UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, ET AL.,

Plaintiffs,

v. **No. 4:22-cv-0915-P**

FOOD AND DRUG ADMINISTRATION,

Defendant.

ORDER

"Democracy dies behind closed doors." *Detroit Free Press v. Ashcroft*, 303 F.3d 681 (6th Cir. 2022). To help prevent that from happening, Congress enacted the Freedom of Information Act ("FOIA"). It allows the public access to agency records upon request. But if an agency improperly denies a request, courts may order the agency to release the records sought. In this case, Plaintiffs filed a FOIA request for the documents the Food and Drug Administration ("FDA") relied on to license two COVID-19 vaccines: (1) Pfizer's 12 to 15-year-olds vaccine and (2) Moderna's adult vaccine. Because the FDA improperly denied Plaintiffs' request, the Court **ORDERS** the FDA to produce all documents relating to the two vaccines by **June 31, 2025**.

BACKGROUND

This is Plaintiff Public Health and Medical Professional for Transparency's ("PHMPT") second case involving a FOIA request submitted to the FDA for documents related to COVID-19 vaccines. In the first case, PHMPT's expedited FOIA request sought the documents related to the FDA's licensing of Pfizer's COVID-19 vaccine for those over 15 years old. *See Pub. Health & Med. Pros. for Transparency v. FDA*, No. 4:21-CV-1058-P, 2022 WL 90237, at *1 (N.D. Tex. Jan. 6, 2022) (Pittman, J.). Because the FDA denied PHMPT's FOIA request, PHMPT

sued to obtain the documents. *Id.* And after the Parties failed to agree on a production schedule, this Court held that PHMPT was entitled to expedited processing and ordered the FDA to produce the expected 450,000 pages at a rate of 55,000 per month. *Id.* at *1. The Parties later agreed to modify the rate of production. But the expected end date for producing all documents—November 1, 2022—remained unchanged.[1]

Plaintiffs PHMPT and Patrick and Stephanie de Garay[2] now seek a production schedule for the documents the FDA relied on to license Pfizer's COVID-19 vaccine for 12 to 15-year-olds and Moderna's COVID-19 vaccine for adults. As in the first case, the FDA denied Plaintiffs expedited FOIA request, and the Parties have failed to agree on a production schedule. The Court thus held a conference with the Parties to determine whether Plaintiffs are entitled to expedited processing and, if so, an appropriate production schedule.

LEGAL STANDARD

FOIA generally gives citizens the right to access federal agency records. *See* 5 U.S.C. § 552. To do so, a person must submit a request to a federal agency describing the records sought. § 552(a)(3)(A). Generally, federal agencies process these requests on a first-in/first-out basis. *See Open Am. v. Watergate Special Prosecution Force*, 547 F.2d 605, 616 (D.C. Cir. 1976). Sometimes, however, agencies must expedite the processing of certain requests—cutting all non-expedited requests in line. *See Daily Caller v. U.S. Dep't of State*, 152 F. Supp. 3d 1, 8 (D.D.C. 2015). If an agency denies a request for expedited processing under FOIA, the decision is subject to immediate judicial review. § 552(a)(6)(E)(iii). District courts have "jurisdiction to enjoin the agency from withholding agency records and to order the production of any

[1] Under the rate of production ordered by the Court and later modified by the Parties, all documents were set to be produced by November 1, 2022. Because the 450,000-page estimation provided by the FDA, however, is nowhere close to the number of actual documents—1.2 million—only 64% of the total documents have been produced.

[2] Patrick and Stephanie de Garay's daughter was part of the clinical trial to license Pfizer's COVID-19 vaccine for 12- to 15-year-olds. Directly after her second shot, she was rushed to the emergency room and now requires a wheelchair and a feeding tube for daily life.

agency records improperly withheld." 5 U.S.C. § 552(a)(4)(B). These determinations are made de novo. *See Bloomberg, L.P. v. FDA*, 500 F. Supp. 2d 371, 374 (S.D.N.Y. 2007).

ANALYSIS

This case presents two issues. *First*, whether the FDA erroneously denied Plaintiffs' request for expedited processing. *Second*, the appropriate production schedule for the documents sought.

A. Expedited Processing

Plaintiffs contend that the FDA wrongfully denied their request for expedited processing. A requestor is entitled to expedited processing if they show a compelling need. § 552(a)(3)(6)(E)(i)(I). A need is compelling if there is (1) "an imminent threat to the life or physical safety of an individual" or (2) for "a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity." *Id.* This case falls under the second definition.

First, PHMPT has shown—and Defendants do not dispute—that it "exists for the sole purpose of disseminating to the public the data and information in the biological product files for each of the COVID-19 Vaccines." ECF No. 1 at 21. *Second*, Plaintiffs have shown an urgent need to inform the public about the health and safety of the COVID-19 vaccines based on the massive push to vaccinate, persistent effort to eradicate COVID-19, and continued government and private efforts to enforce these vaccines.[3] The FDA's own regulations also recognize this urgency—"[a]fter a license has been issued, the following data and information in the biological product file are immediately available for public disclosure unless extraordinary circumstances are shown: (1) All safety and effectiveness data and information . . . ." 21 C.F.R. § 601.51(e).

[3] As political theorist Jeremy Bentham once said, "[s]ecrecy, being an instrument of conspiracy, ought never to be the system of regular government." *See The Oxford Handbook of Public Accountability* 275 (2014). Indeed, conspiracies flourish where information is not transparent. And they often expand with great harm beyond their initial target. As such, this information is not only necessary for the good of our American medical system, but also for the health of our society at large.

Because Plaintiffs have shown a compelling need, the FDA wrongfully denied their request for expedited processing.

B. Production Schedule

The Court must next determine the appropriate production schedule. FOIA "does not assign any particular time frame to release of the records sought." *Landmark Legal Found. v. EPA*, 910 F. Supp. 2d 270, 275 (D.D.C. 2012). So courts have "broad discretion" to determine a reasonable processing schedule. *Colbert v. FDA*, No. 16-1790, 2018 WL 6299966, at *1 (D.D.C. 2014).

Defendants propose a production schedule that would take at least 23.5 years. And while the Court recognizes the limited resources that the FDA has dedicated to FOIA requests, the number of resources an agency dedicates to such requests does not dictate the bounds of an individual's FOIA rights. *See Open America*, 547 F.2d at 621 (Leventhal, J., concurring). Instead, the Court must ensure that the fullest possible disclosure of the information sought is timely provided—as "stale information is of little value." *Payne Enters., Inc. v. United States*, 837 F.2d 486, 494 (D.C. Cir. 1988). To do so and provide the FDA with as much time as possible to comply, the Court **ORDERS** the FDA to produce all data and information relating to the approval of the two vaccines by **June 31, 2025**.

CONCLUSION

The Court recognizes the burden the FDA faces in releasing the documents by the abovementioned date and thus **ORDERS** the Parties to meet and confer and submit a joint production rate that maximally reduces this burden by **May 23, 2023**.

SO ORDERED on this **9th day** of **May 2023**.

Mark T. Pittman
UNITED STATES DISTRICT JUDGE