UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CHILDREN'S HEALTH DEFENSE, Plaintiff, v. FOOD AND DRUG ADMINISTRATION, Defendant.	Civ. A. No. 23-0220 (RDM)

DEFENDANT'S OPPOSITION
TO PLAINTIFF'S MOTION FOR ORDER FOR TIMELY PROCESSING

On October 24, 2024, this Court ordered Defendant Food and Drug Administration ("FDA") to begin processing Plaintiff Children's Health Defense's ("CHD") FOIA request No. 2022-5587 no later than 24 months from the filing of FDA's August 9, 2024, status report, i.e., August 9, 2026. *See* Min. Order (Oct. 24, 2024). Less than a month later, however, CHD sought to undo that time frame by requesting that this Court order FDA to complete its searches for potentially responsive records and produce previously collected records within 30 days. Pl.'s Mot. for Order for Timely Processing ("Mot."), ECF No. 35. Although the Court's October 24 Order allowed CHD to seek a processing date earlier than August 9, 2026, CHD's opportunity was conditioned "on changed circumstances or new information." Min. Order (Oct. 24, 2024). In its present motion, CHD argues that the public has an urgent need for the requested records and, therefore, its FOIA request is entitled to immediate processing under FOIA's expedited-processing provision or under *Open America*. But this "urgent need" argument is simply a rehashing of CHD's prior arguments and does not justify an earlier processing date, let alone immediate

processing. Because CHD has not identified "changed circumstances or new information," FDA respectfully requests that the Court deny CHD's motion.

BACKGROUND

The Court is familiar with the facts of this case. *See* Min. Order (Oct. 24, 2024). As relevant here, CHD submitted a FOIA request to FDA seeking certain records. Compl. Ex. 1 at 16–25, ECF No. 1-1. On January 26, 2023, CHD sued in this district. *See generally* Compl., ECF No. 1. Because FDA was and remains subject to an extraordinary production order from another district court, FDA moved for an *Open America* stay. *See* Mot. for Stay, ECF No. 17. CHD opposed that motion. Pl.'s Opp'n to Mot. for Stay, ECF No. 19. While FDA requested a stay of eighteen months, Mot. for Stay at 1, ECF No. 17, this Court stayed this case for six months and ordered the parties to file a joint status report on or before June 14, 2024. Mem. Op. & Order at 9, ECF No. 25.

Thereafter, FDA requested an extension of the *Open America* stay. Joint Status Rep. at 8 (June 14, 2024), ECF No. 28. The parties filed several rounds of briefing on the issue of FDA's efforts to process CHD's and all other FOIA requests in the Complex Track. *See, e.g.*, Def.'s Status Rep., ECF No. 31; Pl.'s Resp. to Def.'s Status Rep., ECF No. 32; Joint Status Rep. (Oct. 18, 2024), ECF No. 34. The Court held two hearings on the matter, as well. *See* Hr'g Tr. (July 9, 2024), ECF No. 30; Hr'g Tr. (Oct. 4, 2024), ECF No. 33.

This extensive briefing by the parties and engagement by the Court culminated in the Court's October 24, 2024, Minute Order, in which the Court ordered that FDA begin processing CHD's FOIA request "no later than August 9, 2026, and, to the extent possible and consistent with the placement of the request in the queue of similarly situated requesters, at an earlier date." Min. Order (Oct. 24, 2024). The Court recognized "the unusual and extraordinary demands placed on

the FDA in other litigation" and observed that "other, similarly situated FOIA requesters filed their requests before the request at issue in this case was filed and that it would be unfair to push those requests further back in the queue." *Id.*

The Court also addressed the very position that CHD advances again here. *See* Pl.'s Mot. at 12–13, ECF No. 35 (noting that "timely disclosure of records is . . . essential to the core purpose of FOIA," and arguing that "the fact that CHD's request sits in a severely backlogged queue does not eliminate the FDA's obligations . . . under the FOIA"). Specifically, the Court acknowledged that "the purposes of FOIA require agencies to process FOIA requests as promptly as possible and that the delay in this case—even if unavoidable in light of the demands placed on the FDA in other litigation—is antithetical to the purposes of FOIA." Min. Order (Oct. 24, 2024). However, the Court found that FDA "has hired and trained additional staff to assist with the extraordinary burden that it currently faces" and "all that the Court can do is require the most expeditious processing of the request at issue, consistent with reality." *Id.*

The October 24 Order was entered "without prejudice to Plaintiff seeking an earlier processing date based on changed circumstances or new information." Min. Order (Oct. 24, 2024). It is that Order that CHD now seeks to amend.

ARGUMENT

In its present motion, CHD makes two main arguments: first, that the public has an urgent need for the records at issue here, Pl.'s Mot. at 14–16, and second, that CHD's request is entitled to expedited processing, *id.* at 16–19. Because the standard for expedited processing requires a showing of urgency, *see* 5 U.S.C. § 552(a)(6)(E)(v)(II) (defining "compelling need" for expedited processing as "urgency to inform the public concerning actual or alleged Federal Government

activity"), the gravamen of CHD's argument is that the Court should order immediate processing of the records because the public has an urgent need for them.

CHD's "urgent need" argument is not new. As CHD recounts in its motion, "CHD's July 2022 FOIA request included detailed, fully-cited arguments" that it was entitled to expedited processing because of the public's alleged "urgent need" for the records. Pl.'s Mot. at 6, ECF No. 35 (citing Compl. Ex. 1 at 7–10, ECF No. 1-1); *see* Pl.'s Opp. to Mot. for Stay at 43–44, ECF No. 19. In June 2024, CHD again argued that "[t]he need for the requested safety-monitoring records remain[ed] urgent." Joint Status Rep. at 6, ECF No. 28 (June 14, 2024).[1] Yet again in August, CHD requested a production order, citing the "urgent need for the records." Pl.'s Resp. to Def.'s Status Rep. at 1–2, ECF No. 32. Most recently, in October, CHD reiterated its requests for expedited processing, again repeatedly citing "urgent need." Joint Status Rep. ¶¶ 13, 15, 18, 19, 20, ECF No. 34 (Oct. 18, 2024). CHD's rehashing of the same argument it has pressed time and again in this case does not constitute "new information."

CHD's motion also fails to identify changed circumstances that have any bearing whatsoever on the basis for the Court's Order, i.e., "the unusual and extraordinary demands placed on the FDA in other litigation." Min. Order (Oct. 24, 2024). To be clear, the demands placed on FDA have not abated. Indeed, on December 6, 2024, the district court in *PHMPT I* ordered FDA to produce an additional set of records deemed by that court to be responsive (estimated to consist of, at a minimum, over a half million pages), by the same production deadline that has been ordered in *PHMPT II*. *See* Mem. Op. & Order, *Pub. Health & Med. Professionals for Transparency v.*

[1] In that filing, CHD quoted public comments by Dr. Peter Marks, Director of CBER, about the importance of transparency in the context of vaccine safety. Mot. at 7, ECF No. 35. CHD now attempts to construe similar comments by Dr. Marks as a "new basis for urgency." *Id*. at 14 (emphasis in original removed).

Food & Drug Admin. ("*PHMPT I*"), Civ. A. No. 21-1058 (N.D. Tex. Dec. 6, 2024), ECF No. 101 ("It is ordered that the FDA shall produce the responsive [Emergency Use Authorization] file on or before June 30, 2025."); *see also PHMPT I*, Burk Decl., ECF No. 99 (Nov. 21, 2024) at 12 ¶ 25 ("[I]nitial estimates are that Pfizer's submissions in support of its request(s) for emergency use authorization are approximately 589,600 pages."). In response, FDA has moved to alter or amend the June 2025 production deadline for the emergency use authorization file, requesting a stay of that deadline until the conclusion of production in *PHMPT II*. *Id.*, ECF Nos. 103–05. The *PHMPT* parties are currently briefing FDA's request.

Finally, CHD turns to *Buc v. FDA* to argue that, "even in the absence of the expedited processing standard, its FOIA request is entitled to immediate processing under *Open America* itself." Pl.'s Mot. at 16, ECF No. 35; *id.* at 16-17 (citing *Buc v. FDA*, 762 F. Supp. 2d 62, 63, 65–66 (D.D.C. 2011)). But the circumstances of that case have no bearing on this one. In *Buc*, the court found that an *Open America* stay was not warranted because the volume of FOIA requests was "predictable," "the norm," and "routine." *Buc*, 762 F. Supp. 2d at 69. Here, in contrast, this Court repeatedly has found that the task before FDA is "Herculean," "unprecedented," "exceptional," "overwhelming," "unusual," and "extraordinary." Mem. Op. & Order at 5–6, ECF No. 25; Min. Order (Oct. 24, 2024).[2]

[2] CHD's motion also fails under Federal Rule of Civil Procedure 54(b), which provides that any order or decision that is not a final judgment "may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities." Fed. R. Civ. P. 54(b). The Court has "broad discretion to hear a motion for reconsideration brought under Rule 54(b)[,] *Isse v. Am. Univ.*, 544 F. Supp. 2d 25, 29 (D.D.C. 2008), and may grant the motion "as justice requires." *Capitol Sprinkler Inspection, Inc. v. Guest Servs., Inc*, 630 F.3d 217, 227 (D.C. Cir. 2011) (quotation marks omitted). "Considerations a court may take into account under the 'as justice requires' standard include whether the court 'patently' misunderstood the parties, made a decision beyond the adversarial issues presented, made an error in failing to consider controlling decisions or data, or whether a controlling or significant change in the law has occurred." *Isse*, 544 F. Supp. 2d at 29. CHD does not even attempt to show that any of those circumstances exist

In sum, CHD has not presented any reason for the Court to deviate from its original, carefully considered order providing that the FDA begin processing CHD's FOIA request "no later than August 9, 2026, and, to the extent possible and consistent with the placement of the request in the queue of similarly situated requesters, at an earlier date." Min. Order (Oct. 24, 2024).

* * *

here. Absent extraordinary circumstances not present here, Rule 54(b) is not a vehicle for CHD to relitigate issues this Court already has decided. *See Singh v. George Washington Univ.*, 383 F. Supp. 2d 99, 101 (D.D.C. 2005).

CONCLUSION

For the foregoing reasons, FDA respectfully requests that the Court deny CHD's motion.

Dated: January 9, 2025

Respectfully submitted,

MATTHEW M. GRAVES, D.C. Bar #481052
United States Attorney

BRIAN P. HUDAK
Chief, Civil Division

By: /s/ *Dimitar P. Georgiev*
DIMITAR P. GEORGIEV, D.C. Bar #1735756
Assistant United States Attorney
601 D Street, NW
Washington, DC 20530
(202) 815-8654

Attorneys for the United States of America

OF COUNSEL:

MARK RAZA
Chief Counsel

WENDY VICENTE
Deputy Chief Counsel, Litigation

ELIZABETH BONOMO
Assistant Chief Counsel
Office of the Chief Counsel
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20903

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CHILDREN'S HEALTH DEFENSE, Plaintiff, v. FOOD AND DRUG ADMINISTRATION, Defendant.	Civ. A. No. 23-0220 (RDM)

[PROPOSED] ORDER

UPON CONSIDERATION of Plaintiff's motion, and the entire record herein, it is hereby ORDERED that Plaintiff's motion is DENIED.

SO ORDERED:

_____
Date

_____
RANDOLPH D. MOSS
United States District Judge