IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

MICHAEL BAZZREA, *et al.*,
Plaintiffs,

v.

LLOYD AUSTIN, III, *et al.*,
Defendants.

Case No. 3:22-cv-265

PLAINTIFFS' MOTION FOR EVIDENTIARY HEARING AND SUPPORTING MEMORANDUM OF LAW

Plaintiffs move this Honorable Court to convene an evidentiary hearing to make findings regarding two outcome-determinative issues: (1) the provenance and legal status of what Defendants have represented as "Comirnaty-labeled" COVID-19 vaccines and which Defendants contend moots certain Plaintiff claims; and (2) whether the Coast Guard has employed "digital tools," including the "Religious Accommodation Appeal Generator" ("RAAG") and Denial Letter Template Generator, *see* Ex. 1 (ECF 44-1), and a Denial Letter Template, *see* Ex. 2 (ECF 44-2), to categorically and automatically deny the Religious Accommodation Requests ("RARs") of Coast Guard members without any individualized determinations or consideration of the merits of the request.

Since the issuance of the Department of Defense's ("DoD") COVID-19 vaccine mandate ("DoD Mandate") through the present day, the DoD has continuously and repeatedly mandated unlicensed Emergency Use Authorization ("EUA") vaccines. Official records of the Department of Defense ("DoD"), the

Centers for Disease Control and Prevention ("CDC"), and the Food and Drug Administration ("FDA") confirm that over 49,000 of the 50,000 (or roughly 98%) of the DoD's inventory of FDA-licensed vaccines that they seek to mandate (and the purportedly renders Plaintiffs' claims moot) are in fact unlicensed and misbranded EUA vaccines, most of which expired no later than November 1, 2022.

In a related proceeding in the Northern District of Florida, the DoD filed the declaration of Air Force Colonel Tanya Rans, which includes a spreadsheet listing all "BLA-Approved, Comirnaty-labeled" shots in the DoD inventory as of October 18, 2022. *See* Ex. 3, originally filed in *Coker v. Austin*, No. 3:21-cv-1211-AW-HTC (N.D. Fla. Oct. 18, 2022), ECF 124-1, Rans Decl. & Ex. A. This official DoD record and sworn testimony confirms Plaintiffs' allegation that the DoD and Coast Guard are mandating the unlicensed and untested "bivalent" vaccines that were granted EUA on August 31, 2022, without any human testing whatsoever – *see* ECF 25, PL Reply Br., at 9-10 – notwithstanding Defendants denials. *See, e.g.,* ECF 47, DF Sur-Reply Br., at 6-7 n.2 (dismissing Plaintiffs' claims as speculation).

The Rans Declaration and spreadsheet includes unlicensed bivalent EUA vaccines from lots GH9667, GH9702, and GJ6665 (collectively, the "G Lots") that are identified as "BLA-approved, Comirnaty-labeled" or "PFIZER GREY CAP COMIRNATY" shots. *See* Ex. 3, Rans Decl., ¶ 4 & Ex. A. This is an admission that each of the listed vials of bivalent vaccine is necessarily misbranded in violation of numerous federal and state laws. It also demonstrates that Plaintiffs' claims are not moot because: (1) it represents yet another repetition of Defendants' previous

statutory violations;[1] and (2) that this violation is likely to be repeated by Defendants against Plaintiffs because, even if they were to receive a primary series of FDA-licensed vaccine, there is a reasonable expectation that they would be required to take unlicensed EUA boosters as a condition for deployment or face discharge for being non-deployable. *See infra* Section II.

The Rans Declaration and spreadsheet also includes "BLA-approved Comirnaty-labeled" shots from Lots FW1330, FW1331, and FW1333 (collectively, the "FW Lots").[2] Each of these lots were manufactured at the Pharmacia & Upjohn facility in Kalamazoo, Michigan ("Kalamazoo Facility"), which was not an FDA-licensed manufacturing facility when these lots were manufactured, released into interstate commerce, or received by the DoD and Coast Guard. Accordingly, none of the shots from these lots is FDA-licensed and cannot be labeled as FDA-licensed Comirnaty. *See infra* Section III.A. In addition, each of the shots from these lots

[1] The previous violations of the prohibition on mandating EUA products are set forth in: (1) the September 13, 2021 Interchangeability Directive for Pfizer EUA and licensed products, *see* ECF 1-7; (2) the May 3, 2021 Interchangeability Directive for Moderna EUA and licensed products, *see* ECF 1-8; and (3) Defendants' previous offer of FW Lots of "Comirnaty-labeled" products that are unlicensed EUA products. *See generally* ECF 25, PL Reply Br., at 7-10 & *infra* Section IV.

[2] The list also includes 60 doses from Lot 4302MF023 (which is Novavax, rather than Pfizer, and subject to an EUA) and 11,298 "Comirnaty-labeled" doses from an unidentified "(blank)" lot that "refers to sites that have not updated the logistics system with the associated lot number." Ex. 3, Rans Decl., Ex. A. The unidentified doses should be presumed to be EUA bivalents lot because these lots were the most recently manufactured (July 2022) and acquired (August or September 2022), while the DoD has been in possession of the FW Lots for over four months starting in June 2022.

expired no later than October 31, 2022, and many expired well before that in August or September 2022. *See infra* III.D. The unlicensed and/or expired FW and G Lots account for over 49,000 of the just over 50,000 purportedly licensed COVID-19 vaccines listed in the Rans Declaration.

The final section of this motion will address the Coast Guard's "Digital Tools" (*i.e.*, the RAAG and Denial Letter Template) to categorically deny all RARs, including those of Plaintiffs and Intervenor Plaintiffs. This can be easily demonstrated by comparing the language in the Denial Template Generator with the denial letters, as shown *infra* in Section V.

I. COMPOSITION, REGULATION AND LABELING OF BIOLOGICAL PRODUCTS.

A. Biologics Are Unstable and Difficult to Ship and Store.

The federal Food, Drug, and Cosmetic Act ("FDCA") proceeds from a presumption of exclusion: a drug – or any "product" under the FDCA – is presumptively NOT allowed to be distributed in commerce until the manufacturer proves that the product can meet the statute's extensive requirements. *See* 21 U.S.C. §355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.")(emphasis added). The entire reason for a new drug application – and the burden on the applicant – is to prove by "adequate and well-controlled studies," *see* 21 C.F.R. §314.126, that the drug is "safe" for mass distribution and "effective" for the purposes it claims. *See*

21 U.S.C. §355(b)(1)(A)(i) ("…Such person shall submit…as part of the application – full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use.").

Biologics are regulated and held to analogous, but higher standards under the Public Health Service Act ("PHSA"). 42 U.S.C. § 262. This is due in large part to the chemical differences between drugs and biologics: drugs are, generally speaking, stable chemical formulations, while biologics are not. Drugs are produced in a form (pill, capsule, or liquid) with relatively long shelf-lives and (typically) can be stored at room temperature or a normal household refrigerator. By comparison, biologics are unstable formulations of viruses (or fragments) that have been isolated and then attenuated in some fashion. They (typically) have very limited shelf-lives; are frozen during shipment; and required to be stored in commercial grade freezers, because they break down at normal room temperatures. Notwithstanding that the current mRNA products at issue in this case contain no Covid-19 virus at all, the shots have similar challenges to traditional vaccines with regard to stability and storage.[3]

Because of the chemical instability of biologics, the PHSA requires that a biologics manufacturer demonstrate that the biologic: (1) is "safe, pure, and potent"

[3] *See, e.g.*, Uddin MN, Roni MA. "Challenges of Storage and Stability of mRNA-Based COVID-19 Vaccines." *Vaccines* (Basel). 2021 Sep 17; 9(9):1033. PMCID: PMC8473088. ("…instability and ultracold storage requirement of mRNA vaccines remain major limitations. The stability of this emerging and fast-growing vaccine platform is poorly understood, and it likely depends on multiple factors, such as excipients, pH, and temperature.").

(the equivalent of a drug's requirement to be "safe and effective"); and (2) that "the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product *continues* to be safe pure and potent." 42 U.S.C. §262(a)(2)(C)(emphasis added).

B. Biologics Have Stringent Labeling Requirements.

The PHSA includes detailed requirements regarding the labeling for biologics.

> *No person shall* introduce or deliver for introduction into commerce any biological product unless –
> (A) a biologics license under this subsection or subsection (k) is in effect for the biological product; and
> (B) each package of the biological product is plainly marked with –
> (i) the proper name of the biological product contained in the package;
> (ii) the name, address, and applicable license number of the manufacturer of the product; and
> (iii) the expiration date of the biological product.

42 U.S.C. §262(a)(1). A regulated product – biologic or drug – must be meticulously correct in its labeling in order to track potentially adulterated or dangerous products, any adverse reactions to them, to aid in product identification (and if necessary, recall efforts), and ultimately ensure the health and safety of individuals being injected with these substances. The FDA has even gone so far as to issue guidance to industry on *naming conventions* for biologics after the passage of the 2009 Biologic Price Competition and Innovation Act ("BPCI").

Among other things, the proper name of a biological product

> helps health care providers identify the product's drug substance and distinguish biological products from one another…
>
> To help ensure patient safety and allow the Agency and the manufacturer to swiftly identify and address a problem, FDA aims to track adverse events to a specific manufacturer (and as appropriate, to a lot or manufacturing site for a particular biological product) and allow surveillance systems to detect safety signals throughout the life cycle of a product. Identifying a biological product's manufacturer can help target remedial action (including recall) to avoid implicating a broader set of products for which no such problem exists.[4]

Mislabeling is a crime under both the FDCA and the PHSA. "A drug or device shall be deemed to be misbranded… [i]f its labeling is false or misleading in any particular." 21 U.S.C. §352(a)(1)(emphasis added); *see also* 21 U.S.C. §333(a) (describing penalties for misbranding with intent to defraud or mislead). The PHSA states that "No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark." 42 U.S.C. §262(b) (penalties for violations are listed under subsection (f), including a fine not exceeding $500 or imprisonment not to exceed one year, or both). It is a violation to misbrand a product, or to introduce or receive a misbranded product. 21 U.S.C. §331(a)-(c). District courts are specifically given the authority to enjoin violations of misbranding or adulteration of products. *See* 21 USC § 332(a).

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[4] *See* U.S. DHHS, FDA, CDER, CBER, "Nonproprietary Naming of Biologic Products" at 4 (Jan. 2017), *available at*: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/nonproprietary-naming-biological-products-guidance-industry (last visited Nov. 4, 2022).

The code of federal regulations supplements the statutes with the FDA's extensive requirements on mislabeling and misbranding. *See, e.g.*, 21 C.F.R. § 201.1 - 201.328 (for drugs), and 21 C.F.R. §610.60 - 610.68 (for biologics). Package labeling requirements are not optional, nor are they discretionary. "The following items *shall* appear on the label affixed to each container…" 21 C.F.R. §610.60(a)(emphasis added). In the event that a product's container does not have sufficient space to include all of the required label items, then the biologic container must be in a package that includes all of the required labeling information. *Id.*

The FDA – as the agency charged with overseeing these requirements – has a number of mechanisms in place to help ensure that both the biologics themselves and the facilities where they are "manufactured, processed, packed, or held" can account for a biologic's care and handling from its initial manufacture, packing, shipping, storage, delivery, holding, and ultimately injection into its intended human recipients. Defendant FDA's need (and statutory duty) to track biologics relies upon a number of different mechanisms, particularly in an age of digital submissions, alongside the demands of tracking massive numbers of doses of a vaccine.

II. DEFENDANTS ARE MANDATING MISBRANDED, UNLICENSED BIVALENT EUA VACCINES.

The Rans Declaration provides a list of "BLA-approved, Comirnaty-labeled" vaccines, Ex. 3, Rans Decl., ¶ 4, that are identified as "PFIZER GREY CAP COMIRNATY." *Id.*, Ex. A. This list includes the FW Lots, as well as vaccines from

Lot Numbers GH9667, GH9702, and GH6665.

On October 20, 2022, Air Force Master Sergeant Nickolas Kupper accessed the Centers for Disease Control and Prevention's ("CDC") vaccine lot number database to identify the National Drug Code ("NDC") for the G Lots. The NDC for each of the three G Lots is 59267-0304. *See* Ex. 4, Kupper Decl., ¶ 4 & Kupper Ex. A (query results from CDC database). According to the CDC NDC website, NDC 59627-0304 is the NDC assigned to the EUA Pfizer bivalent COVID-19 vaccine,[5] rather than 0069-2025, which is the NDC for Pfizer Grey Cap Comirnaty. *See infra* Section III.A.

This demonstrates that Defendants seek to mandate EUA products that are both unlicensed and misbranded as "Comirnaty-labeled." Ex. 3, Rans Decl., ¶ 4. The PHSA prohibits unlicensed products from being labeled using the proprietary name for an FDA-licensed product. *See* 42 U.S.C. § 262(a)(1)(B)(i). Misbranding an unlicensed product as a licensed product violates not only the PHSA and FDA regulations, *see supra* Section I.B, but also numerous federal and state laws regarding consumer protection, unfair or deceptive trade practices, and product liability. The Rans Declaration and Exhibit A thereto constitute a binding

[5] *See* CDC, *COVID-19 Vaccine Related Codes*, available at: https://www.cdc.gov/vaccines/programs/iis/COVID-19-related-codes.html ("CDC NDC Website") (last visited Oct. 25, 2022); *see also* Ex. 5, Pfizer-BioNTech COVID-19 Vaccine, Bivalent, Package Insert, at 29 (identifying "Multiple Dose Vials" of Pfizer bivalent vaccines as having NDC "59267-0304-2" for a carton of 10 multiple dose vials and NDC "59267-0304-1" for a multiple dose vial); *id.* at 35-38 (FDA-approved product labels for Pfizer bivalent vaccines stating "For use under Emergency Use Authorization.").

admission of knowing illegal conduct by all Defendants that also implicates the manufacturers.

III. NONE OF THE FW LOTS ARE FDA-LICENSED.

A. Each of the FW Lots Was Manufactured at the Kalamazoo Facility, Which Was Not an FDA-Approved Facility.

Each of the FW Lots was manufactured at the Kalamazoo Facility in January 2022 (FW1330 and FW1331 expiring September 30, 2022) or February 2022 (FW1333 expiring October 31, 2022). *See* Ex. 5, FW1330 Lot Release Letter, at 1; Ex. 6, FW1331 Lot Release Letter, at 1 (same as ECF 37-1, Burk Decl., Ex. 1); Ex. 7, FW 1333 Lot Release Letter, at 1. As explained below, official FDA and CDC records confirm that the Kalamazoo Facility was not an FDA-approved on any of the relevant dates (*i.e.*, manufacturing, lot release, or shipment date).[6]

1. The FDA-Approved Product Labeling in Effect on All Relevant Dates Did Not List the Kalamazoo Facility as an FDA-Approved Facility.

The first Biologics License Application ("BLA") for a COVID-19 vaccine approved was granted to the German company BioNTech Manufacturing, GmbH,

[6] Moreover, each of these lot release letters includes the Submission Tracking Number ("STN") 125742/36 associated with the December 16, 2021 Supplemental Approval ("December 16 Letter"), *see* Ex. 8, December 16 Letter, at 1, of the Puurs, Belgium facility as the sole manufacturer of the at that time new Tris/Sucrose formulation, rather than the STN 12574/44 associated with the non-public January 14, 2022 letter ("January 14 Letter") submitted by Defendants. *See* ECF 37-2, Burk Decl., Ex. 1. The January 14 Letter purported to approve the Kalamazoo Facility, and thus any lots manufactured there would have been associated with the January 14 Letter STN (12574/44), rather than the December 16 Letter, which was assigned STN (12574/36). *See* Ex. 8, December 16 Letter, at 1. The December 16 Letter could not have authorized manufacture at the Kalamazoo Facility.

on August 23, 2021, license No. 2229, with the licensed, proprietary name "Comirnaty." *See* ECF 1-15, August 23, 2021 Comirnaty Purple Cap Approval Letter, at 1. The BLA Approval Letter authorized the final formulated product to be "manufactured, filled, labeled and packaged" at the Pfizer facility in Puurs, Belgium and at the Kalamazoo Facility, *id.*, as set forth in the Pfizer Comirnaty Purple Cap package insert (Ex. 9), a screenshot of which is reproduced below.[7]

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125742	08/23/2021	08/23/2021

Labeler - Pfizer Laboratories Div Pfizer Inc (134489525)

Establishment

Name	Address	ID/FEI	Business Operations
Pfizer Manufacturing Belgium NV		370156507	ANALYSIS(0069-1000) , MANUFACTURE(0069-1000) , PACK(0069-1000) , LABEL(0069-1000)

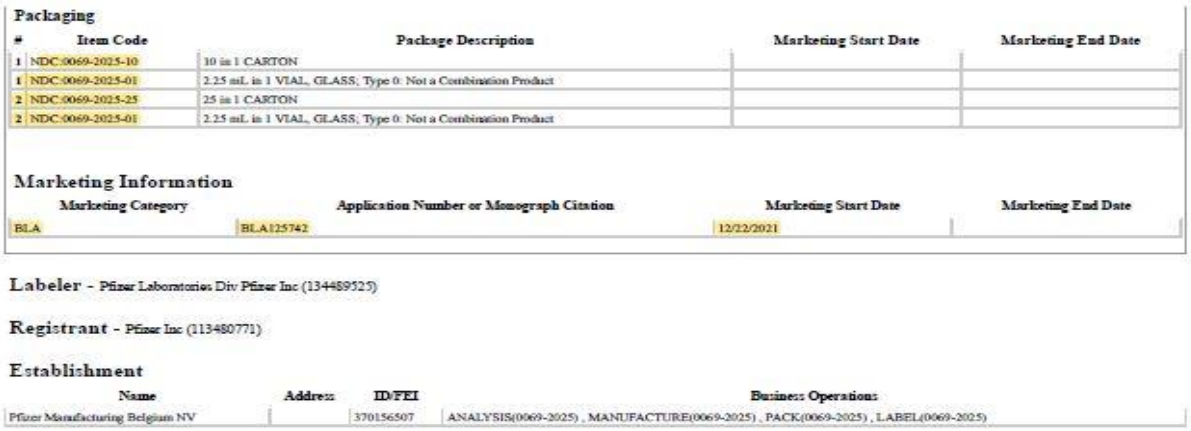
Establishment

Name	Address	ID/FEI	Business Operations
Pharmacia & Upjohn Company LLC		618054084	ANALYSIS(0069-1000) , MANUFACTURE(0069-1000) , PACK(0069-1000) , LABEL(0069-1000)

On December 16, 2021, the FDA granted approval for a BLA Supplement for a new 30 microgram dose of a Tris/Sucrose formulation in a "Grey Cap" (non-dilute) to be manufactured at only one facility: Belgium, NV in Puurs, Belgium. *See* Ex. 8, December 16 Letter, at 1. The December 24, 2021 package insert for the Comirnaty Tris/Sucrose "Grey Cap" vial reflects only one facility approved to conduct all four functions, analysis, manufacture, pack, and label: Pfizer

[7] The NDC label identifier for the original Purple Cap COMIRNATY is 0069-1000. *See* Ex. 10, August 23, 2021 Comirnaty Purple Cap Package Insert at 14-15. Purple Cap Comirnaty was never produced or marketed in the United States because the marketing start and end date were both August 23, 2021. *See id.* at 20.

Manufacturing Belgium NV (i.e., Puurs, Belgium). *See* Ex. 10, Dec. 22, 2021 Comirnaty Tris/Sucrose Package Insert, at 18. The package insert has a marketing start date of December 22, 2021, with NDC label identifier of 0069-2025 (Grey Cap, Comirnaty-labeled, do not dilute). The package insert has no current marketing end date. Accordingly, the Kalamazoo Facility was not an FDA-licensed manufacturing location when the FW Lots were manfuactured.



Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0069-2025-10	10 in 1 CARTON		
1	NDC:0069-2025-01	2.25 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
2	NDC:0069-2025-25	25 in 1 CARTON		
2	NDC:0069-2025-01	2.25 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125742	12/22/2021	

Labeler - Pfizer Laboratories Div Pfizer Inc (134489525)

Registrant - Pfizer Inc (113480771)

Establishment

Name	Address	ID/FEI	Business Operations
Pfizer Manufacturing Belgium NV		370156507	ANALYSIS(0069-2025) , MANUFACTURE(0069-2025) , PACK(0069-2025) , LABEL(0069-2025)

For reasons that are not entirely clear, Pfizer/BioNTech submitted an updated package insert that the FDA approved on May 19, 2022 (the day before it became orderable by the DoD), and with a May 18, 2022 marketing start date and no marketing end date. *See* Ex. 11, May 19, 2022 Comirnaty Tris/Sucrose Package Insert, at 32. Once again, only the Pfizer site in Puurs, Belgium is listed as the only location where analysis, manufacture, pack and labeling may be performed. *See id.* at 32-33. Neither the Kalamazoo Facility, nor any other U.S. location is listed in the package insert. Accordingly, the Kalamazoo Facility was not an FDA-approved manufacturing location when it was released into interstate commerce by the Lot Release Letter or when it became orderable by DoD.

Even assuming *arguendo* that the manufacturing site information was not required, the previous, archived package inserts submitted by Plaintiffs listed the approved manufacturers, a list that did *not* include the Kalamazoo Facility. *See* Ex. 10, Dec. 22, 2021 Comirnaty Tris/Sucrose Package Insert at 19; Ex. 11, May 19, 2022 Comirnaty Tris/Sucrose Package Insert, at 33-34. The currently effective version of the package insert for the bivalent lots also lists the approved manufacturers, a list that *now* includes the Kalamazoo Facility and the Hospira facility in McPherson, Kansas. *See* Ex. 12, Pfizer Bivalent COVID-19 Vaccine Package Insert, at 39-40.

2. The Supplemental Approval Letters and Product Labeling Confirm that the Kalamazoo Facility was Not an FDA-Approved Facility.

First, all of the Supplemental Approvals expressly approve the manufacture of "COMIRNATY" at specific manufacturing locations. *See* Ex. 9, December 16 Letter, at 1; Ex. 13, July 8, 2022 2021 Supplemental Approval Letter ("July 8 Letter"), at 1; Ex. 14, August 25, 2022 Supplemental Approval Letter ("August 25 Letter"), at 1. For the January 14 Letter, by contrast, the word "COMIRNATY" is not used and thus does not approve the manufacture of COMIRNATY at the Kalamazoo Facility. The letter uses only the generic name "Covid-19 vaccine (mRNA)." ECF 37-2, Burk Decl., Ex. 1., January 14 Letter, at 1.

Second, each of the other approval letters specifically require or approve draft labels and package inserts that reflect the new approved locations, formulation and/or indications. *See* Ex. 8, December 16 Letter, at 1-2; Ex. 13, July

8 Letter, at 1-2; Ex. 14, August 25 Letter, at 1-2. This is because a manufacturer must file a supplemental BLA, and receive prior FDA approval, before the manufacturer can use a new manufacturing location (or formulation or indication). *See* 21 C.F.R. § 601.12(b)(1) ("a supplement shall be submitted for any change in the product, production process, … facilities …"). Further, the manufacturer must submit proposed changes to the label and package insert to reflect the changes for which approval is sought in the supplemental BLA. *See* 21 C.F.R. § 601.12(f). The January 14 Letter, by contrast, makes no reference to any labeling changes to add the Kalamazoo Facility as an approved manufacturing location on the label and package insert, as required by FDA regulations. This should render the January 14 Letter invalid on its face, as there is no indication that the FDA did (or legally *could*) waive the mandatory labeling requirements in its regulations and governing statute.

Third, the vials themselves do not list Pharmacia & Upjohn or the Kalamazoo Facility as the manufacturer. Instead, the vials list "BioNTech Manufacturing GmbH & Pfizer Inc." *See* ECF 25-2, Aug. 18, 2022 Letter from Sen. Ron Johnson to CDC, DoD and FDA, at 1 (vial from Lot FW1331 with "9/2022" expiration date).

Fourth, the STN for the three FW Lot Release Letters, *see* Exs. 5-7, matches that for the December 16 Letter (STN BL 125742/36), *see* Ex. 8, rather than for the January 14 Letter (STN BL 125742/44). *See* ECF 37-2, Burk Decl., Ex. 1. Defendants have not even attempted to explain this discrepancy.

B. The FW Lots Expired No Later Than October 31, 2022.

The product labels and the Lot Release Letters both state that the expiration date for Lots FW1330 and FW1331 is September 30, 2022, *see* Ex. 5-6, and the expiration date for Lot FW 1333 is October 31, 2022. *See* Ex. 7. Further, the currently effective and all previous, archived versions of the Pfizer Comirnaty Grey Cap package insert state that: "***Regardless of storage condition, the vaccine should not be used after the expiration date printed on the vial and cartons***."[8]

In the *Coker v. Austin* proceeding, Defendants also submit an April 14, 2022 FDA letter that purports to "extend[] the expiration period … from 9 months to 12 months." *See* Ex. 15, *Coker v. Austin*, No. 3:21-cv-1211-AW-HTC (N.D. Fla. Oct. 18, 2022), ECF 124-2, Burk Decl., Ex. 1. Defendants do not, however, cite any authority that would permit the FDA to waive or override a labeling requirement mandated by statute and FDA regulations, or the actual expiration date stated in the product labeling. *See* 42 U.S.C. 42 U.S.C. § 262(a)(1)(B)(iii); 21 C.F.R. §610.60(a)(4).

At most, the April 14 Letter would have permitted Pfizer to modify the expiration date printed on the product labeling, which was not done.[9] Pfizer could

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[8] Aug. 22, 2022 Comirnaty Tris/Sucrose Package Insert at 15 (Current, effective Aug. 22, 2022)(emphasis added), available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=48c86164-de07-4041-b9dc-f2b5744714e5&type=display (last visited Oct. 25, 2022); Ex. 10, Dec. 22, 2021 Comirnaty Tris/Sucrose Package Insert, at 13; Ex. 11, May 19, 2022 Comirnaty Tris/Sucrose Package Insert, at 27.

[9] This would have been trivially easy to do because, as of April 14, 2022, all of these lots were in Pfizer's possession and were not even orderable by the DoD until May

have revised the package insert to state that the expiration should be extended in accordance with the April 14 Letter, but it did not do so, and all versions of the FDA-approved package inserts (whether before or after April 14, 2022) contain the same directive not to use the product after the expiration date stated on the label. Moreover, the PHSA and FDA labeling regulations all refer to the requirements that must be stated on the "product," 42 U.S.C. §262(a)(1), 21 C.F.R. §610.60(a), and do not refer to the FDA's approval letter. These package inserts, approved by the FDA after the issuance of the April 14 Letter, must trump the previous April 14 Letter, both as a matter of law and the practical reality that patients, doctors and pharmacists must rely on what is actually stated on the packaging. Accordingly, all doses from Lot FW1330 and FW1331 expired as of September 30, 2022, and all doses from Lot FW1333 will expire at the latest on October 31, 2022 (*i.e.*, six days from the date of this filing).[10]

C. Many FW Lots and Nearly All FW1333 Lots Expired Prior to Expiration Date Printed on Label.

The FDA-approved labeling provides that, regardless of the expiration date stated on the label, once the vials are taken out of deep freeze they may be

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18, 2022. The FDA's FW1333 Lot Release Letter, issued several days later on April 19, 2022, states that the expiration date is "October 31, 2022." Ex. 7, FW 1333 Lot Release Letter, at 1.

[10] Even assuming *arguendo* that the April 14 Letter could override FDA regulations and the FDA-approved labeling, Defendants have provided no evidence whatsoever that any of the doses in the FW Lots met the requirement for expiration date extension, namely, that these vials were continuously stored "between -90 ºC and -60 ºC." ECF 124-1, April 14 Letter, at 1.

refrigerated at "2 ºC to 8 ºC" at which point they have a "10-week refrigerated expiry date." Ex. 11, May 19, 2022 Comirnaty Tris/Sucrose Package Insert, at 25-26 ("16 How Supplied/Storage and Handling"). Any vials shipped or received at 2 ºC to 8 ºC must "be stored at 2 ºC to 8 ºC" and "they should not be refrozen." *Id.* These FDA requirements are reflected in DoD and Armed Services transportation and storage procedures, which stipulate that Pfizer Gray Cap Comirnaty must be "ship[ped] refrigerated" at "2C to 8C with a 10 week shelf life." Ex. 4, Kupper Decl., ¶ 8 & Ex. C, Slide 18.

Defendants' filings indicate that they received the FW Lots in early June 2022. These lots were then redistributed from Ft. Detrick to military facilities at refrigerated temperatures rather than deep freeze, which triggered the 10-week expiration period that ended in August 2022. *See* Ex. 4, Kupper Decl., ¶ 10.

This is confirmed by the testimony submitted by U.S. Marine Corps Captain Joshua Hoppe. CAPT Hoppe is stationed in Yuma, Arizona, which according to the Rans Declaration had doses of Pfizer Grey Cap Comirnaty from Lot FW1333 as of October 18, 2022. *See* Ex. 3, Rans Decl., Ex. A. On October 19 and 21, 2022, the Yuma Clinic informed CAPT Hoppe that the Yuma Clinic no longer had any Comirnaty-labeled vaccines because all of the doses they had expired August 26, 2022 (*i.e.*, due to the 10-week refrigeration expiration period). *See* Ex. 16, Hoppe Decl., ¶¶ 4-5.

D. Unrebutted Evidence that CDC Lists the FW Lots as EUA.

The CDC maintains a listing of "all lots for COVID-19 vaccines made

available under Emergency Use Authorization (EUA) for distribution in the United States." *See* CDC's EUA Lot Release Database, available at: https://vaccinecodeset.cdc.gov/LotNumber. The CDC listed all of the FW Lots as EUA products until as recently as October 18, 2022. This is confirmed by the August 4, 2022 Declaration of Army Lieutenant Mark Bashaw, which was included in the declaration of Coast Guard Lieutenant Chad Coppin referenced in Plaintiffs' September 6, 2022 Reply Brief. *See* ECF 27-1, Coppin Decl., at 26 (Bashaw Decl., ¶¶ 10-11). In the attached declaration LT Bashaw reaffirms his August 4, 2022 testimony. *See* Ex. 17, Bashaw Decl., ¶ 8.

IV. PLAINTIFFS' STATUTORY CLAIMS ARE NOT MOOT.

Plaintiffs' statutory claims are not moot because Defendants' violations are "capable of repetition, yet evading review" and "there [is] a reasonable expectation that [Plaintiffs will] be subjected to the same action again." *Fla. Bd. of Bus. Regul. v. N.L.R.B.,* 605 F.2d 916, 920 (5th Cir. 1979) (citation and quotation marks omitted). Defendants have consistently mandated unlicensed EUA shots from at least September 14, 2021, *see* ECF 1-7, Pfizer Interchangeability Directive, through the present, as confirmed by the fact that they are mandating unlicensed, misbranded bivalent EUA shots.

In fact, Defendants have been requiring EUA boosters as a condition for deployment for several months. Plaintiffs provide the sworn declaration U.S. Marine Corps Senior Chief Petty Officer ("SCPO") Dixon Brown, who serves as a Senior Enlisted Medical Advisor responsible for EUA and informed consent

compliance matters at Camp Pendleton, California. SCPO Brown's declaration confirms that the U.S. Marine Corps requires EUA boosters for new accessions and for deployments.[11]

Accordingly, there is a reasonable expectation that Plaintiffs will be subject to this same statutory violation again because, even if each Plaintiff were to become fully vaccinated with an FDA-licensed vaccine, they would be required to take an unlicensed EUA vaccine to be deployable. Refusal to take the unlicensed vaccine could thus still result in discharge or other adverse consequences.

V. THE COAST GUARD HAS USED DIGITAL TOOLS TO CATEGORICALLY DENY COAST GUARD MEMBERS' RELIGIOUS LIBERTIES.

The Coast Guard has employed "Digital Tools," including the RAAG and Denial Letter Template, to categorically deny all Coast Guard members' RARs, including those of several Plaintiffs and Intervenor Plaintiffs. This can be easily demonstrated by comparing the language in the Denial Template Generator with the denial letters of Plaintiffs. Plaintiffs provide the sworn declaration and supporting documents of Coast Guard LT Chad Coppin, an Intervenor Plaintiff, showing how the Denial Letter Template was (incorrectly) used for his denial letter. *See* Ex. 20, Coppin, Decl.

The Congressional Letter and whistleblower documents demonstrate the

[11] *See* Ex. 18, SCPO Brown Decl., ¶¶ 14-15 & SCPO Brown Ex. 4. Due to the credible threat of retaliation, Plaintiffs intend to submit, under seal, additional declarations and testimony from other fully vaccinated service members throughout the Armed Services who have been required to take EUA boosters.

USCG denied all, or nearly all, RARs and dismissed appeals "*en masse* with the help of computer-assisted technology, indicating that no case-by-case determinations were taking place." ECF 43-1, at 2. The use of these tools to implement the Categorical RAR Ban is fully consistent with the sworn testimony presented by Plaintiffs, including that of Navy Chaplain Lieutenant Justin Brown, who is assigned to the Coast Guard, describing the directives from Coast Guard leadership that RARs would not be granted and that, even if an RAR was granted, the member would still be separated.[12]

It is also consistent with the findings of the DoD's Office of the Inspector General's ("IG") June 2, 2022 Report to Secretary Austin ("DoD IG Report"). *See* Ex. 19. There, the DoD IG made DoD-wide preliminary findings that the RAR processes implemented by the various Armed Services applied "generalized assessments rather than the individualized assessments required by Federal law and the DoD and Military Services policies," Ex. 19, DoD IG Report at 1, *i.e.*, RFRA, DoDI 1300.17 and COMDTINST 1000.15.

This is also consistent with the findings of several courts that Secretary Austin and the DoD have implemented a DoD-wide Categorical RAR Ban. The Department of the Navy, of which the Coast Guard is a part, also employed similar

[12] *See, e.g.*, ECF 25-9, Brown Supp. Decl., ¶ 7 (September 20, 2021 email informed service members that "even if a religious accommodation or medical exemption were approved the member was likely to still be administratively separated."); ECF 1-2, Wilder Decl., ¶ 7 (commander informed Plaintiff Wilder that members would not "be allowed to continue to serve if exempted. …. either way if they don't get the vaccine, [you] will be discharged.").

"digital tools" to implement the Navy's Categorical RAR Ban and to automatically generate denial letters. *See* ECF 60-9, Navy Whistleblower Testimony; *Navy SEALs 1-26 v. Austin*, 2022 WL 34443, at *6 (N.D. Tex. Jan. 3, 2022) (granting PI based on Navy process).

VI. THE COURT MUST CONVENE AN EVIDENTIARY HEARING AND PERMIT PLAINTIFFS TO DEPOSE DEFENDANTS' OFFICIALS.

Plaintiffs have provided official records and sworn testimony from Defendants demonstrating that: (1) Defendants have once again attempted to mandate unlicensed, misbranded, and expired EUA vaccines and misrepresented those products as FDA-licensed "Comirnaty-labeled" vaccines; and (2) that the Coast Guard has unlawfully used "Digital Tools" to categorically deny Coast Guard members' RARs and therefore their religious liberties, including those of Plaintiffs and Intervenor Plaintiffs. This Court should permit Plaintiffs to seek discovery of relevant documents that would bear these issues and to depose Defendants' officials who have generated these records or who can testify on behalf of the agency pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure.

VII. CONCLUSION

The Court should grant Plaintiffs' motion to convene an evidentiary hearing, or find based on the record before it that Plaintiffs' statutory claims are not moot; that the G Lots are misbranded, unlicensed EUA lots; that all FW Lots expire no later than November 1, 2022; and that the Coast Guard's "Digital Tool" and RAAG have been used to categorically deny Coast Guard members RARs, without any individualized determination, in violation of Plaintiffs' and putative Class

Members' rights under RFRA, the First Amendment Free Exercise Clause, and the Fifth Amendment's Procedural Due Process Clause.

Dated: November 7, 2022

Respectfully Submitted,

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CERTIFICATE OF SERVICE

This is to certify that on this 7th day of November, 2022, the foregoing Plaintiffs' Reply Brief was e-filed using the CM/ECF system.

Respectfully Submitted,

/s/ Travis Miller
Travis Miller

CERTIFICATE OF CONFERENCE

I hereby certify that I conferred with counsel for Defendants by email on November 4, 2022, and that Defendants oppose this motion.

/s/ Travis Miller