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

JOINT SCHEDULING REPORT

Counsel for Plaintiffs Public Health and Medical Professionals for Transparency ("PHMPT") and Patrick and Stephanie de Garay (together, the "de Garays"), and Defendant United States Food and Drug Administration ("FDA") submit the following joint report pursuant to this Court's Order dated January 13, 2023 (the "Order"). *See* Doc. 19. The parties have conferred regarding the subjects set forth in Parts I and II of the Order and respectfully submit the following:

1. **Scheduling Conference:**

The parties conducted the scheduling conference on January 23, 2023, pursuant to this Court's Order. The conference was held at the office of the United States Attorney for the Northern District of Texas at 801 Cherry Street, Suite 1700, Fort Worth Texas, 76102. On behalf of Plaintiffs, attorney John Sullivan appeared in person and attorneys Aaron Siri and Elizabeth Brehm appeared by virtual means. On behalf of the Defendant, AUSA Clay Mahaffey appeared in person and FDA attorney Danli Song appeared by virtual means. Although a settlement was not reached,

the parties made progress toward a potential settlement of the case and agreed to make efforts to exchange additional information about the nature of the requested documents to further future discussions about the scope of Plaintiffs' Freedom of Information Act ("FOIA") requests and an appropriate production schedule for non-exempt portions of responsive records.

2. A brief statement of the claims and defenses:

a. Plaintiffs: This case involves Plaintiffs' FOIA requests, which sought expedited processing for: (1) "[a]ll data and information for the Moderna Vaccine enumerated in 21 C.F.R. § 601.51(a), with the exception of publicly available reports on the Vaccine Events Reporting System ['VAERS']"; and (2) "[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 [public VAERS reports.]"

b. Defendant: FDA raised five defenses in its answer: (1) Some or all of the requested records or information may be exempt from disclosure, in whole or in part, under 5 U.S.C. § 552(b); (2) Plaintiffs' FOIA request is improper and unduly burdensome to the extent it does not reasonably describe the records sought as required by 5 U.S.C. § 552(a)(3)(A); (3) Defendant is entitled to invoke all exemptions under the FOIA and any other applicable laws; (4) To the extent Plaintiffs' complaint seeks documents or information that were not asserted in their original FOIA requests. such matters are barred as unexhausted; and (5) Plaintiffs are not entitled to attorneys' fees or costs. FDA further contends that Plaintiffs' requests do not meet the requirements for expedited processing under the FOIA, 5 U.S.C. § 552(a)(6)(E), and even if Plaintiffs were entitled to expedited processing, the FOIA only requires an agency to "process as soon as practicable," 552 U.S.C. § 552(a)(6)(E)(iii).

3. A proposed time limit to amend pleadings and to join parties;

Plaintiffs reserve the right to amend the pleadings and join parties as provided in the Federal Rules of Civil Procedure. Defendant's position is that no amendment to the pleadings or joinder of parties will be necessary in this FOIA case.

4. A proposed time limit to file various types of motions, including dispositive motions;

There are no pending motions at this time. The parties agree that filing dispositive motions prior to completion of production of non-exempt, responsive records would be premature and the parties instead propose that, should the parties not reach agreement on the timeframe for future steps, the parties will make efforts to reach agreement on an appropriate briefing schedule and brief their positions on an appropriate production schedule.

5. A proposed time limit for initial designation of experts and responsive designation of experts;

At this time, the parties agree that designations of experts are likely unnecessary in this FOIA action.

6. A proposed time limit for objections to experts (i.e., *Daubert* and similar motions);

The parties agree that objections to experts are likely unnecessary as designations of experts are likely unnecessary.

7. A proposed plan and schedule for discovery, a statement of the subjects on which discovery may be needed, a time limit for completing factual and expert discovery, and a statement of whether discovery should be conducted in phases;

"'Discovery is 'generally inappropriate' in FOIA cases.'" *Brewer v. DOJ*, No. 3:18-CV-1018, 2019 WL 3948351, at *5 n.8 (N.D. Tex. July 30, 2019), *report and recommendation adopted*, No. 3:18-CV-1018, 2019 WL 3947132 (N.D. Tex. Aug. 21, 2019); *see also In re Clinton*, 973 F.3d 106, 113 (D.C. Cir. 2020) ("[A]s a general rule, discovery in a FOIA case is 'rare.'") (quoting *Baker & Hostetler LLP v. U.S. Dep't of Commerce*, 473 F.3d 312, 318 (D.C. Cir. 2006)). The

parties agree that discovery is not necessary at this time based on the information currently available.

8. **A statement on whether any limitations on discovery need to be imposed, and if so, what limitations;**

As explained in Paragraph 7, the parties agree that discovery is not necessary at this time.

9. **A statement on how to disclose and conduct discovery on electronically stored information ("ESI") and any statement on disputes regarding disclosure and/or discovery of ESI;**

The parties do not anticipate any issues regarding disclosure or discovery of electronically stored information. As explained above in Paragraph 7, the parties agree that discovery is not necessary at this time.

10. **Any proposals regarding handling and protection of privileged or trial-preparation material that should be reflected in a Court Order;**

As explained in Paragraph 7, the parties agree that discovery is not necessary at this time. The parties do anticipate that some records sought by Plaintiffs will contain information exempt from disclosure under the FOIA, including material that the government is required to protect from disclosure, such as material exempted by Exemption 4 (confidential commercial information/trade secrets) or Exemption 6 (privacy). Consistent with the FOIA, the parties agree that, where FDA contends that an exemption applies, it will produce "[a]ny reasonably segregable portion of [the] record . . . after [redaction or] deletion of the portions which are exempt." 5 U.S.C. § 552(b).

11. **A proposed trial date, the estimated number of days for trial, and whether a jury has been demanded;**

The parties believe the setting of a trial date is not necessary, as "the vast majority of FOIA cases can be resolved on summary judgment." *Brayton v. Office of the U.S. Trade Representative*, 641 F.3d 521, 527 (D.C. Cir. 2011).

12. **A proposed mediation deadline;**

The parties believe that they will be able to negotiate regarding the scope of the Plaintiffs' FOIA requests and a production schedule without the assistance of a mediator or other ADR provider. During the parties' meet and confer, Plaintiffs asked Defendant to provide indices or tables of contents of the larger biological product file and the biologic license application ("BLA") for Moderna's Spikevax vaccine and Pfizer's Comirnaty vaccine for 12-15-year-olds, including breakdowns of the approximate number of pages for each item in the indices or table of contents, to the extent possible. Defendant agreed to make efforts to provide information to that end with respect to the BLAs for both vaccines. Because the Complaint requests production in this case to begin after the completion of production in a similar matter concerning documents related to the Comirnaty vaccine for individuals above the age of 16 years, *see* Doc. 1 at 29 (citing *Pub. Health & Med. Pros. for Transparency v. Food & Drug Admin.*, No. 4:21-CV-1058-P, 2022 WL 90237 (N.D. Tex. Jan. 6, 2022) ("*PHMPT 1*")), Plaintiffs also asked Defendant to provide an estimated date of completion and/or a page count of records produced so far in *PHMPT 1*. In *PHMPT 1*, the next joint status report ("JSR"), in which FDA expects to provide an estimated date by which production will be completed, is due March 24, 2023.

Defendant's position is that given that FDA expects to provide an estimated date of completion for PHMPT 1 in the March 2023 JSR in that case, an initial JSR in this case regarding the status of negotiations can be filed by April 14, 2023. Plaintiffs' position is that the parties file an initial JSR in two weeks to keep the parties on track to reach a resolution and because it otherwise should not take two months for the FDA to get an approximate count of pages left to produce in *PHMPT 1*. Additionally, Plaintiff notes that its request in the Complaint was made with the understanding that production in PHMPT would be completed shortly.

13. A statement as to when and how disclosures under Fed. R. Civ. P. 26(a)(1) were made or will be made;

As explained above in paragraph 7, the parties agree that discovery is not necessary at this time. The parties agree that disclosures under Fed. R. Civ. P. 26(a)(1) are not required in this FOIA case.

14. A statement as to whether the parties will consent to trial (jury or non-jury) before United States Magistrate Judges Cureton or Ray;

The parties respectfully do not consent to trial before a magistrate judge. For the reasons set forth in paragraph 11, they believe a trial date is not needed.

15. Whether a conference with the Court is desired, and if so, a brief explanation why; and

Plaintiffs' position is that having a conference with the Court on the calendar tends to focus the parties towards resolving open issues and that conferences with the Court have been useful in the past in related matters. Therefore, Plaintiffs respectfully request a conference with the Court. Defendant is not requesting a conference with the Court at this time.

16. Any other proposals on scheduling and discovery that the parties believe will facilitate expeditious and orderly preparation for trial, and other orders that the Court should enter under Fed. R. Civ. P. 16(b), 16(c), and 26(c).

At this time, the parties believe no additional orders under Rules 16(b), 16(c), or 26(c) are necessary at this time.

Respectfully submitted,

/s/ Aaron Siri
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