UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

CHILDREN'S HEALTH DEFENSE, Plaintiff, v. FOOD AND DRUG ADMINISTRATION, Defendant.	**Case No. 1:23-cv-00220 (RDM)**

JOINT STATUS REPORT

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." Additionally, the Court scheduled an Initial Scheduling Conference for May 19, 2023.

The parties conferred on May 10, 2023. Pursuant to this order, the parties submit the following report and proposal:

Background

1. On July 27, 2022, Plaintiff submitted the First Request, which seeks, in relevant part, the following records associated with FDA's monitoring of the Vaccine Adverse Events Reporting System:

   - 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);
   - 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;
   - 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
   - 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.

2. On October 4, 2022, the FDA provided a final response to the First Request, denying it *in toto*. In relevant part, the denial indicated that the authority for denying access to the information sought was Exemption 5, "Certain interagency and intra agency communication." The denial indicates:

> [T]he following sections of the implementing regulations of FDA and reason(s) applicable to this denial are contained in the CFR, Title 21. Section 20.62 Intra-agency memoranda consisting of opinions, recommendations, and policy discussions within the deliberative process of FDA, from which factual information is not reasonably segregable. The information also contains a discussion of legal and policy matters and fall within the attorney work product and attorney-client privileges as enunciated by the Supreme Court in National Labor Relations Board v. Sears, Roebuck & Co., 421 U.S. 132 (1975)."

3. On October 11, 2022, Plaintiff timely filed an administrative appeal of the denial of the First Request. FDA did not rule on the Appeal.
4. On September 8, 2022, Plaintiff filed the Second Request, which seeks records of the Empirical Bayesian data mining underlying the analysis in *Reporting Rates for VAERS Death Reports Following COVID-19 Vaccination, December 14, 2020-November 17, 2021* (B. Day et al., MEDRXIV 2022.05.05.22274695, https://doi.org/10.1101/2022.05.05.22274695, https://www.medrxiv.org/content/10.1101/2022.05.05.22274695v1.full).
5. FDA has not provided a determination on or records responsive to the Second Request.
6. On January 26, 2023, Plaintiff filed its Complaint. On April 4, 2023, Defendant filed its answer.

Current Status

7. **Documents still to be produced**: FDA has conducted a search for records potentially responsive to Plaintiff's Second Request and will be reviewing the collected records to determine responsiveness. Afterwards, FDA will conduct a releasability review on responsive records. FDA has agreed to conduct supplemental searches for all four items in Plaintiff's First Request. To date, FDA has conducted searches for records potentially responsive to certain items in Plaintiff's First Request. FDA is currently reviewing the collected records for responsiveness. After this review is complete, FDA will conduct a releasability review of responsive records. FDA is currently in the process of formulating searches for records potentially responsive to the remaining items in Plaintiff's First Request. As a result, all responsive, non-exempt records are still to be produced.
8. **Anticipated schedule for processing and producing documents**: Because FDA is still in the process of conducting searches for Plaintiff's First Request, FDA has not yet determined

the volume of potentially responsive records and is unable to provide a schedule for processing and production of the records at this time. Accordingly, FDA seeks an additional forty-five (45) days, at which time it anticipates being able to propose a processing and production schedule.

9. **Substantive areas of disagreement**: At this point, the parties are uncertain as to what the substantive areas of disagreement will be.

Proposal

10. The parties propose filing a further joint status report by June 27, 2023, to more fully address the issues identified in the April 5 Minute Order. At this time, FDA anticipates that it will be able to report the nature and volume of potentially responsive records to be reviewed and whether the previously denied records contain reasonably segregable portions.
11. The parties respectfully request that the Court vacate the May 19, 2023, date, and reschedule the Initial Scheduling Conference to a date set shortly after the further joint status report would be filed.

Dated: May 12, 2023

Respectfully submitted,

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