UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CHILDREN'S HEALTH DEFENSE, Plaintiff, v. U.S. FOOD AND DRUG ADMINISTRATION, Defendant.	)	Civ. A. No. 23-220 (RDM)

JOINT STATUS REPORT

Pursuant to the Court's order, issued May 14, 2023, the parties respectfully submit this Joint Status Report ("JSR"):

1. This case concerns two FOIA requests: Request #2022-5587 (First Request) and Request #2022-6498 (Second Request). On April 5, 2023, the Court ordered that, "on or before May 12, 2023, the parties shall confer and file a joint status report addressing (1) any documents still to be produced pursuant to FOIA; (2) an anticipated schedule for processing and producing any such documents; and (3) any substantive areas of disagreement between the parties."

2. The parties filed their last JSR on May 12, 2023. In that JSR, FDA stated that it conducted searches for records potentially responsive to certain items in Plaintiff's First Request. FDA was referencing item 4 of Plaintiff's First Request, which seeks records related to Proportional Reporting Ratio data mining, and Plaintiff's Second Request, which seeks records related to the Empirical Bayesian data-mining analyses conducted for a specific published article. *See* ECF No. 1, Complaint, Exh 1. FDA collected approximately 1,300 potentially responsive records for item 4 of Plaintiff's First Request and 1 record for Plaintiff's Second Request.

3. FDA is in the process of finalizing its responsiveness and releasability determinations for the records collected for item 4 of Plaintiff's First Request. After these determinations are finalized, FDA will provide Plaintiff with the non-exempt, responsive records.

4. FDA has finalized its responsiveness and releasability determinations for the record collected for Plaintiff's Second Request and is preparing to produce that record to Plaintiff by July 3, 2023.

5. FDA has also collected 150 records that are potentially responsive to items 3 and 5 of Plaintiff's First Request, which seek records related to Empirical Bayesian data mining analyses conducted in accordance with the Vaccine Adverse Event Reporting System Standard Operating Procedures and any consultations between FDA and CDC in connection with any "signals" that were detected, respectively. *See* ECF No. 1, Complaint, Exh. 1. FDA is in the process of conducting additional searches to capture the universe of records potentially responsive to these items in Plaintiff's First Request.

6. FDA is also in the process of conducting a search for records that are potentially responsive to item 2 of Plaintiff's First Request, which seeks records related to manual reviews of serious Adverse Events of Special Interest reports in accordance with the Vaccine Adverse Event Reporting System Standard Operating Procedures. *See* ECF No. 1, Complaint, Exh 1.

7. After these searches are complete, FDA will review the collected records for responsiveness and releasability.

8. With 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.

9. The parties respectfully request that the Court permit them to file another JSR by August 11, 2023.

10. The parties respectfully request that the Court vacate its order setting an Initial Scheduling Conference for July 7, 2023 and issue a new order setting an Initial Scheduling Conference for a date following August 11, 2023, after the next JSR is filed.

Date: June 27, 2023

Respectfully submitted,

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