dramatically – including for requests seeking information from CBER related to COVID-19.

24. Borrowing resources from other agency components also comes with tradeoffs for the agency. As CBER requests assistance from other parts of OCOD and CBER, as well as other FDA disclosure offices in an effort to satisfy this Court's order, those offices will have fewer staff members available to perform their work. Many of those offices are already constrained by a lack of resources, and in the case of other FDA disclosure offices, many are experiencing their own FOIA backlogs. *See* Kotler Decl. ¶¶ 24-38. Any resources diverted from those offices to support CBER's efforts in this matter will inevitably exacerbate their own resource constraints, likely leading to longer backlogs – and greater exposure to costly litigation

– in those agency components as well. Further, although FDA does not yet know from which offices the eight proposed detailees will come, the detailees' home offices will lose the productive capacity of a staff member, likely leading to reduced output.

25. For these reasons, and as expressed in the Kotler Declaration, FDA simply cannot take these same measures in response to every FOIA request or every FOIA litigation. The steps FDA has taken in this case have already placed an extraordinarily heavy burden on the agency's disclosure capability and its public health mission. Extending this type of response beyond this case would dramatically compound the harm. Thus, the agency's efforts in this case should not be viewed as precedent for what may be possible in future situations, including for FOIA requests for other records related to COVID-19. Indeed, as outlined above (*see*, *supra*, ¶¶ 20-23), and in the Kotler Declaration, the agency's processing of this request is diverting resources from other agency priorities. It is also reducing the agency's capacity to process other FOIA requests, thereby extending wait times of other FOIA requesters – including other requesters seeking records related to the COVID-19 pandemic.

BENEFIT OF MODIFYING ORDER

26. Modifying the current order to reduce FDA's March 1 and March 31, 2022, productions to 10,000 pages and making FDA's first 55,000-page production due on May 2, 2022,[1] would increase FDA's likelihood of being able to comply with the Court's Order. First, and most importantly, it would allow many of the unprecedented measures described above to take effect. It would allow time for many, if not all, of the contingent of contract and detail staff to be brought on board before requiring FDA to produce 55,000 pages every thirty days.

[1] Under the Court's current order, FDA's first 55,000-page production would be due on March 1, 2022; the second would be due on March 31, 2022. The deadline for the third production would then fall on Saturday, April 30, 2022. FDA interprets deadlines that would fall on weekends or holidays to be due on the next business day – in this case, Monday, May 2, 2022.

27. Second, it would allow FDA more time to work with the vaccine sponsors to accurately locate any trade secret or confidential commercial information that may be protected from disclosure by statute. As noted above, FDA sent a letter to the vaccine sponsors on January 14, 2022, requesting that they identify any sections of the Comirnaty BLA that they knew did not contain any trade secret or confidential commercial information. FDA continues to look for opportunities to work with Pfizer-BioNTech to create efficiencies in the review process, and it expects to make additional requests in the future. Extending the date for the first 55,000-page production to May 2, 2022, will allow more time for the initial phase of the agency's work with the vaccine sponsors to occur.

28. Although it cannot be guaranteed, I expect that reducing the size of FDA's March 1 and 31, 2022 productions to 10,000 pages would significantly increase the likelihood that FDA will be able to comply with the Court's order.

CONCLUSION

29. FDA is committed to transparency and is doing everything possible to achieve compliance with this Court's January 6, 2022, Order. The efforts FDA has begun to undertake will significantly enhance its ability to review and produce records in this litigation, but many of them will take time to be fully implemented. Extending the deadline for FDA's first 55,000-page production to May 2, 2022, would reduce the chances that FDA will be unable to comply with the Order.

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

Executed on January 18, 2022, in Silver Spring, Maryland.

Suzann H. Burk -S

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Suzann Burk
Director
Division of Disclosure and Oversight Management,
Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
U.S. Department of Health and Human Resources

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

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

DECLARATION OF DOUGLAS WEINFIELD

I, Douglas Weinfield, do hereby declare and state:

1. I have served as the Associate Chief Counsel for Discovery within the Office of the Chief Counsel ("OCC"), United States Food and Drug Administration ("FDA") since July of 2018. As Associate Chief Counsel for Discovery, I am responsible for case-related discovery issues, including electronic discovery on behalf of FDA. My duties include, among other things, developing discovery-related policies; training FDA employees regarding discovery; assisting FDA in responding to discovery requests; advising FDA regarding discovery software and implementation relating to electronic discovery; and coordinating with other government entities, including the U.S. Department of Justice ("DOJ"), regarding electronic discovery.

2. Prior to joining FDA, I was at the law firm of Williams & Connolly, LLC, for more than 13 years, where I directed single and multiple teams of attorneys in complex document review projects, and performed document review myself. In all, I have more than 18 years of experience performing and directing electronic discovery reviews, ranging from basic, short review, to complex reviews spanning millions of documents and multiple years, including

international matters. This experience includes document review related to sensitive criminal and civil litigation. I have directed and/or performed document review in more than 125 matters and cases.

3. The statements made in this declaration are based upon my personal knowledge and expertise in litigation and eDiscovery both in private practice and at FDA. Hereafter, references to "documents" include electronic documents and references to "document review" include electronic document review.

4. In my experience, there are significant differences between document review conducted by a private law firm with commercial clients and that conducted by the federal government. Those differences preclude a simple apples-to-apples comparison, primarily due to the differences in the nature of the material reviewed, and the nature of the review and redaction process.

5. During my time in private practice, a review speed of 50 documents per hour was within the normal range for document review in a complex matter, with different document reviews going at a slower or faster rate depending on the nature of the material. Variables that might shift that number up or down in private practice included the length of the documents, the complexity of the issues, the complexity of the law, and the relative prevalence of privileged material.

6. In my experience in private practice reviews, it was commonplace that a notable number of documents were promptly identifiable as non-responsive, which allowed each document to be reviewed in less than a minute. Moreover, in private practice reviews, frequently most of the documents in a review were emails, often short emails of one to three pages, which usually could be reviewed in a minute or less.

7. In comparison, the documents under review in the present matter, explicitly requested under the Freedom of Information Act, contain limited non-responsive documents. This also largely moots the use of Artificial Intelligence ("A.I.") or technology assisted review ("TAR") approaches to reviewing these documents. Further, they contain relatively few or no emails. Therefore, these documents cannot be reviewed at such a rapid pace.

8. In private practice, the review of documents was relatively straightforward. Identifying relevance, responsiveness, privilege, hot documents, confidentiality, attorney-eyes only designation, and coding categories were usually simple tasks. Issues such as privilege were typically readily discernable via a scan for readily identifiable terms such as "attorney-client" or the names of attorneys or paralegals, or in the case of confidentiality or coding categories, via a scan for other readily identifiable terms.

9. In private practice, the bases for redaction in the overwhelming majority of reviews were attorney-client privilege and/or the work-product doctrine, which are usually easily identifiable by the reviewing attorney. These reviews rarely required consultation with subject matter or programmatic staff or experts, if at all. Additionally, there were infrequent redactions of material as confidential or as containing personally identifiable information, again depending on the nature of material under review.

10. In contrast, at FDA, redactions are made for a broader range of reasons than is the case for private law firms, and an FDA document review typically contains much more redacted or withheld material than is true in a private practice review. Relevant to the present case, FDA redactions are made to protect trade secret information, confidential business information, and personally identifiable information. Many of these redactions or withholdings implicate the commercial and privacy interests of third parties, as well as FDA's statutory and/or regulatory

duty to protect such information, which is often provided to FDA by a third party with the expectation that the information will not be further disseminated. Identifying the material to be redacted is usually more difficult and time-consuming than identifying the attorney-client or work product material to be redacted in private practice reviews.

11. Based on my experience in private practice, for efficiency's sake it is the usual practice there to conduct a two-pass review. The first, quicker, pass usually identifies relevance, privilege, and specific issues of particular importance for that matter, as well as documents that need redaction or further review or are unreadable. The second, slower, pass usually redacts the relatively smaller number of documents which contain privileged material, which, generally, was readily identifiable. In addition, it is common for an attorney substantively involved with the matter to conduct a third review of some or all of the documents, for quality control.

12. Document reviews in private practice rarely require significant specific subject matter expertise; rather, the document reviews are highly similar from review to review. A small degree of training regarding the specific content at the beginning of a new review is common, usually lasting a day or two at most, and often less, with further learning over the course of the review.

13. At FDA, document review and redaction are usually performed by reviewers with subject matter experience, usually with years or decades of experience reviewing documents in a particular area, such as drugs, devices, food, biologics, tobacco, or veterinary medicine. This knowledge is important to identify often subtle issues which arise in the course of document review and identifying material which needs to be redacted. Identification of commercially sensitive information in a biologics license application, for example, is usually significantly harder (and requires more specialized expertise) than identification of redactions based on

attorney-client privilege or work-product doctrine, which comprise the vast majority of redactions in private practice document reviews. Due to the challenges in identifying these issues, and the relatively high number of redactions to be made, it is FDA's practice to conduct a single pass review which includes redacting protected material at the time it is identified, because a second pass would require a re-identification of these subtle issues, and nearly double the effort and time to find them. In addition to this single pass review, FDA often conducts a quality control review, similar to reviews in private practice. This intermittent process of identifying issues, pausing the review to redact, and continuing the review, is intrinsically slower than the comparatively simple two-pass reviews usually conducted by private law firms, which require no such pausing, and which typically have much less material to redact.

14. Even in the unusual circumstance that the third party that submitted documents is involved in helping the agency identify trade secrets or confidential commercial information in them, FDA will still have a role in reviewing records prior to release.

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

Executed on this 18th day of January 2022 in Washington, District of Columbia.

Douglas B. Weinfield -S

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Douglas Weinfield

Associate Chief Counsel for Discovery

US Food and Drug Administration