UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CHILDREN'S HEALTH DEFENSE,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION,

Defendant.

Civ. A. No. 23-0220 (RDM)

JOINT STATUS REPORT

Pursuant to the Court's order, issued July 3, 2023, the parties, Plaintiff Children's Health Defense ("CHD") and Defendant United States Food and Drug Administration ("FDA"), respectfully submit this Joint Status Report:

BACKGROUND

1. This case concerns two FOIA requests: Request #2022-5587 ("First Request"), filed on July 27, 2022, and Request #2022-6498 ("Second Request"), filed on September 8, 2022.

2. The First Request has four items, all of which seek records containing or relating to FDA's analysis of adverse event reports submitted to the Vaccine Adverse Event Reporting System ("VAERS" or "the Reporting System") after the administration of a COVID-19 vaccine[1]:

- Item 2: Records of any manual review of serious Adverse Events of Special Interest reports conducted by FDA and/or the Center for Biologics Evaluation and Research ("CBER");

[1] The item numbers in this Joint Status Report correspond to the item numbers used in the original FOIA request. *See* CHD's First Request (ECF No. 1-1) at 5. Because Item 1 in the original FOIA request was withdrawn by CHD and is not a part of this case, the first item presented in this Joint Status Report is listed as "Item 2." *See* CHD's Email (ECF No. 1-1) at 19.

- Item 3: Records of any Empirical Bayesian data mining conducted by FDA and/or CBER, and records of any sharing or discussion of results and signals with the Centers for Disease Control and Prevention ("CDC");

- Item 4: Records of any results and signals received by FDA and/or CBER from the CDC's own PRR data mining, and any discussion of those results; and

- Item 5: Records of any consultations by FDA and/or CBER with VAERS staff within the CDC's Immunization Safety Office in connection with any signal that was detected.

3. The Second Request seeks records containing or relating to Empirical Bayesian data mining conducted by FDA on adverse event reports submitted to the Reporting System after the administration of a COVID-19 vaccine that were referenced on pages 9–10 of an article entitled *Reporting Rates for VAERS Death Reports Following COVID-19 Vaccination, December 14, 2020-November 17, 2021*. *See* CHD's Second Request (ECF No. 1-1) at 40.

4. The parties filed their previous Joint Status Report on June 27, 2023. *See* Joint Status Report (ECF No. 14). In that Joint Status Report, the parties stated: "'[w]ith searches still underway, FDA is unable to propose a processing schedule for all of the non-exempt, responsive records sought by Plaintiff's First Request at this time. Accordingly, FDA seeks an additional forty-five (45) days to continue conducting searches that address the remaining items in Plaintiff's First Request.'" *Id*.

5. In the June 27, 2023 Joint Status Report, FDA also provided the following status updates for each of the request items:

- First Request
    - Item 2: FDA was in the process of searching for records.
    - Items 3 and 5: FDA collected 150 potentially responsive records and was in the process of conducting additional searches for records.

- Item 4: FDA collected 1,300 potentially responsive records and was "in the process of finalizing its responsiveness and releasability determinations for [these] records," after which it would produce non-exempt responsive portions of these records to CHD.

- Second Request: FDA collected one record responsive to this request and would produce it by July 3, 2023.

6. Since filing the June 27, 2023 Joint Status Report, FDA completed its responsiveness review of the 1,300 potentially responsive records collected with respect to Item 4 of CHD's First Request and determined that none of the records are, in fact, responsive to this item. FDA also provided CHD with a copy of the record responsive to CHD's Second Request.

7. In addition, FDA has completed its responsiveness review of the 150 records collected for Items 3 and 5 of CHD's First Request and determined that these records are responsive. The page-by-page, line-by-line reviews that FDA must conduct to determine releasability and prepare redactions have not been completed.

8. Finally, searches for records potentially responsive to Item 2, and additional searches for records potentially responsive to Items 3 and 5 have not been completed. Once these searches have concluded, reviews for responsiveness and releasability will then need to be conducted prior to disclosure of any records.

PLAINTIFF'S POSITION

9. Plaintiff's First Request was filed over a year ago. At least 150 responsive documents have been identified since June 2023, and the FDA has yet to provide a date for production. Plaintiff requests that the Court order the following:

a. By September 15, 2023, Defendant shall provide Plaintiff with all non-exempt portions of the 150 responsive records it has already located for Items 3 and 5;

b. By September 15, 2023, defendant shall complete searches for records potentially responsive to Item 2, and complete the additional searches necessary to locate records potentially responsive to Items 3, 4, and 5.

c. On or before September 15, 2023, the parties shall file a further joint status report, in which Defendant shall (i) describe the searches completed and the volume of potentially responsive records located for Items 2, 3, 4, and 5 of the First Request; and (iii) provide an anticipated timeframe for processing and producing responsive records.

10. Defendant has expressed an intention to file a motion to stay. Plaintiff anticipates it will oppose such a motion.

DEFENDANT'S POSITION

11. FDA is facing an unprecedented FOIA workload due to a Texas federal court's entry of two orders requiring the production of approximately 5.7 million pages of COVID-19 vaccine-related records. *See Pub. Health & Med. Pros. for Transparency v. FDA*, Civ. A. No. 21-1058 (N.D. Tex.) ("*PHMPT 1*"); *PHMPT & Stephanie and Patrick de Garay v. FDA*, Civ. A. No. 22-0915 (N.D. Tex.) ("*PHMPT 2*"). The court orders in those cases require FDA to produce records to the FOIA requestors at an unprecedented rate: at least 90,000 to 110,000 pages per month from July 2023 to November 2023, and at least 180,000 pages per month from December 2023 to June 2025. *See PHMPT 1*, ECF Nos. 35 and 55; *PHMPT 2*, ECF No. 38.

12. In light of the extraordinary burdens created by *PHMPT 1* and *PHMPT 2*, FDA is not in a position to agree to a processing schedule at this time. Moreover, CHD's proposal is untenable because it would not give FDA sufficient time to complete all of the work necessary to

collect, review, redact, and produce non-exempt responsive information for this case while also complying with the production orders in *PHMPT 1* and *PHMPT 2*.

13. Within thirty (30) days of the filing of this Joint Status Report, FDA anticipates filing a motion for a stay of the proceedings in this case.

14. FDA respectfully requests that the Court permit the parties to file their next joint status report within fifteen (15) days after the Court has ruled on FDA's motion for a stay.

Date: August 11, 2023

Respectfully submitted,

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