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

BENJAMIN COKER, *et al.*,

Plaintiffs,

v. **Case No. 3:21-cv-01211-AW-HTC**

LLOYD AUSTIN, III, *et al.*,

Defendants.

PLAINTIFFS' MOTION FOR EVIDENTIARY HEARING AND SUPPORTING MEMORANDUM OF LAW

Plaintiffs move this Honorable Court to convene an evidentiary hearing to determine the provenance and legal status of the Pfizer/BioNTech COVID-19 "Comirnaty-labeled" mRNA vaccine from Lot FW1331, which expires September 30, 2022 according to the product label and Defendants' previous filings. Defendants have represented that Lot FW1331 is a product licensed by the Food and Drug Administration ("FDA"). Defendants claim that the possession and offer of this product to Plaintiffs renders Plaintiffs' claims moot and requires dismissal of all of their claims. Thus, the factual question of the product's legal status—licensed or not—of this product and the facility where it was manufactured is now the central issue in this litigation.

Pursuant to the Court's August 18, 2022 order, ECF 105, and grant of leave at the September 2, 2022 hearing, Plaintiffs filed supplemental briefs on August 22, 2022, ECF 106, and on September 9, 2022 ("September 9 Response"). ECF 117.

Plaintiffs presented evidence demonstrating that the "Comirnaty-labeled" product offered to Plaintiffs is not FDA-licensed and instead appears to be misbranded emergency use authorization ("EUA") product that cannot be mandated.

On September 12, 2022, without requesting leave of the Court or satisfying their meet and confer obligations under Local Rule 7.1(B)-(C), Defendants attached to their brief on the Administrative Procedure Act's ("APA") exhaustion requirements, *see* ECF 118, the supplemental declaration of Suzann Burk ("Burk Declaration"), along with a heretofore non-public January 14, 2022 FDA "Supplemental Approval" letter ("January 14 Letter"). *See* ECF 118-1. The Burk Declaration and the January 14 Letter are an impermissible reply to Plaintiffs' September 9 Response, as they have no bearing whatsoever on the APA exhaustion. Plaintiffs respectfully request that they be granted leave, to the extent necessary, to respond to Defendants' September 12 reply.

The non-public January 14 Letter in the September 12 Reply revealed for the first time in Defendants' impermissible reply does not, as Defendants' claim, demonstrate that Lot FW1331 is licensed or that the Pharmacia & Upjohn Kalamazoo, Michigan facility was an FDA-approved manufacturing facility for the "Grey Cap" Tris/Sucrose formulation at the time the lot was manufactured, when the product was shipped (*i.e.*, introduced into interstate commerce), or when Defendant Department of Defense ("DOD") took possession of the product. In this

Brief, Plaintiffs submit or rely on a number of other publicly available documents and labeling materials posted on government agency website[1] to demonstrate that Kalamazoo, Michigan was not an FDA-licensed manufacturing facility and that Lot FW1331 is therefore not an FDA-licensed product, specifically:

- Unlike all other Supplemental Biologics License Application ("BLA") approval letters—namely, the December 16, 2021, July 8, 2022, and August 25, 2022 Supplemental Approvals, *see* Ex. 1-3—the word "COMIRNATY" does not even appear in the January 14 Letter, so the January 14 Letter does not in fact authorize Kalamazoo, Michigan to manufacture COMIRNATY;

- Also unlike all other approval letters, the January 14 Letter does not require Pfizer or BioNTech to submit for FDA review and approval updated labels and package inserts to reflect the approval of the new manufacturing location;

- If Kalamazoo, Michigan was approved as a manufacturing location on January 14, 2022, it would not have been necessary to obtain the approval granted for that same location on July 8, 2022, *see* Ex. 2;

- The FDA approved package inserts in effect at the time of production[2] and at the time of shipment[3] do not list the Kalamazoo, Michigan facility as an FDA-approved manufacturing facility;

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[1] All exhibits submitted by Plaintiffs are documents obtained from government websites, namely, those of the FDA, the Centers for Disease Control and Prevention ("CDC"), and the National Institute of Health ("NIH"). This Court may take judicial notice of documents posted on government websites. *See* Fed. R. Evid. 902(5); *Newton v. Holland*, 2014 WL 318567 (E.D. Ky. Jan. 29, 2014).

[2] *See* Ex. 4, December 24, 2021 Comirnaty Tris/Sucrose Package Insert, at 18 (archived version with a marketing start date of December 22, 2021 listing all FDA-approved locations for manufacturing, filling and labeling).

[3] *See* Ex. 5, December 24, 2021 Comirnaty Tris/Sucrose Package Insert, at 32-33 (May 19, 2022 archived version with a marketing start date of May 18, 2022). This was the package insert in effect when "Comirnaty-labeled" first became "orderable"

- The vials themselves do not list the Pharmacia & Upjohn Kalamazoo, Michigan facility as the manufacturer, and instead list BioNTech (whose facilities are in Europe), *see* ECF 106-1, Aug. 18, 2022 Letter from Sen. Ron Johnson to CDC, DOD and FDA, at 1 (pictures of Lot FW1331 including the "9/2022" expiration date); and

- The Submission Tracking Number ("STN") for the lot release letter included with Ms. Burk's previous declaration on August 26, 2022, *see* ECF 108-1, Burk Decl., at 3-4, match that for the December 16, 2021 Supplemental Approval Letter (STN BL 125742/36), *see* ECF 117-1, Coppin Decl., ¶¶ 7-8, rather than for the January 14 Letter (STN BL 125742/44).

In addition, Plaintiffs include the declaration and a transcript of a September 8, 2022, conversation between Military Whistleblower and Marine Captain Joshua Hoppe and Elizabeth Sly of the FDA's Access Litigation and Freedom of Information Branch. *See* Ex. 6, Hoppe Decl. & Transcript. In this conversation, Captain Hoppe is seeking information on the provenance and licensure status of Lot FW1331. Ms. Sly, an FDA official in the FDA office that oversees records access, not only was not aware of the January 14 Letter, but she appears to contend that the August 23, 2021 Comirnaty Approval Letter (*i.e.*, for the original and distinct PBS/Sucrose formulation of Comirnaty, not the Tris/Sucrose formulation for Lot FW1331) granted approval for Kalamazoo, Michigan facility to manufacture the Tris/Sucrose formulation despite the fact that the FDA did not approve that formulation until four months later. *See* Ex. 7, Hoppe Decl., ¶ 21 & Transcript at 3.

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by DOD on May 20, 2022 "with the latest vial expiration date [of] September 30, 2022." *See* ECF 89-5, Rans Decl., at ¶ 8.

Ms. Sly is an FDA official responsible for access to FDA records regarding Comirnaty approval, and she should be expected to be knowledgeable about the universe of available FDA records and have access to those records (including those that are not required to be disclosed or published). She could have easily addressed Captain Hoppe's concerns by pointing to the January 14 Letter or the mere possibility that not all approval letters are public (a fact she first mentioned after the submission to this Court of the January 14 Letter). But she did not, which suggests she did not have access to this critical heretofore non-public FDA record that determines the legal status of the only FDA-licensed products in the DOD's possession and/or that the January 14 Letter was not in the FDA's system on September 8, 2022.

Finally, Plaintiffs provide the declaration of Military Whistleblower U.S. Coast Guard ("USCG") Lieutenant Chad Coppin. *See* Ex. 7, Coppin Decl. Lieutenant Coppin's declaration shows that the DOD violated essential storage requirements for a portion of Lot FW1331 because the freezers in which these products were transported exceeded the maximum permitted temperature for a period of 12 hours over a roughly two-day period and that these vials should have been discarded. He subsequently learned of numerous other instances of temperature/storage violations and that Fort Detrick personnel had waived mandatory safety protocols and permitted compromised products to be used.

The consequences of this evidence regarding the provenance and unlicensed status of Lot FW1331 are difficult to overstate. Kalamazoo, Michigan was not an FDA-licensed facility when Lot FW1331 was manufactured or shipped meaning that Lot FW1331 that Defendants seek to mandate and use as their core argument for dismissal is not an FDA-licensed product. Putting the "Comirnaty" label on products from Lot FW1331 and introducing them into interstate commerce renders them intentionally misbranded products. Such intentional and knowing misconduct would permit Plaintiffs to bring entirely new claims, on behalf of themselves and other similarly situated service members, against the FDA, federal officials acting in their personal capacity, and the manufacturers or labelers responsible for the misbranding.

Plaintiffs submit that the Court can resolve the factual issue—whether or not Lot FW1331 is in fact an FDA-licensed product—based on the evidence before the Court included with this filing and Plaintiffs' other filings. However, given the stakes, and the conflicting nature of the government's own documents for tracking this specific lot, Plaintiffs urge this Court to convene an evidentiary hearing to give Plaintiffs the opportunity to examine the government witnesses and evidence, as well as present their own in an adversarial setting with cross-examination and the full panoply of due process rights to confront the witnesses against them who claim that these apparently misbranded and adulterated products not only can be sold to the public, but can be mandatorily injected into service members.

Finally, Defendants' actions have given rise to a fundamentally different set of violations involving misbranding and related intentional misconduct—and involving a new set of parties (namely, the manufacturers and likely federal officials acting in their personal, rather than official, capacities) and distinct bases for injunctive relief and monetary damages—than those in the currently operative Second Amended Complaint. Plaintiffs therefore must have the opportunity to amend their complaint to include the distinct causes of actions against Defendants and other non-parties for misbranding and intentional misconduct.

I. Composition, Regulation and Labeling of Biological Products.

A. Biologics Are Unstable and Extremely 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.[4]

[4] *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.").

Because of the chemical instability of biologics, the PHSA requires that a biologics manufacturer demonstrate that the biologic: (1) is "safe, pure, and potent" (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 and Tracking 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.[5]

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

[5] *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 Sept. 26, 2022).

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).

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. Lot FW1331 Is Not FDA-Licensed and Is Therefore Misbranded.

A. Kalamazoo, Michigan Is Not An Approved Manufacturing Location for Lot FW1331.

1. Original "Purple Cap" Formulation

The first Biologics License Application ("BLA") for a COVID-19 vaccine approved was granted to the German company BioNTech Manufacturing, GmbH, on August 23, 2021, license No. 2229, "which is indicated for active immunization to prevent coronavirus disease 2019… in individuals 16 years of age or older." *See* ECF 1-4, August 23, 2021 Comirnaty Purpose Cap Approval Letter, at 1. The BLA Approval Letter authorized the applicant to:

> manufacture COVID-19 Vaccine, mRNA drug substance at Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC, 1 Burtt Road, Andover, Massachusetts. The final formulated product will be manufactured, filled, labeled and packaged at Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium and at Pharmacia & Upjohn Company LLC, 7000 Portage Road, Kalamazoo, Michigan.

Id. FDA authorized BioNTech to "label [the] product with the proprietary name COMIRNATY, and market it in 2.0 mL glass vials, in packages of 25 and 195 vials," but, as is usual, no lots may be distributed "until you receive a notification of release from the Director, Center for Biologics Evaluation and Research." The most critical point about this product however, is that it was *never produced* – because it was

prohibited from being marketed in the United States by the Defendant FDA.[6]

The National Drug Code (NDC) label identifier for the original Purple Cap COMIRNATY is 0069-1000 and the package insert lists relevant (and required information), including the authorized manufacturing locations.[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)

2. The New "Grey Cap" Tris/Sucrose Formulation

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. 1, December 16, 2021 Comirnaty Tris/Sucrose Supplemental Approval, at 1. The

[6] In an unprecedented and still unexplained regulatory action, the Defendant FDA removed the Comirnaty Purple Cap product from the market *the same day it approved it* – August 23, 2021 – a day before the DoD Mandate was announced.

[7] On September 13, 2021, Pfizer subsequently confirmed that "it does not plan to produce any product with these new NDCs [*i.e.*, 0069-1000] and labels over the next few months." *See* Ex. 8, Sept. 13, 2021 Pfizer Announcement, at 1. A review of the NIH site confirms that there are no active NDCs for the original "Purple Cap" formulation; instead this package insert was obtained from the NIH labeling archives.

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 Manufacturing Belgium NV (i.e., Pfizer, Puurs). *See* Ex. 4, 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, Kalamazoo, Michigan was not an FDA-licensed manufacturing location at the time that Lot FW1331 was manufactured on January 28, 2022.

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. 5, 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 (with several additional European locations listed for analysis and API Manufacture). *See id.* at 32-33. Neither Kalamazoo, Michigan, nor any other U.S. location is listed in the package insert. Accordingly, Kalamazoo, Michigan was not an FDA-approved manufacturing location when it became orderable by DOD (*i.e.*, the latest possible date it was introduced into interstate commerce).

Kalamazoo, Michigan was not approved by the FDA to manufacture the Grey Cap Tris/Sucrose formulation until July 8, 2022. *See* Ex. 2, July 8, 2022 Comirnaty Tris/Sucrose Supplemental Approval, at 1. And even then, it appears that the approval applied only for adolescents 12-15 years old, but not for adults like Plaintiffs. This of course begs the question that if Kalamazoo, Michigan were already an FDA-approved manufacturing location as of January 14, 2022, why was the July 8, 2022 approval necessary?

B. Defendants' Position Is Contradicted by Supplemental Approval Letters, Product Labels and Other Labeling Materials.

In addition to being contradicted by the package inserts as described above, there are at least four additional ways in which Defendants' position and testimony that Lot FW1331 manufactured in Kalamazoo, Michigan is contradicted by FDA and other government documents the authenticity of which is not in dispute.

First, all of the Supplemental Approvals expressly approve the manufacture of "COMIRNATY" at specific manufacturing locations. *See* Ex. 1, December 16,

2021 Supplemental Approval, at 1; Ex. 2, July 8, 2022 2021 Supplemental Approval, at 1; Ex. 3, August 25, 2022 Supplemental Approval, 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, Michigan facility. The letter uses only the generic name "Covid-19 vaccine (mRNA)." ECF 118-1, 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. 1, December 16, 2021 Comirnaty Tris/Sucrose Supplemental Approval Letter, at 1-2; Ex. 2, July 8, 2022 2021 Comirnaty Tris/Sucrose Supplemental Approval Letter, at 1-2; Ex. 3, August 25, 2022 Comirnaty Tris/Sucrose Supplemental Approval 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 Kalamazoo, Michigan 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 could) waive mandatory labeling requirements in its regulations and governing statute.

Third, the vials themselves do not list the Pharmacia & Upjohn Kalamazoo, Michigan facility as the manufacturer. Instead, the vials list "BioNTech Manufacturing GmbH & Pfizer Inc." *See* ECF 106-2, Aug. 18, 2022 Letter from Sen. Ron Johnson to CDC, DOD and FDA, at 1 (pictures of vial from Lot FW1331 and expiration date of "9/2022").

Fourth, the Submission Tracking Number ("STN") for the lot release letter included with Ms. Burk's previous declaration on August 26, 2022, *see* ECF 108-1 at 3-4, matches that for the December 16, 2021 Comirnaty Tris/Sucrose Supplemental Approval Letter (STN BL 125742/36), *see* ECF 117-1, Coppin Decl., ¶¶ 7-8, rather than for the January 14 Letter (STN BL 125742/44). Defendants have not even attempted to explain this discrepancy.

C. Unrebutted Evidence that CDC Lists Lot FW1331 as EUA.

While EUA products are not held to anywhere near the same standard as licensed biologics regarding safety, purity, and potency, they are allowed to be entered into commerce only pursuant to the EUA statute. They must also be tracked and monitored as fully licensed products because they are in the stream of commerce

and the same considerations apply. 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."[8]

In the September 9 Response, Plaintiffs presented the testimony of USCG LT Chad Coppin, who is stationed at USCG Sector Juneau and was present when vials of the government's "Comirnaty-labeled" product arrived on June 10, 2022, and provided pictures confirming the lot number. *See* ECF 106-2, Aug. 18, 2022 Letter from Sen. Ron Johnson to CDC, FDA and DOD). The vial depicted in this exhibit is a "Comirnaty-labeled" biologic with the lot number FW1331 and "9/2022" expiration date on the side, as required by law. This lot number appears in the CDC's EUA database. To be clear – the government agency charged with tracking these lots lists FW1331 as an EUA biologic – not a *licensed* one. *See* CDC's lot release database at: https://vaccinecodeset.cdc.gov/LotNumber.

D. Captain Hoppe Conversation with FDA Official Elizabeth Sly.

Plaintiffs include the declaration and a transcript of a September 8, 2022 conversation between Captain Hoppe and Elizabeth Sly of the FDA's Access Litigation and Freedom of Information Branch. *See* Ex. 7, Hoppe Decl. & Transcript. In this conversation, Captain Hoppe is seeking information on the provenance and

[8] *See* CDC's EUA lot release database at https://vaccinecodeset.cdc.gov/LotNumber.

licensure status of Lot FW1331. Ms. Sly, an FDA official in its office that oversees records access, not only was not aware of the January 14 Letter, but she appears to contend that the August 23, 2021 Comirnaty Approval Letter (*i.e.*, for the original and different formulation of Comirnaty) granted approval for the Kalamazoo, Michigan facility to manufacture the Tris/Sucrose formulation. *See* Transcript at 3.

While Plaintiffs do not rely on her legal conclusions, Ms. Sly is an FDA official with access to FDA records on Comirnaty; she could have easily addressed Captain Hoppe's concerns by pointing to the January 14 Letter. But she did not, which suggests she did not have access to this critical heretofore non-public FDA record that determines the legal status of the only FDA-licensed products in the DOD's possession and/or that the January 14 Letter was not in the FDA's system.

Plaintiffs also note that in an email exchange on September 13-14, 2022—following the September 12, 2022 submission of the Burk Declaration and the January 14 Letter—Ms. Sly emailed Captain Hoppe to inform him for the first time that not all approval letters are posted on the FDA website. *See* Ex. 6, Hoppe Decl., ¶¶ 22-24 (discussing September 13-14, 2022 email exchange). If she had been aware of the January 14 Letter in the September 8, 2022 recorded conversation, she could have immediately addressed Hoppe's questions without reliance on the other, public FDA approval letters. Which suggests one of two things: (1) she was not aware of the letter and did not have access to the letter or (2) she was instructed not to reveal

the existence of the non-public letter. Either way, it is appropriate for Plaintiffs to be permitted to depose Ms. Sly to ascertain the state of her knowledge on September 8, 2022, and what changed to prompt her to suggest the existence of non-public letters on September 14, 2022.

III. Lot FW1331 Was Compromised Due to Violations of Storage Requirements.

In addition to the products being mislabeled and misbranded, Lot FW1331 or portions thereof appear to be adulterated. The original BLA letter illustrates that the shelf life/expiration date of these vials is tied directly to the product being kept in a specific temperature range. The original August 23, 2021 Approval Letter, under "Dating Period," states:

> The dating period for COVID-19 Vaccine, mRNA shall be 9 months from the date of manufacture when stored between -90ºC to -60ºC (-130ºF to -76ºF).

ECF 1-4, August 23, 2021, Comirnaty Purple Cap Approval Letter, at 2.

As LT Coppin's declaration illustrates, this lot spent a significant amount of time outside of its required storage temperature. When LT Coppin called to ask about this issue, he was provided a printout of the temperature readings during transport by Fort Detrick personnel. Visual inspection of this printout included as Attachment 3 to the Coppin Declaration reveals that "the temperatures … fluctuated in and out of the required parameters for about 11-12 hours over the duration of its 48 hour transit." Ex. 7, Coppin Decl., ¶ 6. Lieutenant Coppin alleges that Fort Detrick

personnel misinterpreted the "12-hour rule," which "states that once the vial has exceeded the 2-8C storage requirement, then the vial may be stored at the temperature of 8-25C for up to 12 hours prior to the first puncture." *Id.* This misinterpretation and temperature violation should have required disposal of these vials, but instead "enabled a compromised product to be made available to service members." *Id.*, ¶ 8.

Lieutenant Coppin also discovered that other USCG units had tripped temperature alarms that "required Ft. Detrick to clear and release for use," and that "not one shipment that had a temperature exceedance had been recalled." *Id.*, ¶ 7. He further noted that the printout states that: "'One or more sensors limits displayed on graph have been modified' which also raises suspicion of the actual temperatures that our shipment and other shipments to other USCG bases may have been subjected to." *Id*, ¶ 7.

The BLA Approval letter requires the manufacturer "to submit reports of biological product deviations under 21 CFR 600.14," including those associated with "processing, testing, packaging, labeling, storage, holding and distribution." Presumably there are reports that the Plaintiffs should have access to regarding this temperature violation. ECF 1-4 at 2.

IV. The Court Must Convene An Evidentiary Hearing and Permit Plaintiffs to Depose Defendants' Officials.

The Court cannot resolve this issue by relying upon a "presumption of regularity" and accuracy of government acts or documents because Plaintiffs have relied solely on government documents or recorded statements of government officials of which this Court may take judicial notice. These documents demonstrate that FW1331 was not manufactured in an FDA-approved facility and that Lot FW1331 therefore is not an FDA-licensed. This Court should permit Plaintiffs to seek discovery of relevant documents that would bear on the provenance and legal status of Lot FW1331. This Court should further permit the Plaintiffs to depose Suzann Burk and Elizabeth Sly, as well as individuals designated by Defendants who can answer questions on behalf of the DOD and FDA as to the provenance of the January 14 Letter and the licensure status of Lot FW1331 pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure.

V. CONCLUSION

The Court should grant Plaintiffs' motion to file a reply to the September 12 reply, to convene an evidentiary hearing, and to permit Plaintiffs to pursue the limited discovery detailed herein.

Dated: September 26, 2022

Respectfully submitted,

s/ Brandon Johnson
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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing via CM/ECF on September 26, 2022, which notifies counsel of record of the filing.

/s/ Brandon Johnson

CERTIFICATE OF COMPLIANCE

I hereby certify that I filed the foregoing memorandum is 5,224 words according to Microsoft Word's word count function.

/s/ Brandon Johnson

CERTIFICATE OF CONFERENCE

I hereby certify that I conferred with counsel for Defendants by email on September 23, 2022, and that Defendants' counsel has not responded or stated their position.

/s/ Brandon Johnson