## IN THE UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF TEXAS DALLAS DIVISION

DEFENDING THE REPUBLIC,	8
Plaintiff,	Ş Ş
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FOOD AND DRUG ADMINISTRATION,	8 8 8
Defendant.	ş

CIVIL ACTION NO. 3:22-1237-E

## <u>JOINT STATUS REPORT AND</u> MOTION TO VACATE BRIEFING SCHEDULE (ECF NO. 26)

Plaintiff, Defending the Republic, and Defendant, United States Food and Drug Administration ("FDA") jointly move to vacate the briefing schedule (ECF No. 26) previously ordered and file the following joint status report:

1. This case involves Plaintiff's Freedom of Information Act ("FOIA") request to FDA for "all data and information submitted by Moderna relating to the FDA review and approval of Spikevax." *See* ECF No. 1.

2. On January 23, 2023, the parties submitted a joint motion discussing the status of negotiations relating to the FOIA request and proposing a briefing schedule to present their arguments on the issue of an appropriate production schedule. ECF No. 25 at ¶¶ 2-3.

3. On March 2, 2023, the Court entered an electronic order granting the joint motion and ordering Plaintiff and Defendant to file their briefs concerning their proposed production schedules by April 3 and May 3, 2023, respectively. ECF No. 26.

4. The parties have now reached an agreement regarding an appropriate production schedule. Plaintiff has narrowed the scope of its FOIA request to selected records in Moderna's Biologics License Application for Spikevax totaling approximately 23,751 pages. FDA will

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provide the first set of records (the Section 16.2.7 Adverse Event Listing, totaling approximately 13,685 pages) to Plaintiff by July 17, 2023, and produce all remaining records in the amended request on a monthly basis, to be completed no later than December 31, 2023.

5. Given this agreement, the parties respectfully request the Court vacate its March 2, 2023 Order and enter a scheduling order that requires the parties to report to the Court on the status of production, starting on July 31, 2023, and due every 60 days thereafter, and, if necessary after FDA's productions for Plaintiff's amended FOIA request have been completed, directing the parties to propose dates for dispositive motions.

Respectfully submitted,

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Attorney for Defendant

## **CERTIFICATE OF SERVICE**

I hereby certify that on March 31, 2023, I e-filed the foregoing using the CM/ECF system,

which serves all counsel of record.

<u>s/ Travis Miller</u> Travis Miller