IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA

BENJAMIN COKER, *et al.*, Plaintiffs, v **LLOYD AUSTIN, III, in his official capacity as Secretary of Defense, *et al.*,** Defendants.	Case No. 3:21-cv-01211-AW-HTC

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL

INTRODUCTION

As Plaintiffs admit, this is "largely" an action for judicial review on an administrative record ("AR"). *See* Pls.' MTC at 2, ECF No. 89-1; *see generally* ECF No. 50. Although the Court declined to stay discovery entirely, *see* ECF No. 58, the Court indicated that it may look beyond the AR in some instances, particularly as to whether a Plaintiff "was specifically denied a BLA-compliant dose [of vaccine] or offered only a dose from a non-BLA-compliant vial." *See* ECF No. 58, at 1–2. Information about Plaintiffs' purported efforts to obtain BLA-compliant doses is likely held by Plaintiffs, not Defendants. DoD Defendants have nonetheless produced more than 2,600 pages of responsive materials—including more than 1,400 pages of ARs and more than 1,200 additional pages from guidance and trainings, as well as materials that were cited in individual declarations and an informational paper. *See generally* Pls.' Ex. 2 (describing planned productions); DEX1 (Avallone Letter responding to Pls.' Ex. 3). Defendants asked what information was still sought by Plaintiffs, *see* DEX2 (email thread memorializing discussions), and produced a targeted declaration and documents, *see* Pls.' Ex. 4 (Supp. Rans. Decl.), ECF No. 89-5. Defendants have thus provided substantial discovery in this matter, but reasonably objected to broad-ranging fishing expeditions for large categories of documents that are either unrelated to this case, improper extra-record discovery, or better resolved through more targeted responses already provided.

STANDARD OF REVIEW

"Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case." Fed. R. Civ. P. 26(b)(1). *See, e.g., Marllantas, Inc. v. Rodriguez*, 806 F. App'x 864, 867 (11th Cir. 2020) (discovery beyond the record inappropriate absent strong showing); *Blake v. Union Camp Int'l. Paper*, 622 F. App'x 853, 856 (11th Cir. 2015) (finding district court reasonably limited discovery beyond the record). "Proportionality requires counsel and the court to consider whether relevant information is discoverable in view of the needs of the case." *Brown v. Vivint Solar, Inc*, No. 8:18-CV-2838-T-24JSS, 2019 WL 10786018, at *1 (M.D. Fla. July 23, 2019).

ARGUMENT

RFP1. Plaintiffs' first request for production ("RFP") seeks broad categories of documents about all COVID-19 vaccines, including, *inter alia*, purchase orders, inventory records, shipping and distribution records. *See* Pls.' Ex. 1. Purchase-related documents sought by RFP 1 would be in the possession of HHS, and none of the documents are relevant to the claims presented here. The request is therefore disproportionate to the needs of the case. Pls.' Ex. 2. Plaintiffs admit as much because they now claim to need more targeted information about the location and availability of BLA-compliant vaccines in particular, and DoD policies about BLA-compliant vaccines. *See* Pls.' MTC, at 4-5. But information about DoD policy does

not fall within RFP1. And Defendants have already provided the location and availability of BLA-manufactured vaccines, including the shipment dates, locations and lot numbers of BLA-compliant doses ordered by DoD (including redistributions), *see* Supp. Rans Decl. Ex. C (pdf pp. 10-12); and the locations and lot numbers of currently available BLA-compliant doses, *see id*. Ex. E (pdf p. 69); and confirmation that the vials can be redistributed, *id*. ¶ 9. Defendants also now have Comirnaty-labeled vaccine. *Id*. ¶ 11. With this filing, Defendants are providing current numbers and location of these Comirnaty-labeled doses obtained by DoD. DEX3. Defendants have offered to provide Plaintiffs a BLA-compliant or BLA-labelled Comirnaty vaccine. *See* DEX4, DEX5. Plaintiffs have not responded. Plaintiffs do not explain why the information provided is insufficient, or why information responsive to RFP1 would provide them what they need.[1]

RFP8. RFP 8 seeks all communications between the military defendants and FDA employees on seven detailed topics. Pls.' Ex. 1. Plaintiffs admit the claims relevant to this request should be decided on an AR, and now fashion their opposition as a challenge to the sufficiency of the AR. MTC, at 5. A district court "may order discovery beyond the AR only where there is 'a strong showing of bad faith or improper behavior.'" *Marllantas, Inc.*, 806 F. App'x at 867 (quoting *Dep't of Com.*

[1] Plaintiffs include a footnote arguing that DoD has had insufficient BLA-compliant, EUA-labelled doses to vaccinate everyone vaccinated by DoD. DoD has never claimed that it has sufficient BLA-compliant doses to vaccinate everyone in DoD, and it is hard to see what bearing this has on the discovery dispute.

v. New York, 139 S. Ct. 2551, 2573-74 (2019)). Idle speculation such communications might exist and might be part of the record does not meet this exacting standard. It is not unreasonable for DoD rely in part on FDA's public findings and decisions about these vaccines, and Plaintiffs' arguments to the contrary go to the merits of their arguments, not the propriety of discovery. [2]

RFP9. RFP 9 seeks DoD communications with Pfizer regarding alleged attempts to order Comirnaty and why it was unavailable. Pls.' Ex. 1. These communications are irrelevant. These communications logically would not be part of an AR for the policies challenged here, and Plaintiffs have admitted these claims should be resolved on the basis of an AR. [3] It bears noting that the full explanation for why

[2] Plaintiffs incorrectly suggest that if responsive communications existed, they would be necessarily part of the AR. The request is not limited to the time period leading up to the implementation of the vaccine mandate and is not limited to information that was considered by the decisionmaker. Moreover, the hypothetical communications could have been purely deliberative; information protected by the deliberative process privilege is not ordinarily considered part of the AR, and thus would not ordinarily be included. *Oceana, Inc. v. Ross*, 920 F.3d 855, 865 (D.C. Cir. 2019) ("[A]bsent a showing of bad faith or improper behavior, '[a]gency deliberations not part of the record are deemed immaterial.'") (citation omitted). That is no less true for "interagency" communications that fall within the privilege. *See, e.g., FBME Bank Ltd. v. Lew*, 209 F. Supp. 3d 299, 323 (D.D.C. 2016) (holding that the substance of interagency consultations would be privileged and outside the scope of the record).

[3] Plaintiffs insinuate some bad faith by citing statements about whether "Comirnaty" was available. But neither the facts nor DoD's policy has ever been in dispute. Defendants have confirmed that they did not have Comirnaty-labelled vaccine until recently, Supp. Rans Decl. ¶ 11 & n.7, but Defendants have had BLA-compliant vaccine, and other EUA-labelled Pfizer doses. And Defendants have consistently confirmed DoD's position, based on FDA guidance, that EUA-labelled Pfizer vaccine may be used interchangeably for the purposes of the mandate as if it were the licensed Pfizer vaccine. *See* ECF No. 65-1, at 28; Supp. Rans Decl. ¶¶ 4-5, 10. Plaintiffs also cite a website that published a redacted, purportedly leaked email suggesting that providers can order Comirnaty-labeled Comirnaty sufficient to comply with legal obligations. It is hard to see how that amounts to even an insinuation of bad faith, given that there are multiple lawsuits pending around the country raising claims similar to this one.

Pfizer was not previously producing Comirnaty-labelled vaccine is not likely to be in DoD's possession in any case. It is also now a moot point because Comirnaty-labelled vaccine is available, and specifically available to these Plaintiffs. DEX5.

RFP18. RFP18 sought training and guidance for medical personnel on four detailed topics. Defendants have already provided publicly available guidance regarding implementation of the mandate, *see* DEX1, but the more specific categories of "training" and "guidance" for medical personnel sought here are not at issue in this case, and the discovery is therefore not proportionate to the needs of the case. Defendants have explained consistently that the BLA-labelled Pfizer vaccine is exactly the same vaccine as the respective EUA-labelled Pfizer vaccine for those 16 and older, and according to FDA guidance, they may "use doses distributed under the EUA to administer the series as if the doses were the licensed vaccine." *See* Defs.' MTD at 28, ECF No. 65-1; AR, at DOD000001. The recent declaration confirms that position and clarifies that the interchangeability guidance is not limited to the BLA-compliant vials. Supp. Rans Decl. ¶ 10. Beyond that, complying with lawful orders is the responsibility of the service member, and they have several options for doing so. *Id*. ¶ 12. Plaintiffs challenge the policy itself, and the requested medical guidance is not relevant.

RFP19.a. Similarly, RFP 19.a seeks "policies or procedures governing . . . [c]ompliance with requirement that only BLA-compliant, EUA-labeled vaccines may be mandated." Pls.' Ex. 1. Defendants do not describe any of their policies as a

"requirement that only BLA-compliant, EUA-labeled vaccines may be mandated." Defendants have provided the relevant policies and procedures implementing the mandate, *see* Pls.' Ex. 2, and described repeatedly, in detail, DoD's policy regarding the interchangeability of vaccines. *See, e.g.,* Supp. Rans Decl. ¶¶ 4-5, 10. And, of course, it is wholly irrelevant now because both BLA-compliant and Comirnaty-labelled vaccines were made available to the Plaintiffs.

RFP17.d/19.b. RFPs 17.d and 19.b seek policies and guidance regarding reporting of adverse events related to vaccines, using vaguely worded and confusing terms. Pls.' Ex. 2. Defendants identified the overarching policy about reporting adverse events, *see* ECF No. 31-5 Ch.2-10, and produced related policies, *see* Pls.' Ex. 2; DEX6; *see also* https://www.health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Vaccine-Preventable-Diseases/Standing-Orders. But none of this has any bearing on the Court's evaluation of the DoD mandate and implementation, based on the record that was before the decisionmaker at the time it was made. *Marllantas, Inc*., 806 F. App'x at 867. There is no basis for extra-record discovery here.[4] The existence, nonexistence, or substance of additional reporting policies has no bearing on whether the information considered by the decisionmaker is adequate to support his decision.

[4] Plaintiffs point to alleged disputes over an internal database. A Plaintiff participated in the release of inaccurate, misinterpreted, and misrepresented data selectively taken from that database, which he incorrectly concluded showed a spike in vaccine injuries. Defendants produced the DoD paper explaining why that data was incorrectly interpreted. DEX7. But this incident has no bearing on the claims before the Court, and Plaintiffs do not seek discovery about it.

RFP20. RFP 20 seeks documents relating to several categories of procedures allegedly prescribed by DoDI 6205.02, and argue that these documents are necessary to show whether DoD complied with its own procedures. Pls.' Ex. 2. Defendants have produced certified ARs, as well as related DoD directives and policies. Plaintiffs fail to explain why the requested documents are relevant if they do not appear in the AR. There is certainly no showing of bad faith or impropriety; nor have Plaintiffs specifically identified what portion of the instruction they believe was not followed so that Defendants can attempt to search for missing documents.[5]

Extension. In the alternative, Plaintiffs seek to extend the discovery period against DoD to serve wholly new discovery requests that they wish they had served sooner. Plaintiffs had months to serve such requests. No extension is warranted, and the parties and the Court have everything they need to brief summary judgment.

CONCLUSION

For the foregoing reasons, the Court should deny the motion to compel.

[5] Some of the cited subsections, for example, apply to deliberately released biological agents, and some language describes duties for non-defendants in this action (like the Coast Guard). *See* Pls.' Ex. 2, at 31-33.

Dated: June 17, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this submission contains 1876 words, not including case style, signature block, and certificate of service, according to Microsoft Word's word count function and thus is in compliance with Local Rule 7.1(F).

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