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 SARAH B. KOTLER

I, Sarah B. Kotler, declare as follows:

1. I am the Director of the Division of Freedom of Information ("DFOI"), Office of the Executive Secretariat, Office of the Commissioner, Food and Drug Administration ("FDA" or "the agency"), United States Department of Health and Human Services ("HHS"), in Rockville, Maryland.

2. I have held the position of Director of DFOI since January 2015. Prior to becoming Director, I served as Acting Director of DFOI from November through December 2014, after the former Director of DFOI retired. I previously served as DFOI's Deputy Director and Denial & Appeals Officer from September 2013 through October 2014; and as Denials & Appeals Officer from March 2007 through August 2013.

3. As both Deputy Director and Director, I have had supervisory authority over DFOI, which serves as FDA's official point of receipt for all requests for records under the Freedom of

Information Act (FOIA), 5 U.S.C. § 552. *See* 21 C.F.R. § 20.40. In addition, DFOI is responsible for FDA's FOIA reporting to HHS and the U.S. Department of Justice, consulting with other federal agencies regarding FOIA requests, agency-wide FOIA training, and expedited processing, among other functions. DFOI processes about 25% of all FOIA requests received by FDA; the other 75% are processed by the FOIA reviewers within FDA's other components.

4. As part of my duties, I coordinate FDA's processing of FOIA requests that relate to the novel coronavirus known as SARS-CoV-2, also known by the disease it causes, COVID-19. Due to the nature of my official duties, I am familiar with the procedures followed by FDA in responding to requests for records pursuant to applicable law, including provisions of the FOIA, 5 U.S.C. § 552. I am also aware of the workload obligations of offices that process FOIA requests across the agency.

5. The statements contained in this declaration are based upon my personal knowledge, upon information I have learned in my official capacity, and upon conclusions I reached based on that knowledge or information.

6. The purpose of this declaration is to provide an overview of FDA's procedures for handling FOIA requests, FOIA workloads across the agency, and FDA's ability to process the FOIA requests at issue in this proceeding made by Public Health and Medical Professionals for Transparency ("PHMPT") and Stephanie and Patrick de Garay (collectively, "Plaintiffs"). This declaration also documents the agency's basis for denying Plaintiffs' requests for expedited processing.

7. As explained below, Plaintiffs' FOIA requests did not satisfy the standard for expedited processing because they did not establish an urgent need to inform the public about federal government activities. Further, Plaintiffs' proposed production schedule is not feasible

given that, among other things, FDA cannot reallocate resources from other components of the agency. Since the beginning of the COVID-19 pandemic, the number of FOIA requests submitted to FDA has significantly increased, as has their complexity and the amount of subsequent FOIA litigation. Because of these factors and the agency's existing FOIA and non-FOIA workload, other FDA components cannot assist the Center for Biologics Evaluation and Research ("CBER") in attempting to satisfy Plaintiffs' proposed production schedule without diverting significant resources away from the processing of other FOIA requests that are also in litigation, requests that are ahead of Plaintiffs' requests, and other non-FOIA record requests. This would adversely impact the agency's ability to meet stipulated document processing deadlines and prejudice other important pending requests at the expense of overall transparency and the agency's public health mission.

FDA'S GENERAL PROCEDURE FOR INCOMING FOIA REQUESTS

8. Under FDA's regulations, DFOI is the office responsible for FDA's compliance with FOIA. *See* 21 C.F.R. §§ 20.30, 20.40. When DFOI receives an electronic FOIA request, it generates a control number that begins with four digits reflecting the calendar year in which the request was received, followed by a number reflecting the sequential count of FOIA requests received by DFOI to date in that particular calendar year. Plaintiff PHMPT's request filed on February 23, 2022 related to Moderna's COVID-19 vaccine was the 1,614th FOIA request received by FDA in fiscal year ("FY") 2022 and thus has the control number "2022-1614." PHMPT's request filed on August 8, 2022 related to Pfizer-BioNTech's COVID-19 vaccine for individuals between the ages of 12-15 years old was the 5,812th FOIA request in FY 2022 (FOIA Control # 2022-5812), and Plaintiffs Stephanie and Patrick de Garay's request filed on August 22,

2022 related to Pfizer-BioNTech's COVID-19 vaccine for individuals between the ages of 12-15 years old, was the 6,129th FOIA request in FY 2022 (FOIA Control # 2022-6129).

9. FDA expedites processing of a FOIA request when the requester demonstrates a "compelling need" and in other cases determined by the agency. *See* 5 U.S.C. § 552(a)(6)(E). A "compelling need" exists when: (1) 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) a request is made by "a person primarily engaged in disseminating information" and there is a demonstrated "urgency to inform the public concerning actual or alleged Federal Government activity." *Id*. DFOI reviews requests to determine whether expedited processing is appropriate and sends a letter to the requester documenting its determination. In accordance with 21 C.F.R. § 20.44, requests that have been granted expedited processing are processed as soon as practicable, on a first-in, first-out basis based on the date of receipt.

10. FDA's FOIA program is decentralized because of the agency's size, the large number of records generated during the course of agency business, and the different components within FDA. After a FOIA request is received and logged by DFOI, the request is assigned to the FDA component reasonably likely to possess responsive records, which then processes the request. FOIA reviewers within the assigned component process potentially responsive records and determine whether they should be released in full, redacted in part, or withheld in their entirety under any applicable FOIA exemption or other statutory or regulatory provision.

FDA'S PUBLICATION OF INFORMATION REGARDING THE SPIKEVAX AND COMIRNATY VACCINES

11. In an effort to inform the public about its work related to the COVID-19 vaccines, FDA has published an abundance of relevant information. As relevant to the instant matter, this includes the most important safety and efficacy information about Moderna's Spikevax vaccine,

Pfizer-BioNTech's Comirnaty vaccine, and the supplemental approval of the Comirnaty vaccine for use in individuals ages 12-to-15 years old.

12. FDA features the latest information about the agency's COVID-19 response on the homepage of its website, https://www.fda.gov. For example, the homepage currently prominently features "COVID-19 Bivalent Vaccine Boosters," which takes the user to a page with numerous links to information about the authorization of bivalent vaccine boosters from Moderna and Pfizer, https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-bivalent-vaccine-boosters.

13. From there, among other places, the user can access a main link titled "Coronavirus Disease 2019 (COVID-19)" which takes the user to a collection of linked webpages about FDA's COVID-19 response from January 2020 up to the latest developments. The linked webpages provide information about COVID-19 vaccines, emergency use authorizations, personal protective equipment, FDA guidance documents, Frequently Asked Questions, and resources for health professionals, among other things. FDA, Coronavirus Disease 2019 (COVID-19), https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19.

14. From that main COVID-19 page, the user can access webpages about specific COVID-19 vaccines.

15. **Information About the Spikevax Vaccine:** A Moderna-specific webpage provides updated information about the Spikevax vaccine and Moderna's bivalent booster vaccine. Moderna's COVID-19 Vaccines, at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines. That page contains links to a variety of important information about the Spikevax vaccine (and its bivalent booster), organized

into the following categories designed to make each topic accessible to the public and healthcare providers:

a) **Spikevax Information**: This section provides package inserts, the Summary Basis for Regulatory Action, Frequently Asked Questions (FAQs), an Approval Letter, and an additional link to information on the Centers for Disease Control (CDC) website. These materials were all updated in 2022.

b) **Moderna Fact Sheets (English) and FAQs**: This section includes "Health Care Provider Materials" with updated fact sheets and letters for healthcare providers that describe the primary series and bivalent boosters for the Spikevax vaccine, organized by date and vaccine recipient group. The most recent updates were added to Fact Sheets on December 8, 2022. This section also includes "Recipient and Caregiver Materials" with fact sheets describing primary series and bivalent booster vaccines and an FAQ. The fact sheets were last updated on December 8, 2022.

c) **Moderna COVID-19 Vaccine Regulatory Information**: This section provides decision memoranda and addendums to memoranda, letters, and Advisory Committee Meeting information, beginning in December of 2020. The most recent updates include a decision memorandum (https://www.fda.gov/media/163937/download) and letter of authorization (https://www.fda.gov/media/144636/download) added on December 8, 2022.

d) **Media Materials and Webcasts**: This section provides webcasts of FDA's Vaccines and Related Biological Products Advisory Committee meetings about Spikevax, press conference links, and press releases beginning in December of 2020. More recently, this includes two Advisory Committee webcasts from June of 2022 totaling more than 15 hours

of discussion (found at https://youtu.be/Ixm4UmldTGQ and https://youtu.be/GbNpaZeDPiA).

e) **Translations**: To ensure public accessibility, the webpage also includes translations of certain Spikevax information in multiple languages.

16. The "Spikevax Information" section includes a link to another webpage providing detailed regulatory documents that explain the basis for Spikevax's approval, found at https://www.fda.gov/vaccines-blood-biologics/spikevax. This page contains the "Action Package" for Spikevax, comprising hundreds of pages of materials that the agency expects are the most useful to the public in understanding FDA's approval decision. It includes the Clinical Review Memorandum (which provides information about individual clinical trials, safety and efficacy, and risk-benefit considerations and recommendations, among other things), Package Inserts, Approval Letter, and the Summary Basis for Regulatory Action, as well as a link to a zip file containing the "Approval History, Letters, Reviews, and Related Documents" for Spikevax. The zip file (at https://www.fda.gov/media/156343/download) provides, among other things, Statistical Reviews, Toxicology Review, Benefit-Risk Assessment Review, Pharmacovigilance Plan Review, and Chemistry-Manufacturing Controls Review. The documents in the Action Package thus provide valuable summaries of the information and data submitted by Moderna, as well as FDA's assessment, which together explain FDA's decision to license the Spikevax vaccine.

17. **Information about the Comirnaty Vaccine:** Similarly, a Pfizer-specific webpage provides focused and updated information about the Comirnaty vaccine and its bivalent booster vaccine. Pfizer-BioNTech COVID-19 Vaccines, at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines. Among other things, that page contains links to important information about the

Comirnaty vaccine, FDA's approval of its use in individuals 12 through 15 years of age, and the bivalent booster.

18. The information is organized into the following categories designed to make each topic readily accessible to the public and healthcare providers.

a) **Comirnaty Information**: This section provides package inserts, regulatory information, Frequently Asked Questions (FAQs), and additional links to information on the Centers for Disease Control (CDC) website. Among other things, the package inserts dated July 8, 2022, provide information about clinical trials and adverse reaction frequency in study participants of different ages, including participants 12 through 15 years of age. *See* Package Insert (purple cap), at https://www.fda.gov/media/151707/download; Package Insert (gray cap), at https://www.fda.gov/media/154834/download.

b) **Pfizer-BioNTech Fact Sheets (English) and FAQs**: This section includes "Health Care Provider Materials" with updated fact sheets and letters for healthcare providers that describe the primary series and bivalent boosters for the Comirnaty vaccine, organized by date and vaccine recipient group. The most recent document was a Fact Sheet updated on December 22, 2022, describing the primary series vaccine for those 12 years of age and older. *See* Fact Sheet, at https://www.fda.gov/media/153713/download. This section also includes "Recipient and Caregiver Materials" with fact sheets describing primary series and bivalent booster vaccines and an FAQ. The fact sheets were last updated on December 8, 2022, including a fact sheet for the vaccine recipient group 12 years of age and older.

c) **Pfizer-BioNTech Regulatory Information**: This section provides 35 documents comprising decision memoranda, letters, and Advisory Committee Meeting information, beginning in December of 2020. The most recent updates include a decision memorandum

(https://www.fda.gov/media/163895/download) and letter of authorization (https://www.fda.gov/media/150386/download) added on December 8, 2022, and a letter granting EUA Amendment (https://www.fda.gov/media/164184/download) added on December 22, 2022.

d) **Media Materials and Webcasts**: This section provides 28 records comprised of webcasts of FDA's Vaccines and Related Biological Products Advisory Committee meetings, press conference links, and press releases, beginning in December of 2020, with the most recent update being a press release on December 8, 2022 (https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-updated-bivalent-covid-19-vaccines-children-down-6-months).

e) **Translations**: To ensure public accessibility, the webpage also includes translations of certain information in multiple languages.

19. The "Comirnaty Information" section includes a link to another webpage providing detailed regulatory documents that explain the basis for Comirnaty's approval, found at https://www.fda.gov/vaccines-blood-biologics/comirnaty. This page contains the "Action Package" for Comirnaty, comprising hundreds of pages of materials that the agency expects are the most useful to the public in understanding FDA's approval decision. It includes the Clinical Review Memorandum (which provides information about clinical trials safety and efficacy, and risk-benefit considerations and recommendations, among other things), the Statistical Review, Approval Letters, and the Summary Basis for Regulatory Action, as well as a link to a zip file containing the "Approval History, Letters, Reviews, and Related Documents" for the Comirnaty vaccine. The documents in the Action Package thus provide valuable summaries of the information and data submitted by Pfizer-BioNTech that FDA reviewed and assessed in

determining whether to approve licensure for the vaccine and its subsequent use for individuals 12 through 15 years of age.

20. Additionally, a database of adverse event report data is continually updated by the Centers for Disease Control (CDC), found at https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/.

21. FDA continues to regularly update its website to provide the most current and relevant information about COVID-19 to the public as soon as possible.

FDA'S PROCESSING OF PLAINTIFFS' REQUESTS

22. Collectively, Plaintiffs submitted three FOIA requests to FDA:

a) **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.

b) **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)" (citation omitted). FDA assigned this request control number 2022-5812 (hereafter, "Second Request"). Complaint, Ex. 5.

c) **Third Request**: On August 22, 2022, Plaintiffs Stephanie and Patrick de Garay submitted a request materially identical to Plaintiff PHMPT's August 8, 2022 request.

FDA assigned this request control number 2022-6129 (hereafter, "Third Request"). Complaint, Ex 8.

23. As written, Plaintiffs' requests are extremely broad and would require the agency's careful review of millions of pages of records and data files in the Biologic Product Files ("BPFs") for the Spikevax vaccine and the ages 12 through 15 years indication for the Comirnaty vaccine (hereafter, the "Comirnaty indication") to determine which information is available for release to the public under 21 C.F.R. § 601.51(e).

24. I assigned Plaintiffs' requests to CBER for processing because they sought information—BPF records—in CBER's custody. CBER's processing of Plaintiffs' requests is described in more detail in the Beth Brockner-Ryan Declaration (Brockner-Ryan Decl. ¶¶ 32-34).

REQUESTS FOR EXPEDITED PROCESSING

25. I reviewed Plaintiffs' requests for expedited processing and determined that Plaintiffs did not satisfy the requirements for expedited processing on any request. Complaint, Exs. 2, 6, and 8.

26. I found that Plaintiffs did not demonstrate a compelling need under 5 U.S.C. § 552(a)(6)(E), in substantial part because large amounts of information have already been made available to the public about the Spikevax and Comirnaty vaccines and related FDA activities. A compelling need exists when: (1) 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) With respect to a request made by a person primarily engaged in disseminating information, there is a demonstrated urgency to inform the public concerning actual or alleged Federal Government activity. 5 U.S.C. § 552(a)(6)(E)(v). 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." DOJ, *FOIA Update: OIP Guidance: When to Expedite FOIA Requests*, https://www.justice.gov/oip/blog/foia-update-oip-guidance-when-expedite-foia-requests.

27. First, I found that Plaintiffs' requests did not contain any basis to conclude that a failure to obtain records on an expedited basis would pose a threat to any individual. As a result, I concluded that Plaintiffs had not satisfied the first criterion for expedited processing. Second, I determined that Plaintiffs had not established an urgency to inform the public concerning actual or alleged Federal Government activity, also largely because there is a significant amount of information already available to Plaintiffs and the public concerning FDA's activities surrounding the Spikevax and Comirnaty vaccines.

28. On June 1, 2022, Plaintiff PHMPT appealed the Agency's denial of expedited processing of the First Request. *See* Complaint, Ex. 3. Plaintiff argued that PHMPT was primarily engaged in disseminating information and that it was urgent to release the records underlying licensure of Spikevax because of "widespread and ongoing public debate" about Spikevax, "invasive policy decisions" like COVID-19 vaccine mandates, and a "lack of disclosure regarding the determination of the products [sic] safety and effectiveness." *Id*.

29. As discussed above, FDA has published a significant amount of information related to the Spikevax and Comirnaty vaccines on its website on an ongoing basis. The documents posted by the agency currently contain, among other things, FDA review memoranda, which include summaries of safety and effectiveness data, as well as FDA reviewers' analyses of them. Moreover, the CDC also maintains a website with additional information about ingredients and analyses of safety and effectiveness, among other things, for both Spikevax and Comirnaty. *See* CDC, Overview of COVID-19 Vaccines, https://www.cdc.gov/coronavirus/2019-ncov/

vaccines/different-vaccines/overview-COVID-19-vaccines.html. CDC also provides the public with access to its WONDER database, which contains adverse event report data collected through the U.S. Vaccine Adverse Event Reporting System. *See* CDC, How to Access VAERS Data through VAERS WONDER System, https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/access-VAERS-data.html. As a result, the public has access to a large amount of information about the vaccine, particularly government actions related to the vaccine's approval as well as on-going adverse event information.

30. The fact that people may have differing opinions about a certain FDA-regulated product does not create "urgency" within the meaning of the expedited processing standard – especially in light of the amount of information, and considering that the most relevant information for health care providers and consumers has been, published on FDA's website. Nor does the fact that certain individuals may be administered a certain product. FDA approves medical products regularly in the course of agency business. It is not unheard of for those approvals to be the subject of controversy, and there are almost always people who are administered the products shortly after approval. Such a situation cannot be deemed to create an urgent need for the agency to expedite its review and processing of the millions of pages of records and data files at issue here, especially when the agency routinely publishes summaries of safety and efficacy information on its website (as it did here). If Plaintiffs' view became the standard, a great number of FDA's FOIA requests would qualify for expedited processing, and requesters with non-expedited requests would have their wait times extended – possibly significantly. Thus, Plaintiffs' claims that their requests would fulfill an urgent demand is not supported, and I denied the requests for expedited processing. Complaint, Exs. 2, 6, and 8.

ALLOCATION OF AGENCY RESOURCES

31. As detailed in the Brockner-Ryan Declaration (¶¶ 23-28), CBER's FOIA resources are currently stretched to their maximum capacity due to marshaling its resources to comply with this Court's production order in *PHMPT v. FDA*, No. 4:21-CV-1058 ("*PHMPT I*"). And FDA cannot reallocate resources from other agency functions or components to help process Plaintiffs' requests. Performing disclosure reviews is a specialized skill that requires training and expertise that the vast majority of FDA staff does not have. It is not reasonable to expect that a microbiologist who performs laboratory assays, a pharmacist who reviews drug applications, a badging office employee who issues credentials, or a mail room clerk who organizes mail can simply begin performing disclosure review without significant training. Moreover, it would be contrary to FDA's public health mission to pull staff off reviewing cancer treatment applications or building counterfeit medication investigations to have them conduct work for which they are untrained and unqualified.

32. Further, FOIA administration is an unfunded mandate—that is, it is not a separate "line item" category in legislative appropriations for the agency, and thus FOIA operations must be funded from general budgetary appropriations. *See, e.g.*, DOJ, *FOIA Update: FOIA Affected by Budget Constraints*, https://www.justice.gov/oip/blog/foia-update-foia-affected-budget-constraints. Accordingly, when the agency receives more FOIA requests, it cannot hire more employees with specific FOIA funding.

33. Moreover, even when the agency can allocate new monetary resources to hire new disclosure staff or contractors, it takes substantial time to recruit and hire new staff, bring them on board, and provide them with the necessary training to become competent to perform disclosure reviews. FDA estimates that it takes approximately two years to fully train a new disclosure

reviewer. In the meantime, experienced reviewers are needed to closely supervise and review their work – thus decreasing the amount of time that experienced reviewers can spend reviewing records. Indeed, as explained in the Brockner-Ryan Declaration (¶ 28), CBER staff continue to expend significant time on supervision and review of newly hired contractors on the *PHMPT 1* production matter. As a result, it is not reasonable to expect that FDA will be able to respond to Plaintiffs' requests more quickly by allocating non-disclosure resources. In fact, to do so would significantly impede FDA's public safety role.

34. Moreover, as discussed in more detail in the following section, it is not feasible for the agency to reallocate its existing disclosure resources in components outside of CBER to work on Plaintiffs' requests because other FDA components' disclosure staff are already over-extended by existing disclosure obligations, many of which concern products or issues similarly important to public health. For example, the Center for Devices and Radiological Health, among other things, is processing requests related to COVID-19 test kits; the Center for Drug Evaluation and Research, among other things, is processing requests related to COVID-19 pharmaceutical treatments; the Center for Food Safety and Applied Nutrition, among other things, is processing requests related to infant formula; the Center for Veterinary Medicine, among other things, is processing requests related to animal drugs; the Center for Tobacco Products, among other things, is processing requests related to electronic nicotine delivery systems, colloquially known as e-cigarettes and their components; the Office of Regulatory Affairs, among other things, is processing requests related to their inspections of regulated industry; and the Office of the Commissioner, among other things, is processing requests related to its administrative priorities and responsibilities.

PROCESSING WORKLOAD OF DISCLOSURE OFFICES OUTSIDE OF CBER

35. As an initial matter, the disclosure office of each FDA component has its own specialized responsibilities and expertise. Thus, although all disclosure staff will be familiar with statutory requirements of FOIA and FDA's disclosure regulations, staff from different centers will be trained to review information regularly generated within that center. For example, CBER reviewers are familiar with the types of information regularly contained in BLAs and are trained to identify information that may be exempt from disclosure in those types of files; CBER reviewers would not be familiar with the types of records commonly processed by other parts of the agency, such as premarket tobacco product applications or food additive petitions. The converse is also true; reviewers in FDA's Center for Food Safety and Applied Nutrition ("CFSAN") are familiar with records regularly generated within CFSAN but would not have the same expertise as a CBER reviewer when looking at a BLA. Thus, even disclosure staff within the agency should not be considered interchangeable.

36. Further, on March 13, 2020, the President declared a national emergency due to the ongoing COVID-19 pandemic. Since the beginning of this emergency, FDA has been flooded with FOIA requests related to the pandemic.

37. Specifically, in fiscal year 2022, FDA received approximately 8,529 FOIA requests, many of which are directly related to COVID-19. Complicating matters, many recent FOIA requests are more complex and are expected to take longer to process than typical FOIA requests received prior to the beginning of the COVID-19 pandemic. Many requests for information related to COVID-19 require collaboration among federal agencies because they involve records (such as emails) that may have originated in other agencies. Department of Justice guidance advises federal agencies to consult with the originating agency for disclosure

determinations. DOJ, *FOIA Update: OIP Guidance: Referral and Consultation Procedures*, https://www.justice.gov/oip/blog/foia-update-oip-guidance-referral-and-consultation-procedures. As a result, FDA regularly collaborates with other federal agencies, such as CDC, the National Institutes of Health, and the Department of Health and Human Services, about records responsive to requests. These consultations add both time and complication to the process for responding to FOIA requests.

38. Coupled with the increased number and complexity of requests, FDA has experienced an unprecedented increase in FOIA litigation in recent years. Between calendar years 2018 and 2020, the number of FOIA lawsuits filed against FDA grew by approximately 200%. In 2022, FDA received 26 new FOIA lawsuits. Currently, FDA is involved in approximately 52 active FOIA litigations. Significantly, 20 of those FOIA lawsuits involve COVID-19 records—thus, there are now nearly as many FOIA litigations involving COVID-19 as there were total FOIA litigations brought in 2022.

39. At the review and redaction phase, certain FDA components have had to shift some of their FOIA reviewers from responding to FOIA requests in the normal course to almost exclusively processing FOIA requests in litigation. This diversion of staff resources to respond to ever increasing litigation and impending court deadlines means that fewer initial FOIA requests are being processed, and at a slower pace, which is causing even more litigation.

40. In addition to FOIA, FDA also has numerous other document processing obligations, including those arising from subpoenas; discovery requests in non-FOIA litigations; oversight requests from Congress; requests from domestic and foreign regulatory bodies; and other statutory disclosure mandates. In some agency offices, the same staff that handles FOIA requests also handles these other disclosure projects, as they rely on similar disclosure skills. As a result, it

would not be feasible for FDA to shift resources from other disclosure offices to help CBER process Plaintiffs' requests. In the following paragraphs, I discuss the current workload of various FDA components.[1]

Center for Drug Evaluation and Research ("CDER")

41. As of February 28, 2023, CDER is responsible for processing 987 pending FOIA requests, of which approximately 48 are related to COVID-19. This is a significant increase in pending requests compared to past years. The following chart illustrates the numbers of pending requests in CDER's FOIA queue on February 28 of the previous five calendar years, showing a marked increase in the numbers of requests beginning in 2021.

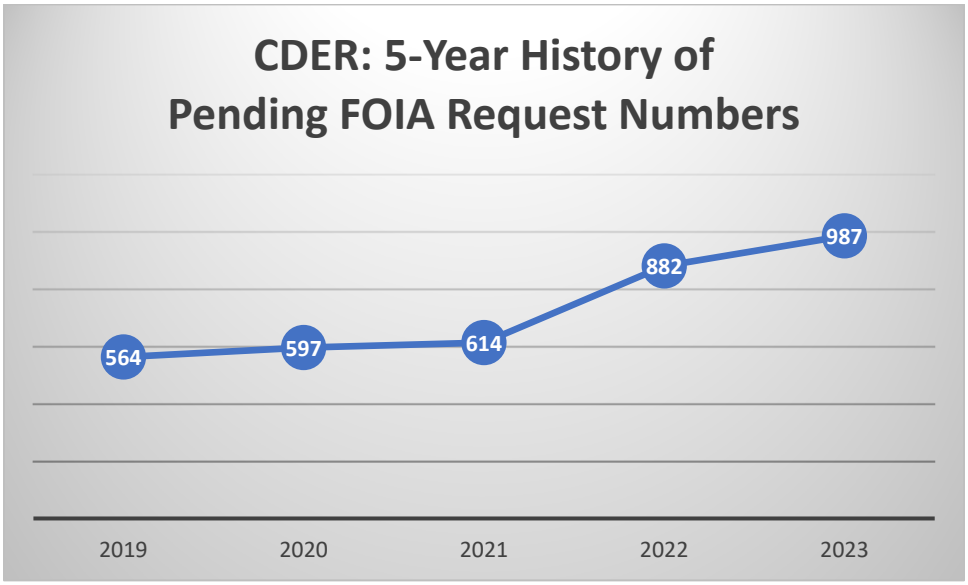

Figure 1: *Pending FOIA Requests in CDER as of February 28 of each year from 2019 to 2023.*

42. In addition to processing FOIA requests, CDER is also responsible for processing other document requests made by Congress; the U.S. Government Accountability Office; foreign, state, and local governments; and other federal agencies. Although these requests are not made

[1] I do not include a discussion of CBER's workload because that information is discussed in the Brockner-Ryan Declaration. *See* Brockner-Ryan Decl. ¶¶ 18-22.

under FOIA and are not processed in CDER's FOIA tracks, they are processed by CDER's FOIA reviewers because of the similar nature of the work to FOIA processing and the need for consistency in reviewing and redacting responses to information requests. Responding to these non-FOIA requests requires a corresponding decrease in reviewers' time available to respond to FOIA requests. For example, in recent years, CDER has been required to devote time to producing tens of thousands of pages in response to requests from foreign regulatory authorities for documents regarding FDA inspections of foreign drug manufacturers, and in response to requests from the Department of Justice related to its investigations of pharmaceutical companies. CDER also has other statutory disclosure obligations under the Food and Drug Administration Amendments Act of 2007, which requires that New Molecular/Biological Entity (NM/BE) action packages be published on CDER's web page within 30 days of approval. In 2022 and the beginning of 2023, CDER reviewed and redacted 37 NM/BE action packages, each of which typically contains thousands of pages.

Office of the Commissioner ("OC")

43. As of February 28, 2023, OC has 378 pending FOIA requests. After 2020, OC experienced a significant increase in FOIA requests, with the number approximately doubling between 2020 and 2021.

44. Prior to May 2022, OC had one full-time employee ("FTE") devoted to processing of FOIA requests for records originating in OC, at times (since the fall of 2020), aided by short-term detailees for 90-120 day periods. In 2022, due to its increasing backlog – particularly as it pertains to FOIA litigation – OC added a second FTE and part-time assistance from others on my team at DFOI (which division resides in OC) and was thus able to slightly decrease its FOIA queue. However, the number of pending FOIA requests, even after more than doubling the FTEs working

on these requests, remains far above pre-pandemic numbers. Indeed, despite my other duties, including management of my division, I have also been assisting with FOIA review for COVID requests in OC, as well as keeping the non-COVID OC FOIA workload moving. OC is currently involved in 6 active litigation matters. The following chart illustrates the number of pending requests in OC's FOIA queue as of February 28 of the previous five calendar years.

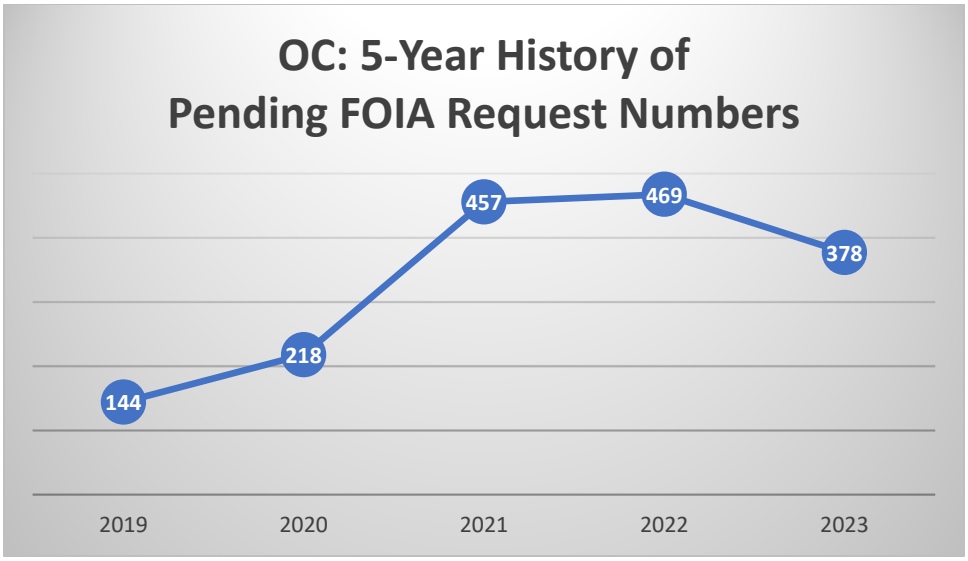

Figure 2: *Pending FOIA Requests in OC as of February 28 of each year from 2019 to 2023.*

Center for Devices and Radiological Health ("CDRH")

45. As of February 28, 2023, CDRH has 1,852 pending FOIA requests, approximately 145 of which are related to COVID-19. The following chart illustrates the length of CDRH's FOIA queue as of February 28 of each calendar year. Although CDRH's queue has not changed as dramatically as other FDA components, it remains the longest queue in the agency.

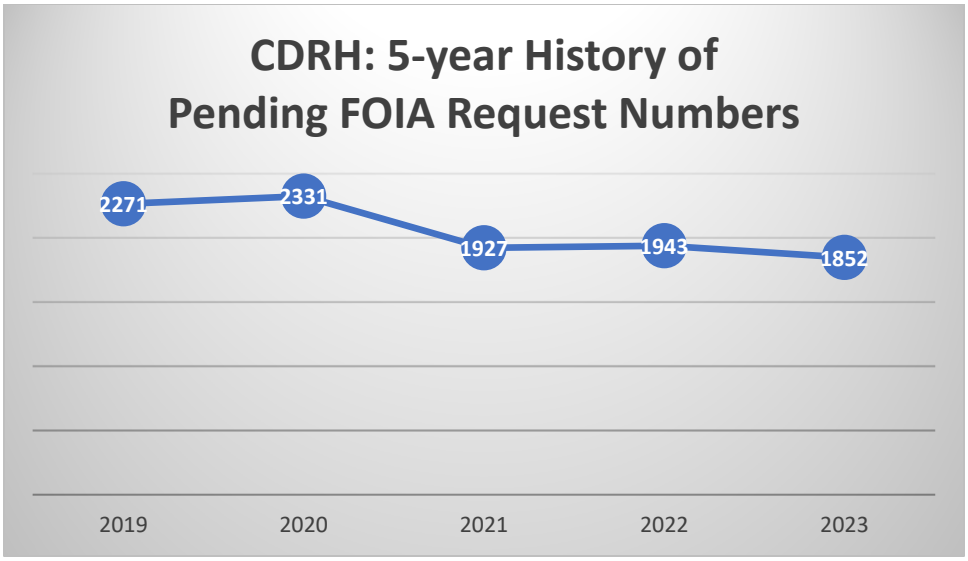

Figure 3: *Pending FOIA Requests in CDRH as of February 28 of each year from 2019 to 2023.*

46. Other than FOIA requests, CDRH's FOIA Office is also responsible for responding to subpoenas and non-FOIA record requests made by Congress; foreign, state, and local governments; and other federal agencies. Responding to these non-FOIA requests requires a corresponding decrease in reviewers' time available to respond to FOIA requests. For example, within the past four years alone, CDRH has been required to devote time to producing hundreds of thousands of pages of documents in response to requests from other federal agencies related to their investigation of medical device companies. Furthermore, since 2018, CDRH has responded to numerous federal subpoenas, with quick turnarounds for productions that have required CDRH reviewers to stop processing FOIA requests to respond to these subpoenas. In 2022, one voluminous subpoena alone yielded hundreds of thousands of pages.

Other FDA Components

47. The components highlighted above are not outliers. Other FDA components have significant queues, some of which have grown due to increased workloads related to COVID-19. Across the Office of Regulatory Affairs and its subcomponents/field offices, the total number of

pending FOIA requests has increased markedly from 162 in February 2021 to 409 in February 2023—more than doubling in just two years.

48. Although largely unrelated to the COVID-19 pandemic, FDA's Center for Veterinary Medicine has also seen its number of pending requests jump from 56 in February 2020 to 150 in February 2023. FDA's Center for Food Safety and Applied Nutrition and Center for Tobacco Products have not encountered the same influx of COVID-19 FOIA requests, so their FOIA queues have remained fairly steady. But they currently maintain queues in the 100 to 150 range, so their resources are fully consumed with their standard responsibilities, which also include non-FOIA disclosure projects, such as Privacy Act requests.

49. Based on all of the information above, none of FDA's other disclosure offices are able to assume the burden of taking on a significant role in the review of CBER records responsive to Plaintiffs' requests without compromising their ability to keep up with their own disclosure review responsibilities, especially considering that these staff are not specifically trained to review the records at issue in this case.

EFFORTS TO REDUCE BACKLOGS

50. FDA's FOIA offices have taken numerous steps to reduce backlogs and improve processing time. Specifically, FDA's FOIA offices are recruiting and hiring new employees where funding allows; proactively posting online frequently requested documents to reduce the need for new FOIA requests; training FOIA employees to handle types of records within their component that they do not typically handle to assist with complex track requests; evaluating requests daily in order to shift them to experienced redactors as needed; and, where possible, proactively contacting FOIA requesters to negotiate the scope of requests to in order to produce records more quickly. As noted in the Brockner-Ryan Declaration (¶ 26), since February 2022, CBER has hired 9.5

contractors (9 full-time and 1 part-time) to assist with FOIA processing and was recently approved to hire and train 6 new full-time disclosure staff for continued processing for *PHMPT 1* and to address its backlog due to the resources already devoted to *PHMPT 1*.

51. Moreover, starting in January 2022, CDER has brought on 7 additional employees (comprised of 6 brand-new FDA employees and 1 employee returning to CDER from the Office of Regulatory Affairs) to assist with FOIA processing. Similarly, CDRH completed a business process improvement review of its FOIA program in October 2019, which included identifying hiring needs; updating workflows, processes, and procedures; training reviewers; and additional tracking of FOIA requests. Between September and December 2019, CDRH acquired a multi-year contract that currently provides 11 contractors to assist in reducing FOIA backlogs and hired additional full-time reviewers to process FOIA requests and other disclosure tasks.

CONCLUSION

52. In sum, FDA is committed to transparency in all aspects of its work, especially its response to the COVID-19 pandemic. The agency has provided, and continues to provide, an abundant amount of information to the public about the Spikevax and Comirnaty vaccines. FDA has also taken reasonable steps to assist Plaintiffs with providing a more targeted FOIA request, as discussed in greater detail in the Brockner-Ryan Declaration (¶¶ 33-35). But Plaintiffs' requests do not satisfy the statutory standard for granting expedited processing. Further, given the limited number of FDA staff available to perform disclosure reviews and the heavy workload FDA's disclosure offices are facing, it would be unduly burdensome for FDA to reallocate resources from agency components outside of CBER. If required to do so, FDA's ability to perform its other agency functions, including responding to other record requests, would likely be impaired.

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.

Sarah B. Kotler -S

Digitally signed by Sarah B. Kotler -S
Date: 2023.03.31 08:39:30 -04'00'

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