UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CHILDREN'S HEALTH DEFENSE, Plaintiff, v. U.S. FOOD AND DRUG ADMINISTRATION, Defendant.	)	Civ. A. No. 23-220 (RDM)

PLAINTIFF'S SUR-REPLY IN SUPPORT OF PLAINTIFF'S OPPOSITION TO DEFENDANT'S MOTION TO STAY

TABLE OF CONTENTS

INTRODUCTION

As discussed in Plaintiff's Memorandum of Law in Support of Plaintiff's Opposition to Defendant's Motion to Stay ("Plaintiff's Opposition Memo"), to qualify for an *Open America* stay, the FDA must show not only that it is exercising due diligence in processing FOIA requests in *general*, but also that it exercised due diligence in responding to *CHD's* FOIA request in *particular*. *See* ECF 19 at 30-35. The FDA's original Motion to Stay and accompanying declaration were bereft of information about how the agency has processed CHD's request, and bereft of argument as to why the agency's treatment of CHD's request should qualify as "diligent." *See* ECF 19, Plaintiff's Opposition Memo, at 31.

Now, the FDA's Reply does not merely address Plaintiff's Opposition, but improperly attempts to make new "due diligence" arguments (*see* ECF 20, Defendant's Reply in Support of its Motion for an Eighteen Month Stay of Proceedings ("Defendant's Reply"), at 10-14) based on new information presented in the declarations filed with the Defendant's Reply. *See* ECF 20-1, Supplemental Declaration of Suzann Burk ("Supplemental Declaration"), ¶¶ 4-6, 11, 13-14, 16 (discussing ALFOI's six processing queues, the placement of CHD's FOIA request within the complex processing queue, and the reasons why the FDA cannot produce the 150 responsive EB-mining records the agency located in the spring of 2023). However, as discussed below, rather than supporting the FDA's claims of diligence, the new information merely confirms the FDA's failure to meet the "due diligence" standard, both in general, and with respect to CHD's FOIA request in particular.

ARGUMENT

I. THE NEW INFORMATION CONFIRMS THAT THE FDA HAS NOT SHOWN "DUE DILIGENCE" IN GENERAL OR WITH RESPECT TO CHD'S REQUEST IN PARTICULAR

A. New Information About ALFOI's Complex Processing Queue Undercuts the FDA's Claim of Diligence

The Supplemental Declaration explains that ALFOI maintains six processing queues for the FOIA requests that it receives, including the "complex track," which is for requests that "usually require extensive time to locate, review, and/or redact the records and often involve voluminous records." ECF 20-1, at ¶ 4. According to the Supplemental Declaration, "As of October 18, 2023, Plaintiff's FOIA request . . . is in the Complex Track behind 368 earlier-submitted FOIA requests pending in that queue." *Id.* at ¶ 11.

This new information confirms the FDA's lack of diligence in processing CHD's individual FOIA request. The FDA does not dispute that in October 2022, the agency told CHD that the records sought in CHD's request were exempt from disclosure, and denied the request outright without actually searching for records, in violation of the FOIA, agency regulations, and ALFOI's own protocols. *See* ECF 19, Plaintiff's Opposition Memo, at 24, 31-33. The FDA does not dispute that in November 2022, the agency told CHD in that it would not rule on CHD's administrative appeal of the denial for nine to twelve months, which far exceeds FOIA time limits. *See id.* at 22. The FDA does not dispute that in May and June 2023 Joint Status Reports, the agency told this Court that it was processing CHD's request and working towards a production schedule, but that instead of following through on these assurances, the agency filed a Motion to Stay. *See id.* at 25. In light of this undisputed treatment, the fact that CHD's request has now been added to the complex queue behind hundreds of other requests is too little, too late, and highlights FDA's failure to process CHD's request with diligence.

The Reply's new information regarding the complex queue also undercuts the FDA's argument that the mere existence of ALFOI's six-queue system demonstrates due diligence (*see* ECF 20, Defendant's Reply in Support of Its Motion for an Eighteen-Month Stay of Proceedings, at 13-15), where the complex queue has a greater request backlog than the other five queues combined and is at a virtual standstill. At the end of Fiscal Year 2022, ALFOI had a backlog of 532 requests. *See* Declaration of Suzann Burk, ECF 17-2 ¶¶ 18-19 (summarizing ALFOI's workload for FYs 2015-2022). Based the new information that in October 2023, there were 368 earlier-submitted requests ahead of CHD's August 2022 request in the complex queue, it appears that at the end of FY 2022, at *least* 369 of ALFOI's backlogged requests were in the complex queue—that is, the complex processing queue contained 70% of the total backlog for all six ALFOI queues, and 9% of the FDA's *entire* FOIA backlog of 4188 requests. *See* Table: FDA Agency-Wide FOIA METRICS 2014-2022, ECF 19 at 28.

The fact that ALFOI maintains six queues and requests in the complex queue are processed on a "first-in-first-out" says nothing about diligence, where the backlog in the complex queue is so great that it takes at least two years for a request in the queue even to be assigned for processing.[1] The FDA's Reply declarations include additional information about the steps the FDA is taking to comply with court orders in the PHMPT litigation, and to process requests in other FDA FOIA offices. *See, e.g.*, ECF 20-1, Declaration of Sarah B. Kotler, at ¶¶ 7, 13, 15. But notably absent from the materials is any suggestion that the FDA has sought to specifically

[1] The FDA received CHD's request in August 2022, and now seeks until at least April 2025 to begin processing the request. *See also* CHD v. FDA, No. 23-2316 (TJK), ECF 13, Plaintiff's Opposition to Defendant's Motion to Stay, at 25, 33, discussing the 24-month wait-time in the complex queue.

address the huge backlog and lag time in ALFOI's complex processing queue, which—as noted above—contained nearly 10% of the FDA's *entire* FOIA backlog in FY 2022.

The FDA states that it is "working on requests" in the complex queue "as much as it can." (ECF 20, Defendant's Reply, at 15). But the declarations do not indicate how many individuals the FDA has actually dedicated to processing the backlog in that queue. The answer seems straightforward: not enough. Indeed, it is not possible to tell from the FDA's new declarations whether the complex processing queue is moving at all. In short, the FDA's use of a six-queue system does not support a finding of "due diligence," where the complex queue is the moral equivalent of cold storage.

B. New Information About the 150 EB-Mining Records Undercuts FDA's Claim of Diligence

The Defendant's Reply also argues that the FDA acted diligently with respect to CHD's request despite the agency's failure to produce 150 Empirical Bayesian data-mining ("EB-mining") records located by the agency in May 2023. *See* ECF 20 at 15-16. In support of this argument, FDA offers new information about the records that mischaracterize the records and their processing status. When these errors are corrected, it becomes apparent that the records are readily produced and that if the FDA were exercising diligence, it would produce the records forthwith.

First, in its Reply pleadings, the FDA claims that the EB-mining records are only "potentially" responsive to CHD's FOIA request, suggesting additional work is required to review the records for responsiveness. *See id*. at 15; *see also* ECF 20-1, Supplemental Declaration, at ¶ 15. But as the FDA well knows and has already acknowledged, the 150 EB-mining records are not "potentially" responsive to CHD's request. Rather, the EB-mining records consist of 75 excel files and 75 emails that *directly* respond to a CHD's request for "[r]ecords of

any Empirical Bayesian data mining conducted by the FDA and/or CBER and records of any sharing or discussion of results and signals with the CDC." *See* ECF 19, Plaintiff's Opposition Memo at 23 (request); 24 (FDA's description of the records); and 25 (FDA's acknowledgment that records are responsive). Thus, there is no additional labor required to determine whether the records are responsive.

Second, in its latest pleadings, the FDA claims that *if* the records are responsive, it will be required to undertake a time-consuming review before they can be produced, a review that is beyond FDA's capacity. *See id*. at 15; *see also* ECF 20-1, Supplemental Declaration, at ¶15. This claim assumes that to determine redactions, the FDA will need to review 150 individual records, but as the FDA well knows, that is not the case. The protocol for the EB mining makes it clear that the EB-data mining analysis was performed regularly, on a bi-weekly basis (*see* ECF 19 at 21), so the 150 records of the EB-mining analysis are repetitive in nature. Thus, to determine which portions (if any) of the 150 records are exempt, FDA needs only to review a single excel file (which presumably includes straightforward, quantitative data) and a single email; any required redactions should be identical throughout the 150 records. The fact that FDA has failed to do this straightforward processing and failed to produce the records—despite having located them at least six months ago—further demonstrates the FDA's lack of diligence in processing CHD's request.

CONCLUSION

For the reasons previously stated, and the added reasons above, CHD respectfully requests that the Court deny the FDA's requested stay.

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Respectfully submitted,

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