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

BENJAMIN COKER, JOSEPH CONNELL, KALEM COSSETTE, SEAN COTHRAN, SAMUEL CRAYMER, KACY DIXON, JAY FURMAN, JORDAN KARR, NICHOLAS HARWOOD, ERIC KALTRIDER, NICKOLAS KUPPER, DAVID LUND, BLAKE MORGAN, TAYLOR ROBERTS, SAMUEL SIGOLOFF, ANDREW SNOW, BRIAN STERMER, and MICHAEL THOMPSON,	)
***Plaintiffs*,**	)
vs.	)
LLOYD AUSTIN, III, in his official capacity as Secretary of Defense, U.S. Department of Defense,	)
FRANK KENDALL, in his official capacity as Secretary of the Air Force, Department of the Air Force,	)
CARLOS DEL TORO, in his official capacity as Secretary of the Navy, Department of the Navy,	)
ROBERT CALIFF, in his official capacity as Commissioner of the U.S. Food and Drug Administration, and	)
CHRISTINE WORMUTH, in her official capacity as Secretary of the Army, Department of the Army,	)
BIONTECH MANUFACTURING GMBH,	)
MODERNATX, INC., and	)
PFIZER, INC.,	)
***Defendants*.**	)

CIVIL ACTION NO. 3:21-cv-01211-AW-HTC

THIRD AMENDED AND SUPPLEMENTAL COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

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Plaintiffs, by and through the undersigned counsel, hereby complain and allege the following:

INTRODUCTORY STATEMENT

1. Plaintiffs bring this action to challenge: (1) the COVID-19 vaccine mandates promulgated by the Department of Defense ("DOD") ("DOD Mandate") and each of the Armed Services (the "Armed Services Mandates", and together with DOD Mandate, the "Military Mandates"); (2) the Food and Drug Administration's ("FDA") unlawful approvals of messenger RNA ("mRNA") COVID-19 treatments ("mRNA Products")—COMIRNATY®, manufactured by Pfizer, Inc. ("Pfizer") and BioNTech Manufacturing GmbH ("BioNTech"), and SPIKEVAX®, manufactured by ModernaTX, Inc. ("Moderna") (collectively, "Manufacturer Defendants")—mandated by the DOD ("Mandated mRNA Products"); and (3) unlawful, unfair and deceptive practices by Defendants to deceive and coerce military service members to take unlicensed products that are known to be ineffective for the prevention and transmission of COVID-19.

2. The Military Mandates rely on the FDA's fatally flawed August 23, 2021 approval of a product, "Purple Cap" COMIRNATY®, that apparently was never made and never marketed in the United States. Defendants' official records and sworn testimony confirm that the Military Defendants did not obtain any FDA-licensed mRNA Products at all until June 2022 at the earliest (*i.e.*, ten months after

the mandates were issued). Further, over 49,000 of the 50,000 doses (*i.e.*, over 98%) they acquired that were purportedly FDA-licensed not only were not licensed, but are also misbranded, expired and/or adulterated.

3. The Military Mandates were adopted and implemented through a series of overlapping misrepresentations and deceptive practices. The mRNA Products are not "vaccines", as that term has been understood for centuries by the public, legislators and courts and as defined by the DOD regulation, DODI 6205.02, ECF 65-5, the sole legal basis cited for the DOD Mandate. It is undisputed that these products cannot prevent transmission of COVID-19, which is why Pfizer/BioNTech did not perform, and the FDA did not require, any testing on prevention of transmission. If they ever were effective at preventing infection, these products were rendered obsolete by Omicron and subsequent variants. Thus, they cannot serve the government's purported purpose of stopping the spread of COVID-19 or "protect[ing] the Force." ECF 1-3, DOD Mandate, at 1.

4. Defendants have long known and acknowledged these facts. As early as January 10, 2022, Pfizer's CEO admitted that the mandated product provided little, if any, protection against Omicron. Official records of the Centers for Disease Control and Prevention ("CDC") indicate that Pfizer/BioNTech made the last lot of COMIRNATY® in February 2022, and that Moderna made the last lot of SPIKEVAX® in April 2022. On August 11, 2022, the CDC finally acknowledged

that the FDA-licensed, Mandated mRNA Products provide minimal, if any, protection and recommended ending discriminatory treatment of the unvaccinated. On August 16, 2022, the U.S. Government, the sole U.S. purchaser and payor for the mRNA Products, announced that it would no longer purchase or provide reimbursement for the "monovalent" products and would instead purchase the new, unlicensed "bivalent" mRNA treatments developed by Pfizer/BioNTech and Moderna ("Bivalent mRNA Products"). Despite these facts, the Military Defendants continued their arbitrary, discriminatory, and punitive treatment of unvaccinated service members like Plaintiffs, and they are now mandating unlicensed Bivalent mRNA Products.

5. Manufacturer Defendants, which were among the top 10 DOD contractors in 2021, knew or should have known of the Military Defendants' unlawful, unfair and deceptive practices in implementing the Military Mandates and administering the products to service members. Military Defendants, who acted as Manufacturer Defendants' distributor, implemented a generally applicable directive to deceive service members that unlicensed Emergency Use Authorization ("EUA") only mRNA Products are legally interchangeable with, or the same as, the legally distinct FDA-licensed products. Official records submitted by Defendants conclusively establish that Pfizer/BioNTech misbranded their unlicensed bivalent product as licensed Grey Cap COMIRNATY® and that Military Defendants are

mandating these bivalent products (the "G Lots"). Official records similarly establish that the Grey Cap "Comirnaty-labeled" products (the "FW Lots") are unlicensed, misbranded, expired and/or adulterated.

6. While the mRNA Products are authorized (or approved) and labeled as prescription drugs, the Military Defendants implemented the mandates through mass inoculations and "vaccine rodeos" (*i.e.*, mustering service members by unit or base and jabbing them in assembly-line fashion) without prescriptions. Moreover, the consistent and very public directive from Secretary Austin down through the military chain of command is for 100% vaccination without exceptions or religious accommodations. For the COVID-19 "vaccines", Military Defendants eliminated any opportunity for medical professionals to perform an individualized assessment of service members, changing long-standing regulations that made the treating physician the decisionmaker on medical treatments, exemptions and ensuring informed consent, and elevated these decisions to a flag officer or even the Surgeon General for the Service in question. Further, Military Defendants adopted a generally applicable policy of removing, destroying or refusing to provide service members the labeling and other product information required by federal and state law.

7. Military Defendants' mass inoculations and coercive and deceptive practices converted a prescription-only drug to a non-prescription or over-the-counter ("OTC") drug. These practices were widespread, publicly reported, and in

some cases formally adopted in writing by Military Defendants, and thus Manufacturing Defendants knew or should have known that their products were being administered without a prescription or the required individualized balancing of risks by the prescribing physician. As such, the Manufacturing Defendants were required to provide each service member subject to the mandates, including Plaintiffs, all labeling and warnings required by federal and state law, which they systematically failed to do. Manufacturing Defendants also violated federal and state law governing drug advertising and marketing, including the Federal Trade Commission Act ("FTCA") and the Florida Unfair and Deceptive Trade Practices Act ("FDUPTA").

8. Plaintiffs are a group of service members on active-duty or reserves, including members from each branch of the armed services, who are subject to Military Mandates. All plaintiffs have been subjected to adverse employment actions and discipline; all have been denied their constitutionally protected religious liberties; and most plaintiffs have been forced into early retirement, commenced the separation process, or would have been discharged already but for a series of nation-wide injunctions granted against the Air Force, Navy and Marine Corps for systematic violations of religious liberties.

9. Plaintiffs file this action seeking a Preliminary Injunction, a Permanent Injunction, and a Declaratory Judgment requesting that this Court:

(1) Declare unlawful, vacate and enjoin the Military Mandates because they are arbitrary, capricious, an abuse of discretion, otherwise contrary to law;

(2) Declare unlawful, vacate and enjoin the DOD Interchangeability Directives and Armed Services Mandates for violations of federal laws and regulations governing informed consent, drug labeling and misbranding;

(3) Declare unlawful and vacate the FDA approvals of COMIRNATY® and SPIKEVAX® and all supplemental approvals of COMIRNATY® and SPIKEVAX®;

(4) Declare unlawful, vacate and enjoin the FDA's Interchangeability Directives and its purported waiver of mandatory statutory requirements ("FDA Waiver") as arbitrary and capricious and for violating federal statutes and regulations governing drug labeling and prohibiting misbranding and unfair and deceptive trade practices;

(5) Declare unlawful and enjoin the administration of any EUA-labeled mRNA Products pursuant to the Armed Services Mandates or the DOD Interchangeability Directives;

(6) Declare unlawful and enjoin the Manufacturer Defendants violations of Florida state law prohibiting misbranding and unfair and deceptive trade practices;

(7) Enjoin all Defendants from the marketing, sale, distribution, and administration of unlicensed, misbranded, expired and/or adulterated mRNA Product, in particular, the G Lots and FW Lots; and

(8) Direct the Manufacturing Defendants to recall and destroy all misbranded, expired, or adulterated mRNA Products.

10. Plaintiffs seek this relief pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 702 and 705; the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 & 2202; the All Writs Act, 28 U.S.C. § 1651; and FDUPTA, Fla. Stat. § 501.201, et seq.

PARTIES

11. Plaintiffs are active-duty or reserve duty service members who are subject to the Military Mandates, the DOD Interchangeability Directives, and the other challenged agency actions and are aggrieved by Manufacturer Defendants' unlawful, unfair or deceptive practices. The Florida Plaintiffs are the eight Plaintiffs who are stationed, reside, and/or domiciled in the State of Florida (Connell, Cosette, Cothran, Dixon, Harwood, Karr, Morgan, and Stermer).

12. As summarized in the attached table in Exhibit 1 (Plaintiff November 2022 Status Chart), all plaintiffs have submitted religious accommodation requests ("RARs"), most of which have been denied; all Plaintiffs have suffered adverse employment actions; and most have been forced into early retirement, commenced separation proceedings, or had separation halted by class-wide injunctions against the Air Force, Marine Corps, and Navy.

13. Plaintiff BENJAMIN COKER is a Chief Petty Officer in the Navy. He is domiciled and stationed in Washington, D.C. He has received two "Page 13" counseling letters in connection with his vaccination orders. Both his initial RAR and appeal have been denied.

14. Plaintiff JOSEPH CONNELL is a Master Sergeant in the Air Force. He is domiciled and stationed at Hurlburt Field, Florida. He has submitted two requests for medical exemption request (due to his prior history with cancer) that were denied.

He has been denied promotion to E-8 for which he is eligible due to vaccination status. Both his initial RAR and appeal have been denied. He is currently undergoing medical board evaluation before retirement.

15. Plaintiff KALEM COSSETTE is a Chief Warrant Officer-3 in the Marine Corps. He is stationed in Twentynine Palms, California, and is domiciled in Flagler County, Florida. He has repeatedly confirmed that his base does not have any FDA-licensed or BLA-compliant products. His initial RAR was denied and his appeal is pending. His command has informed him that he will be separated from the Marine Corps as soon as his appeal is returned denied.

16. Plaintiff SEAN COTHRAN is a Captain in the Air Force. He is domiciled and stationed at Hurlburt Field, Florida. He submitted two requests for medical exemption, which were both denied. Both his initial RAR and appeal have been denied. His separation was halted by the Air Force class injunction.

17. Plaintiff SAMUEL CRAYMER is a Staff Sergeant in the Air Force. He is domiciled and stationed at Eielson Air Force Base, Alaska. He challenged the lawfulness of the order to take the EUA vaccine with his squadron leadership, and he filed a complaint with the DOD Inspector General. He attended a mandatory vaccination line and, upon requesting to view vials being administered, was shown several vials containing the EUA designated label from Pfizer-BioNTech. Both his

initial RAR and appeal have been denied. His separation was halted by the Air Force class injunction.

18. Plaintiff KACY DIXON is a Major in the Air Force. She is domiciled and stationed in Florida. In response to her vaccination orders to take a fully licensed vaccine, she attempted to obtain the licensed Comirnaty vaccine from pharmacists and other healthcare providers, and she was informed that it was unavailable. She sought clarification as to whether she was being ordered to take the unlicensed products that were available, and she was informed that she must take the EUA BioNTech Vaccine because it is interchangeable with the licensed vaccine. She submitted a request for medical exemption due to the lack of supply and because she was nursing a newborn, both of which were denied. Her initial RAR was denied and her appeal is still pending.

19. Plaintiff JAMES FURMAN was a Commander in the Navy. He is domiciled and stationed in Arlington, Virginia. His initial RAR was denied. He had to retire and ended his 22-year military career effective December 7, 2021.

20. Plaintiff NICHOLAS HARWOOD is a Major in the Marine Corps. He is stationed at Camp Pendleton, California, and domiciled in Volusia County, Florida. He has confirmed that Comirnaty is not available at his facility. Both his RAR and appeal were denied. He faced a Board of Inquiry ("BOI") in July 2022,

which recommended separation. His separation was halted by the Marine Corps class injunction.

21. Plaintiff JORDAN KARR was a Captain in the Air Force. She is domiciled in and stationed at Hurlburt Field, Florida. Captain KARR has specifically inquired regarding the availability of Comirnaty and BLA-compliant lots, and she has been informed that it is not available. She sought medical exemption for fertility disorder, which was denied. She was forced into early retirement in May 2022. Her initial RAR was denied, and she was not given the opportunity to appeal due to her involuntary separation.

22. Plaintiff ERIC KALTRIDER is a Major in the United States Marine Corps. He is domiciled in and stationed at Camp Lejeune, North Carolina. He requested a medical exemption, which was denied. Both his initial RAR and appeal were denied. Major KALTRIDER was scheduled for a BOI on August 29, 2022, which was halted by the Marine Corps class injunction.

23. Plaintiff NICKOLAS KUPPER is a Master Sergeant ("MSGT") in the Air Force. He is domiciled in Arizona, and he is stationed at Luke Air Force Base, Arizona. He has repeatedly confirmed with his base immunologist that his base does not have any FDA-licensed or any BLA-compliant lots, and thus would be required to take an EUA-labeled, non-BLA-compliant vaccine to comply with the mandate. MSGT KUPPER has challenged the lawfulness of the order to take an unlicensed

EUA vaccine, and he has submitted a complaint to the DOD Inspector General alleging that the mandates are unlawful. His requests for medical exemption, initial RAR and appeal were all denied. He had commenced the separation process, which was halted by the Air Force class injunction. He is currently pursuing an action before the Air Force Board of Corrections for Military Records.

24. Plaintiff DAVID LUND is a non-commissioned officer in the Air Force. He is domiciled in and stationed at Fort Walton Beach, Florida. He was ordered to get the EUA vaccine because the licensed Comirnaty Vaccine was not available. He objected based on his previous COVID-19 infection, but was pressured into being injected with the EUA Janssen vaccine.

25. Plaintiff BLAKE MORGAN is a Captain in the Air Force. He is domiciled in and stationed at Eglin Air Force Base, Florida. He submitted a request for medical exemption, which was denied. His initial RAR is still pending. Due to his vaccination status, he is subject to travel restrictions and has been required to cancel mission-critical travel.

26. Plaintiff TAYLOR ROBERTS is a Major in the Air Force. He is domiciled and stationed in New Mexico. Major Roberts requested a medical exemption based on genetic predisposition to increased likelihood of adverse effects; he was initially granted a temporary exemption, which was revoked within five days. Both his initial RAR and appeal have been denied. He also challenged the lawfulness

of his vaccination order, by submitting a complaint under Article 138 of the UCMJ, which was dismissed on November 19, 2021. His separation was halted by the Air Force class injunction.

27. Plaintiff DR. SAMUEL SIGOLOFF is a board-certified family physician and a Major in the Army. He is domiciled and stationed in Arizona, where he served as the medical director for Fort Huachucha, Arizona. On September 13, 2021, he was relieved and suspended from treating patients for lawfully granting medical exemptions from the DOD mandate, consistent with the procedures and guidance in effect at that time, and for prescribing alternative treatments like Ivermectin. Both his initial RAR and appeal were denied. Major SIGOLOFF has received a negative counseling statement, and he is the subject of a pending investigation under UCMJ Article 15-6, and he was suspended from medical practice.

28. Plaintiff ANDREW SNOW is a Major in the Air Force Reserve. He is domiciled in and stationed in Delaware. He has confirmed that his base does not have FDA-licensed products. Both his initial RAR and appeal have been denied. He had commenced the involuntary separation process and removal to the Inactive Ready Reserve ("IRR"), which was halted by the Air Force Class Injunction.

29. Plaintiff BRIAN STERMER is a Sergeant First Class ("SFC") in the Army Reserve. He is currently stationed at Fort Leonard Wood, Missouri, and is

domiciled in Santa Rosa County, Florida. He has submitted a complaint under Article 138 of the UCMJ, challenging the lawfulness of several COVID-related restrictions and orders, which was denied. His initial RAR is still pending.

30. Plaintiff MICHAEL THOMPSON is an MSGT in the Marine Corps. He is domiciled in North Carolina, and he is stationed at MCAS Cherry Point, North Carolina. He has repeatedly inquired as to the availability of both Comirnaty and "BLA-compliant" lots at Marine Corps facilities in North Carolina, and he has been informed that no FDA-licensed or BLA-compliant doses were available. Despite the confirmed unavailability of Comirnaty, MSGT THOMPSON has personally observed that the medical records for at least one fellow marine who received the EUA vaccine indicate that he or she instead received Comirnaty. His initial RAR was denied and his appeal is still pending.

31. Defendant DOD is a Department of the United States Government. It is led by the Secretary of Defense, Lloyd J. Austin, III.

32. Defendant Department of the Air Force is a Department of the United States Government. It is led by the Secretary of the Air Force Frank Kendall.

33. Defendant Department of the Army is a Department of the United States Government. It is led by the Secretary of the Army Christine Wormuth.

34. Defendants Marine Corps and Navy are under the Department of the Navy, which is a Department of the United States Government. It is led by Navy Secretary Carlos Del Toro.

35. Defendant FDA is an agency of the United States Government. It is led by Commissioner Robert Califf.

36. Defendant BioNTech is the manufacturer of COMIRNATY® and the Pfizer/BioNTech EUA monovalent and bivalent COVID-19 mRNA treatments.

37. Defendant Moderna is the manufacturer of SPIKEVAX® and the Moderna EUA monovalent and bivalent COVID-19 mRNA treatments.

38. Defendant Pfizer is the manufacturer of COMIRNATY® and the Pfizer/BioNTech EUA monovalent and bivalent COVID-19 mRNA treatments.

JURISDICTION AND VENUE

39. This case arises under federal law, namely, 10 U.S.C. § 1107a; the APA, 5 U.S.C. § 551, et. Seq.; various DOD regulations, including DOD Instruction ("DODI") 6205.02; the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 301 et seq.; the Public Health Safety Act ("PHSA"), 42 U.S.C. § 262 et seq.; FDA regulations implementing the FDCA and PHSA; and the Federal Trade Commission Act ("FTCA"), 15 U.S.C. § 41 et seq.

40. The Military Mandates, the FDA and DOD Interchangeability Directives, the FDA approvals of COMIRNATY® and SPIKEVAX®, and other

challenged agency actions are final agency actions for which there is no other adequate remedy in a court. 5 U.S.C. § 704. These actions mark the consummation of the agency's decision-making process. Each has direct and appreciable legal and life-altering consequences for Plaintiffs and millions of other U.S. citizens.

41. Jurisdiction is proper in this Court under the APA, 5 U.S.C. § 702, and under 28 U.S.C. § 2201, which states that actions involving controversies with federal agencies may be pursued in any United States District Court, and under 28 U.S.C. §§ 1331 and 1346.

42. This case also arises under Florida state law, FDUPTA, Fla. Stat. §§ 501.201, et seq.

43. Jurisdiction over these Florida state law claims is proper in this Court pursuant to this Court's pendent jurisdiction under 28 U.S.C. § 1367.

44. Venue is proper in this Court pursuant to 28 U.S.C. § 1402 and 28 U.S.C. § 1391(e) because a plurality of the Plaintiffs are stationed and/or domiciled in this district, and because a substantial part of the acts or omissions giving rise to the claim have occurred, are occurring, or will occur in this District, namely, the actual and imminent injury due to the unlawful, forced administration of unlicensed, misbranded, expired and/or adulterated products, and the unlawful, unfair and deceptive trade practices, unless this Court grants the relief requested herein.

STATEMENT OF FACTS

I. COVID-19 AND THE DOD RESPONSE

A. DOD Role in Development of mRNA Treatments

45. While most of the COVID-19 treatments were developed with U.S. government funding provided pursuant to Operation Warp Speed, the DOD and the Department of Health and Human Services ("HHS") followed a different approach with Pfizer. On July 20, 2020, DOD and HHS announced an agreement with Pfizer to deliver, for $1.95 billion, 100 million doses of Pfizer's mRNA product if the product received EUA or FDA approval, with the option to acquire up to an additional 500 million doses. *See* Ex. 2, July 20, 2020 DOD-HHS Press Release. Pfizer and BioNTech received an EUA for this product on December 11, 2020.

46. On August 11, 2020, the DOD announced a contract with Moderna to acquire 100 million doses of "COVID-19 investigational vaccine" at a cost of $1.5 billion, with the option to acquire up to 400 million additional doses.[1]

47. Based on these and other contracts, Pfizer was the fifth largest defense contractor in 2021 with $13.3 billion in obligations, and Moderna was the ninth largest defense contractor with $6.9 billion in obligations. *See* Bloomberg

[1] DOD, *Trump Administration Collaborates with Moderna to Produce 100 Million Doses of COVID-19 Investigational Vaccine* (Aug. 11, 2020), available at: https://www.defense.gov/News/Releases/Release/Article/2309561/trump-administration-collaborates-with-moderna-to-produce-100-million-doses-of/ (last visited Nov. 23, 2022).

Government, *The Top 10 Defense Contractors* (July 14, 2022), available at: https://about.bgov.com/top-defense-contractors/ (last visited Nov. 23, 2022).

B. The Military Mandates

48. On August 24, 2021, Secretary Austin issued the DOD Mandate directing the Secretaries of the Military Departments "to immediately begin full vaccination of all members of the Armed Forces … who are not fully vaccinated against COVID-19." ECF 1-3, DOD Mandate, at 1. Mandatory vaccination would "only use COVID-19 vaccines that receive full licensure from the [FDA], in accordance with FDA labeling and guidance." *Id.* Secretary Austin justified the mandate as necessary to "protect the Force", *id.*, and cited DOD Instruction 6205.02, "DOD Immunization Program" (July 23, 2019), ECF 65-5, as the sole legal authority for the mandate. *Id.*

49. Each of the Armed Services issued their own mandates shortly after the issuance of the DOD Mandate. *See* ECF 1-7, "COVID-19 Mandatory Vaccination Implementation Guidance for Service Members" (Air Force Mandate); ECF 31-6, U.S. Army FRAGO 5 (Army Mandate); ECF 1-9, U.S. Marine Corps MARADMINS 462/21 (Marine Corps Mandate); ECF 1-10, U.S. Navy ALNAV 062/21 (Navy Mandate). Each of the Armed Services have issued subsequent orders implementing and modifying the initial Armed Services Mandates.

C. Unavailability of FDA-Licensed Vaccines and Mandate of Unlicensed EUA Products.

50. Military Defendants have adopted a generally applicable policies: (1) to misrepresent that they have FDA-licensed vaccines to service members and that EUA products are instead "FDA-licensed" or describing EUA products as COMIRNATY® or SPIKEVAX®, which Plaintiffs have repeatedly confirmed were not in fact available;[2] (2) to misrepresent unlicensed EUA products by stating that the EUA products available "are" COMIRNATY®, *see* ECF 68-1, Cossette Decl., ¶ 7, and that "interchangeability" includes "legal interchangeability" (*i.e.,* not merely "medical interchangeability"), *see id.*, Dixon Decl., ¶ 14; and (3) to punish and discharge service members like Plaintiffs who refuse to take an unlicensed vaccine, which may not be mandated. *See infra* Section VII (summarizing Plaintiffs' injury and standing) & Ex. 1, November 2022 Plaintiffs Status Chart.

[2] In Plaintiffs' February 4, 2022 Opposition to Defendants' Motion to Dismiss, ECF 68, several Plaintiffs submitted declarations attesting to the unavailability of COMIRNATY® or "BLA-compliant" doses. *See, e.g.,* ECF 68-1, Cothran Decl., ¶ 17 (no BLA compliant doses; EUA only); Dixon Decl., ¶ 16 (same); Kupper Decl., ¶11 (no Comirnaty or BLA-approved lots available); Roberts Decl., ¶ 11 (only EUA lots available); Connell Decl., ¶4 (no Comirnaty); Cossette Decl., ¶5 (same); Harwood Decl., ¶8 (same); Sigoloff Decl., ¶11 & Ex. X (emails); Snow Decl., ¶5 (no Comirnaty); Thompson Decl., ¶13 (no Comirnaty; confirmed all lots available were EUA only). Plaintiffs did so again in May 2022 in response to Defendants' interrogatories. Plaintiffs Cossette, Cothran, Karr, Dixon, Kupper, Stermer, and Roberts inquired and confirmed that no FDA-licensed or BLA-compliant doses were available for either Pfizer/BioNTech or Moderna products. *See* ECF 88-9, PL Response to DF Interrogatories, Response No. 11 at 8.

51. Military Defendants falsely claimed to have Purple Cap COMIRNATY® (*i.e.*, the only FDA-licensed product when the Military Mandates were issued) from the outset, including in filings with this Court. *See* ECF 41, DF Opp'n to PL TRO Motion, at 46 ("DOD has a supply of Comirnaty"). Defendants withdrew this claim upon direct questioning by this Court. *See* ECF 45 at 47:21-48:17. In fact, it would not have been possible for Military Defendants to acquire Purple Cap COMIRNATY® because this product does not appear to exist at all, as it was never manufactured or marketed in the United States. *See infra* ¶¶ 145-146.

52. Even before the DOD Mandate was announced, the DOD issued directives to use the existing supply of unlicensed EUA products to implement the mandate. In an August 18, 2021 memorandum informed Secretary Austin that the DOD "has enough vaccine on-hand … to support … mandatory vaccination." *See* Information Memorandum from Special Assistant to the Deputy Assistant Secretary of Defense for Secretary of Defense, Subject: Mandatory Vaccination Implementation at 1 (Aug. 18, 2021), DOD Administrative Record AR, Tab 15, DOD 000109. A July 30, 2021 presentation to the DOD COVID-19 Task Force should "administer vaccine immediately with existing … supply." DSD COVID-19 Task Force Meeting (Agenda), DOD AR, Tab 36, DOD 000166.

53. It is undisputed that Military Defendants did not have any FDA-licensed COMIRNATY® until at least June 2022 (*i.e.*, ten months after licensure),

while consistently misrepresenting unlicensed products as FDA licensed. Moreover, the products that they represent as "Comirnaty-labeled, BLA-approved" products, ECF 124-1, Rans Decl., ¶ 4, are in fact unlicensed, misbranded, expired, and/or adulterated. *See infra* Section VI.

54. It is further undisputed that Military Defendants did not have any SPIKEVAX® in their possession until September or October 2022 (*i.e.*, more than a year after the adoption of the mandate). This is confirmed by Defendants' August 22, 2022 filing, which asserts that DOD could "order" SPIKEVAX®, ECF 107-16, Rans Decl., ¶ 4, but did not state that they had even a single dose in their possession.

D. DOD Interchangeability Directives

55. On September 14, 2021, Assistant Secretary of Defense for Health Affairs Terry Adirim issued a memo stating that the Pfizer/BioNTech EUA product and the licensed COMIRNATY® "are 'interchangeable' and DoD health care providers should use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine," and that "DoD health care providers will use both [products] interchangeably for the purpose of " implementing the DOD Mandate. Ex. 3, Sept. 14, 2021 Adirim Memorandum, at 1 ("Pfizer/BioNTech Interchangeability Directive").

56. On May 3, 2022, the DOD issued the same directive that EUA Moderna COVID-19 vaccines were to be used interchangeably with, and "as if," they were

the FDA-licensed and labeled Moderna Spikevax vaccine. *See* Ex. 4, May 3, 2022 DOD Memo, at 1 ("Moderna Interchangeability Directive").

57. The Armed Services have also directed that unlicensed EUA products be used "interchangeably" or "as if" they were FDA-licensed products. For example, while the Air Force Mandate states that "[o]nly an FDA-licensed vaccine may be mandated," ECF 1-7, Air Force Mandate, § 3.1.3, it goes on to repeat the FDA's (incorrect) claim that the EUA BioNTech Vaccine is "interchangeable" with the licensed product and that "[p]roviders can use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine." *Id*., § 3.1.1; *see also id.*, § 5.3.2.1 (same). The Navy issued the same interchangeability directive, which also applies to the Marine Corps. *See* Navy Administrative Record DON AR 027, BUMED Memo 6300 6300, *Interchangeability of FDA-Approved Pfizer-BioNTech Vaccine Comirnaty and FDA-Authorized Pfizer-BioNTech Vaccine Under EUA* (Sept. 3, 2021) ("BUMED 6300"), at 1.

E. Subsequent Directives To Take Unlicensed, Misbranded, Expired or Adulterated Products.

58. The Military Defendants have repeatedly issued directives, generally applicable to all service members, that they must take unlicensed mRNA Products, or else face discipline and discharge. The first was the Pfizer/BioNTech Interchangeability Directive on September 14, 2021, followed by the Moderna Interchangeability Directive in May 3, 2022.

59. The third directive, generally applicable to all unvaccinated service members, including Plaintiffs, followed in June 2022, when the DOD claimed that, for the first time, it obtained so-called "Comirnaty-labeled", FDA-licensed products. *See* ECF 107, DF Aug. 22, 2022 Supp. Br., at 8. This is an admission that Military Defendants did not have any FDA-licensed COMIRNATY® before that date.

60. All of the "Comirnaty-labeled, BLA-approved" products obtained by DOD in June 2022 are from lots FW1330, FW1331, and FW1333 (the "FW Lots"). *See* ECF 124-2, Rans Decl., Ex. A. All of the vials from these lots are unlicensed, misbranded, and have now expired. All doses shipped from Fort Detrick, Maryland at refrigerated temperatures are also adulterated due to systemic violations of FDA-approved storage requirements. *See infra* Section VI.F & VI.G.

61. The fourth generally applicable directive is the requirement to take unlicensed, misbranded "bivalent" Pfizer/BioNTech EUA mRNA Products (the "G Lots"). *See infra* Section VI.E. It appears that these were obtained at some point in September or October 2022, given that Military Defendants first asserted to possess these products in their October 18, 2022 response, *see* ECF 124-1, Rans Decl., Ex. A, to Plaintiffs' September 26, 2022 motion for evidentiary hearing. ECF 120.

F. Adverse Actions Taken Against Unvaccinated Service Members

62. Under the UCMJ, a service member who disobeys "any lawful general order or regulation," UCMJ § 892(2), Art. 92(2), faces sanctions up to a court-

martial. UCMJ § 892. To date Military Defendants have separated several thousand unvaccinated service members, and they likely would have separated tens of thousands more, including several Plaintiffs, if this had not been halted by the three class-wide injunctions against the Air Force, Marine Corps and Navy for systemic violations of the Religious Freedom Restoration Act ("RFRA").

63. Military Defendants have imposed a wide range of restrictions and taken disciplinary actions against unvaccinated service members like Plaintiffs, including: training, travel, leave/liberty, and duty restrictions; denial or restriction of promotions; non-deployable status; negative counseling or reprimands; ineligibility for change of station or new assignments; forced early retirement; and/or removal from command. *See infra* ¶ 166 & Ex.1, Plaintiffs November 2022 Status Chart.

G. Implementation of the Military Mandates

64. The Military Mandates have been implemented with a target of 100% vaccination for all service members. To achieve the goal of 100% vaccination of all service members, Military Defendants have directed the military chain of command to employ coercive and deceptive practices to overcome any objections.

65. DOD and Service regulations, including the immunization policies set forth in Army Regulation 40-562, "Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases" (7 Oct. 2013) ("AR 40-562"), ECF 65-4, provide that determinations regarding medical exemptions are to be made by the treating

physician and the base medical commanders or directors. *See id.*, ¶ 1-4(c) (Responsibilities; Medical Commanders, Commanding Officers, and Command Surgeons); ¶ 2-6(a) (Exemptions; Medical Exemptions) ("Granting medical exemptions is a medical function"); ECF 68-1, Sigoloff Decl., ¶¶ 8-9 (describing pre-COVID-19 process for granting medical exemptions).

66. For COVID-19 and the DOD Mandate, however, all decisions are to be made by the Surgeon General or three- or four-star medical Flag Officers to ensure centralized control and denial of exemption or religious accommodation requests. *See, e.g.,* ECF 31-6, U.S. Army FRAGO 5 (Army Mandate), ¶ 3.D.8.B.6.A.1 (approval authority for medical exemption is the Army Surgeon General); ECF 65-9, U.S. Navy ALNAV 190/21, ¶ 3.d (medical exemptions require approval by medical Flag Officer). Medical exemptions previously granted were denied, *see supra* ¶ 26 (Major Roberts medical exemption revoked), and military doctors like Major Sigoloff were punished and suspended for granting them. *See* ECF 68-1, Sigoloff Decl., ¶¶ 8-9 (describing investigation and punishment for approving COVID-19 medical exemptions). This new policy has been executed without exception by the military chain of command.

67. While the Mandated mRNA Products were approved by the FDA as prescription drugs, HHS largely waived the prescription requirement in March 2021 and authorized not just doctors, but any "healthcare professional", including

unlicensed students in a health-related program to give the shots. *See* Notice, HHS, 86 Fed. Reg. 14,462, 14,464 (Mar 16, 2021).

68. More importantly, Military Defendants have implemented the mandates through "mass inoculations" in so-called "vaccine rodeos" where entire units or bases are mustered for mass vaccinations.[3] Service members are lined up and injected in assembly line fashion, with no doctor or medical professional performing any kind of individualized determination, assessment, or balancing of risks and benefits. Service members are not provided the FDA-approved labeling or package inserts required to be included with the product package—or in fact any truthful information at all—and are simply ordered to get the shot or get out of the service. Upon information and belief, Military Defendants have adopted a general policy of removing and/or destroying the FDA-approved labeling and of refusing to provide the FDA-approved labeling to service members.

69. Military Defendants have an express policy to deceive service members—orally and in writing—by stating that unlicensed, EUA products are in fact FDA-licensed products and even referring to these unlicensed products by the proprietary name—COMIRNATY® or SPIKEVAX®—that, pursuant to federal

[3] *See, e.g.*. Douglas Holl, *Vaccine Rodeo Gives APG Solders, Civilians an Opportunity to Be 'Selfishly Selfless'* (Jan. 27, 2021), available at: https://www.army.mil/article/242752/vaccine_rodeo_gives_apg_soldiers_civilians_an_opportunity_to_be_selfishly_selfless (last visited Nov. 23, 2022).

and state law, may only be used for FDA-licensed products. *See supra* ¶ 50 (summarizing deceptive measures and misrepresentations of available products).

70. In addition to these deceptive measures, Military Defendants have employed a wide range of coercive measures to force service members to forfeit their right to refuse an unlicensed product. *See supra* ¶¶ 165-166 (summarizing coercive measures and punishment of Plaintiffs).

H. Impact of COVID-19 and DOD Mandate on Military

71. The DOD Mandate and the Mandated mRNA Treatments have produced few, if any, benefits, while imposing enormous costs on unvaccinated services members, with disastrous effects on readiness, retention, and recruitment.

72. No active-duty service member, whether vaccinated or not, has died in the past year since the Omicron variant became prevalent. *See* Ex. 5, Rans Decl., at 12-13 & Table (filed in *Bazzrea v. Austin*, SDTX No. 3:22-cv-265, ECF 22-2 (Aug. 30, 2022) ("*Bazzrea* Rans Decl.") (no death since November 2021). Further, Defendants' own data shows that the treatment for the virus has killed more service members (119), *see* Ex. 6, Dr. Teresa Long Decl., at 13 (submitted to Sen. Homeland Sec. and Governmental Affairs Comm. (Mar. 9, 2022)), than the virus itself (85). *See* Ex. 5, *Bazzrea* Rans Decl., at 14, ¶ 12.

73. Defendants have not provided, in this or related proceedings, any current or relevant data regarding the marginal risks and benefits—for the service

member and the military in terms of readiness and other asserted compelling interests—of the Mandated mRNA Treatments for healthy service members under current circumstances (namely, 2022 data with respect to the currently prevalent Omicron sub-variants when 98% of other service members are fully vaccinated). Instead, Defendants have provided only "historical data from the 2020 and 2021 pre-Omicron, pre-vaccine phase" that does not "address the present state of 'the force." *Colonel Fin. Mgmt. Officer v. Austin*, No. 8:22-CV-1275-SDM-TGW, 2022 WL 3643512, at *16 (M.D. Fla. Aug. 18, 2022) ("*CFMO*").

74. Over 7,000 service members have already been discharged, and the military faces the loss of at least one hundred thousand service members. The Army will fall short of its FY22 end strength goal by up to 40,000,[4] while over 60,000 unvaccinated Army reserve and National Guard were barred from service and pay on July 1, 2022.[5] The losses are so great that the Commanding General of the Florida

[4] *See* Opinion: Michael R. Bloomberg, *Military Recruitment Woes Endanger National Security*, Bloomberg (Aug. 8, 2022), available at: https://www.bloomberg.com/opinion/articles/2022-08-08/us-military-has-a-recruitment-and-retention-problem-here-s-how-to-fix-it.

[5] *See* Allie Griffin, *Army Bars More Than 60K National Guards, Reservists from Service, Cutting Off Pay*, NY Post (July 8, 2022), available at: https://nypost.com/2022/07/08/army-cuts-pay-from-over-60k-unvaccinated-national-guard-reserves/ (last visited July 17, 2022).

National Guard concludes that the policy "puts national security at risk,"[6] and Senator Thom Tillis (R-N.C.) believes it poses a "long-term threat to the all-volunteer force."[7]

75. Congress has also taken notice of the disastrous effects that the DOD Mandate is having on military readiness and recruiting across the DOD, as set forth in the attached September 15, 2022 letter to Secretary Austin from nearly 50 members of Congress. *See* Ex. 7, Sept. 15, 2022 Congressional Letter to Secretary Austin. These Members of Congress express "grave concern of the effect of the" DOD Mandate because, "[a]s a major land war rages in Europe our own military faces a self-imposed readiness crisis." *Id.* at 1. These Congress Members identify the DOD Mandate as the "primary cause of the [DOD]'s recruiting difficulties," which will result in the loss of at least 75,000 from the Army alone, *id.* at 2, and effectively "disqualifies more than forty percent of the Army's target demographic from service nationwide, and over half of the individuals in the most fertile recruiting grounds." *Id.* at 2.

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[6] Maj. Gen. James Eifert, *The Vaccine Mandate Puts National Security at Risk*, Wall Street J. (Aug. 4, 2022), available at: https://www.wsj.com/articles/vaccine-mandate-puts-national-security-at-risk-involuntary-termination-armed-forces-military-covid-pandemic-lockdowns-11659645396 (last visited Aug. 12, 2022).

[7] Tom Jurkowsky, *The Military Has a Serious Recruiting Problem – Congress Must Fix it*, The Hill (June 21, 2022) (*quoting* Sen. Thom Tillis (R-N.C.)), available at: https://thehill.com/opinion/national-security/3527921-the-military-has-a-serious-recruiting-problem-congress-must-fix-it/ (last visited July 17, 2022).

II. FEDERAL LAWS GOVERNING LICENSING AND EMERGENCY USE AUTHORIZATION OF DRUGS AND BIOLOGICS

A. FDA Licensing of Drugs and Biologics

76. A vaccine is both a drug and a biological product and is therefore subject to regulation under both the FDCA and the PHSA. *See* 21 U.S.C. § 321(g); 42 U.S.C. § 262(i)(1).

77. To obtain approval under the FDCA, the applicant is required to prove through "well-controlled" trials, *see* 21 U.S.C. §§ 355(d)-(e), that the drug is "safe" and "effective" for the purposes it claims. *See* 21 U.S.C. §355(b)(1)(A)(i). The FDCA prohibits anyone from introducing or delivering into interstate commerce any "new drug" or "biological product" unless and until the FDA has approved the drug as safe and effective for its intended use. 21 U.S.C. §§ 331(a).

78. Biologics are held to higher standards than other drugs.[8] The PHSA requires that a biologics manufacturer demonstrate that the biologic: (1) is "safe,

[8] 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. *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

pure, and potent" (where "potent" is equivalent to "effective" under the FDCA); 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). Thus, the biologics application addresses not only the safety and efficacy of the product, but also covers specific labeling and manufacturing requirements, including the manufacturing location, process, and storage requirements.

B. "Interchangeable" Biological Products under the PHSA

79. "Interchangeable" and "interchangeability" are specifically defined terms in Section 351 of the PHS Act, 42 U.S.C. § 262, in relation to a "reference product," which is a biological product licensed under Section 351(a) of the PHSA. 42 U.S.C. § 262(a). For the purposes of determining "interchangeability," the "reference product" must be an FDA-licensed product, *e.g.*, FDA-licensed COMIRNATY® or SPIKEVAX®. But the "interchangeable" product, the unlicensed EUA product, must be the subject of a later filed "abbreviated" application under 42 U.S.C. § 262(k). There is no indication that any such application was ever filed by the Manufacturer Defendants.

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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.").

C. Emergency Use Authorization Laws and Differences Between EUA and FDA-Licensed Products

80. The FDA may issue an EUA for a medical drug, device, or biologic, where it determines that there are no adequate, approved, and available alternatives. *See* 21 U.S.C. § 360bbb-3. There are significant differences between licensed vaccines and those subject to EUA that render them "legally distinct." ECF 1-6, August 23, 2021 Pfizer/BioNTech EUA Reissuance, at 2 n.8.

81. First, the efficacy showing is much lower for EUA products than for licensed products. EUAs require only a showing that, based on scientific evidence "if available," "it is reasonable to believe," the product "may be effective" in treating or preventing the disease. 21 U.S.C. §360bbb-3(c)(2)(A).

82. Second, the safety requirements are minimal. FDA need only find that the "known and potential benefits … outweigh the known and potential risks" of the product, considering the risks of the disease. 21 U.S.C. §360bbb-3(c)(2)(B).

83. Third, EUA products are exempt from certain manufacturing and marketing standards, enjoy broader product liability protections, and cannot be mandated due to informed consent laws and regulations.

D. Informed Consent Requirements for EUA Products

84. The FDA's grant of an EUA is subject to informed consent requirements to "ensure that individuals to whom the product is administered are informed" that they have "the option to accept or refuse administration of the

product." 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III). The FDA imposes and enforces the "option to accept or refuse" condition by requiring distribution to potential vaccine recipients a Fact Sheet that states, "It is your choice to receive or not receive [the vaccine]."

85. These informed consent and labeling requirements are distinct from those that apply to FDA-licensed drugs or biologics. For FDA-licensed non-prescription drugs, all FDA-approved product labeling materials and warnings must be provided to all consumers "foreseeable users," and the manufacturer has a duty to ensure that consumers receive these materials. *See, e.g. Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1277 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096 (1974). For FDA-licensed prescription drugs, by contrast, these materials need not be provided to the consumer because it is the treating physician or other "learned intermediary" is expected to inform recipients of risks and other relevant facts. *Id.*

86. The EUA statute does not draw this distinction between prescription and non-prescription drugs. The FDCA directs that the FDA "shall … ensure that the individuals to whom the product is administered are informed … of the option to accept or refuse administration of the product …" 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III), including the EUA Factsheet informing potential recipients that they have the "the option to accept or refuse administration of the product." The requirement applies without regard to prescription status.

III. EMERGENCY USE AUTHORIZATIONS FOR MRNA PRODUCTS

A. FDA EUAs for Monovalent mRNA Products

87. The FDA issued an EUA for Pfizer/BioNTech on December 11, 2020, and for Moderna on December 18, 2020, in each case based on approximately two months of safety and efficacy data. The FDA concluded that evaluation of whether the product would "reduc[e] SARS-CoV-2 transmission" "was not necessary to support an EUA." Ex. 8, Dec. 11, 2020 FDA Pfizer-BioNTech EUA Decision Memorandum at 55; Ex. 9, Dec. 18, 2020 FDA Moderna EUA Decision Memorandum at 60 (same).

88. The FDA implemented the "option to accept or refuse" condition by requiring that FDA's "Fact Sheet for Recipients and Caregivers" be made available to every potential vaccine recipient. Each Fact Sheet includes the statement that the recipient "has the option to accept or refuse" the product. ECF 1-14, Aug. 23, 2021 Pfizer/BioNTech EUA Fact Sheet, at 9.

B. FDA Interchangeability Determinations

89. When it approved the original Purple Cap COMIRNATY® on August 23, 2021, the FDA re-issued the EUA for Pfizer-BioNTech product in which it found that the unlicensed EUA product could be used "interchangeably" with the licensed "without presenting any safety or effectiveness concerns." ECF 1-6, Aug. 23, 2021 Pfizer-BioNTech EUA Re-Issuance, at 2 n.8. The FDA acknowledged that the two

products were "legally distinct with certain differences that do not impact safety or effectiveness."

90. On January 31, 2022, when the FDA approved Moderna's SPIKEVAX®, the FDA re-issued the Moderna EUA using identical language regarding interchangeability of the Moderna EUA and SPIKEVAX® products and finding the "legally distinct" EUA products to have equivalent safety and effectiveness as the licensed EUA product. Ex. 11, Jan. 31, 2022 Moderna EUA Re-Issuance, at 2 n.8.

91. Military Defendants assert that licensed and EUA vaccines are legally interchangeable for the purposes of the Military Mandates, *i.e.*, that EUA vaccines may be legally mandated, notwithstanding the express prohibition in 10 U.S.C. § 1107a. *See, e.g.,* ECF 68-1, Dixon Decl., ¶ 14 (informed by command that "interchangeability" includes "legal interchangeability"). The FDA has never expressly stated that these products are legally interchangeable. DOD officials have zero authority to make interchangeability determinations regarding "products" or "biologics" regulated by the FDCA or the PHSA.

92. The FDA's EUA reissuance letters have consistently acknowledged that the two vaccines are "legally distinct." *See, e.g.,* ECF 1-6, Aug. 23, 2021 Pfizer/BioNTech EUA Re-Issuance Letter, at 2 n.8. The FDA's witness in this proceeding confirmed that the FDA has not made any "statutory interchangeability

determination" and instead described the products as only "medically interchangeable." ECF 65-14, Marks Decl., ¶¶ 10-11. This simply means that one dose of an EUA vaccine and one dose of a licensed vaccine may be used to administer a two-dose vaccine regimen. *See, e.g.,* Congressional Research Service, *FDA Approval of the Pfizer-BioNTech COVID-19 Vaccine: Frequently Asked Questions* at 5 (Sept. 29, 2021), available at: https://crsreports.congress.gov/product/pdf/R/R46913 (last visited Nov. 23, 2022).

93. While the FDA acknowledges that the EUA and licensed products are legally distinct, it has purported to use its enforcement discretion to waive the unique labeling and informed consent requirements that apply to EUA products. The FDA's witness has stated that "FDA is exercising its enforcement discretion with respect to certain labeling requirements, in that FDA is not taking enforcement with respect to vials that bear the EUA label," and not requiring providers to provide "the Fact Sheet for Recipients, which advises recipients that 'under the EUA, it is your choice to receive or not receive the vaccine.'" ECF 65-14, Marks Decl., ¶ 13.

C. FDA EUA for "Bivalent" mRNA Products

94. On August 31, 2022, the FDA issued EUAs for both the Pfizer/BioNTech and the Moderna "bivalent" vaccines to be used as a booster shot. *See* ECF 117-3, Aug. 31, 2022 Pfizer COVID-19 Bivalent Vaccine EUA Letter; ECF 117-4, Aug. 31, 2022 Moderna COVID-19 Bivalent Vaccine EUA Letter.

95. The August 31, 2022 EUA letters use exactly the same language regarding availability—there is "not sufficient approved vaccine available," ECF 117-3, Aug. 31, 2022 Pfizer/BioNtech Bivalent EUA Letter, at 14 n.30 & ECF 117-4, Aug. 31, 2022 Moderna Bivalent EUA Letter, at 13 n.21—as the FDA has used for all other EUA re-issuance letters starting August 23, 2021 for periods during which no FDA-licensed vaccines were available at all. *Cf.*, ECF 1-6, Aug. 23, 2021 Pfizer/BioNTech EUA Letter, at 5 n.9. In other words, the FDA's consistent practice or policy has been to use the term "not sufficient approved vaccine available," when no FDA-licensed vaccines (*i.e.,* zero) are available.

96. The main new finding in the August 31, 2022 EUA letters is an implicit acknowledgement that there is no licensed mRNA Product that is "adequate" for treating the Omicron variant or sub-variants. *See* ECF 117-3, Aug. 31, 2022 Pfizer/BioNTech Bivalent EUA Letter, at 14 n. 30 (no approved vaccine "contain[s] or encode[s] the spike protein of the Omicron variant."); ECF 117-4, Aug. 31, 2022 Moderna Bivalent EUA Letter, at 13 n. 21 (same).

IV. FDA LICENSURE OF COMIRNATY® AND SPIKEVAX®

A. The FDA Approved the mRNA Products Without Conducting Adequate, Well-Controlled Studies Required by Law.

97. The FDA claims that its approval of COMIRNATY® followed its "standard process for reviewing the quality, safety, and effectiveness of medical

products."[9] The FDA stated that SPIKEVAX® "meets the FDA's rigorous standards for safety, effectiveness and manufacturing quality required for approval."[10]

98. But these statements are belied by FDA's contemporaneous statements and the deficient process it followed. In its August 23, 2021 press conference, FDA Acting Commissioner Woodcock conceded that the FDA followed an "unprecedented timeline"[11] in approving the Purple Cap COMIRNATY® application in just over three months. It did so by violating or waiving procedural requirements and failing to require "well controlled" studies required by law. 21 U.S.C. § 355(d)-(e); 21 C.F.R. § 314.126.

99. Most clinical trial participants were followed for only two months (*i.e.*, the same period as for the EUA), instead of the FDA's recommended period of at least one to two years set forth in the FDA's 2020 Industry Guidance. *See* ECF 1-

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[9] FDA, *FDA Approves First COVID-19 Vaccine*, (Aug. 23, 2021) ("FDA COMIRNATY® Press Release"), available at https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited Nov. 23, 2022).

[10] FDA, *Coronavirus (COVID-19) Update: FDA Takes Key Action by Approving Second COVID-19 Vaccine* (Jan. 31, 2022) ("FDA SPIKEVAX® Press Release"), available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine (last visited Nov. 23, 2022).

[11] Justine Coleman, *FDA Grants Full Approval to Pfizer's COVID-19 Vaccine*, The Hill (Aug. 23, 2021) (quoting then-acting FDA Commissioner Woodcock), available at: https://thehill.com/policy/healthcare/568980-fda-grants-full-approval-to-pfizers-covid-19-vaccine (last visited Nov. 23, 2022).

11, HHS, FDA & CBER, *Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry* (June 2020) ("June 2020 Industry Guidance"). Further, the median period that trial participants were followed was four months, and only about one-fourth were covered for at least six months. *See* FDA Comirnaty Press Release, *supra* note 9.

100. The COMIRNATY® clinical trials were not controlled studies because 93% of study participants were "unblinded", *i.e.*, they were told whether they had taken the experimental mRNA treatment or the placebo, and if they had taken the placebo, to take the mRNA treatment.[12] Unblinding eliminated the control group required for a "well-controlled study" and thus for approval. Accordingly, the FDA's statements that Purple Cap COMIRNATY® was approved based on "randomized, controlled, blinded ongoing clinical trial of thousands of individuals," FDA Comirnaty Press Release, *supra* note 9, is false and misleading.

101. The SPIKEVAX® clinical trials suffered from similar defects. Roughly half of trial participants were followed for at least four months, and less than one-fourth were followed for at least six months. *See* FDA SPIKEVAX® Press Release,

[12] *See* Stephen J. Thomas, MD, *Six Month Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine*, medRxiv Preprint (July 28, 2021), available at: https://www.medrxiv.org/content/10.1101/2021.07.28.21261159v1.full.pdf (last visited Nov. 23, 2022). As a result, only approximately 7% of study participants were blinded after six months. *Id.* at 5.

supra note 10. Moderna also similarly unblinded study participants, vaccinating them all and thereby eliminated the control group required for "well controlled" studies.[13]

102. SPIKEVAX® was not approved until January 31, 2022, long after the Omicron variant had become prevalent. Upon information and belief, the FDA did not require Moderna to provide clinical trial data concerning SPIKEVAX®'s effectiveness against Omicron. This approval was also months after the FDA had already approved a third booster shot for the EUA product for all adults on November 19, 2021,[14] an implicit admission that the mandated two-dose regimen was not effective against the then prevalent Delta variant of COVID-19.

B. The FDA Approved mRNA Products Without Any Data Whatsoever on Whether It Prevented Transmission.

103. On October 10, 2022, Janine Small, President of International Developed Markets at Pfizer, in sworn testimony before the European Union Parliament Covid Hearing on October 10, 2022, admitted "that the Pfizer mRNA

[13] *See, e.g.,* Dina Bair & Katharin Czink, *Vaccine Trial Participants Starting to Find Out if They Got the Real Shot in Unblinding*, WGN9 (Jan. 14, 2021), available at: https://wgntv.com/news/medical-watch/vaccine-trial-participants-starting-to-find-out-if-they-got-the-real-shot-in-unblinding/ (last visited Nov. 23, 2022).

[14] FDA, *Coronavirus (COVID-19) Update: FDA Expands Eligibility for COVID-19 Vaccine Boosters* (Nov. 19, 2021), available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-covid-19-vaccine-boosters (last visited Nov. 23, 2022).

vaccine was never tested or shown before its release, to impact the transmission of the SARS-COV-2 virus."[15]

104. On information and belief, the FDA approved the Moderna mRNA treatment without any clinical trial data or other evidence demonstrating that it prevented transmission.

C. The FDA Approved the mRNA Products Without Evidence That They Provide Long-Term Protection.

105. The FDA approved the original Purple Cap COMIRNATY® without any data demonstrating that it provided long-term protection against infection. Because clinical trials typically run for years, rather than a few months, the FDA has acknowledged that "[i]nformation is not yet available about potential long-term health outcomes." FDA Comirnaty Press Release, *supra* note 9. For SPIKEVAX®, the FDA similarly acknowledged "[i]nformation is not yet available about potential long-term health outcomes" for SPIKEVAX®. FDA SPIKEVAX® Press Release, *supra* note 10.

106. For both products, the Vaccine Information Sheet states that "[t]he [Spikevax] duration of protection against COVID19 is currently unknown." Spikevax Vaccine Information Fact Sheet for Recipients and Caregivers, at 4 (Mar.

[15] Robert Turner, *Pfizer Confirms mRNA Vaccine Never Tested for Preventing COVID Transmission*, Medika Life (Oct. 12, 2022) (emphasis added), available at: https://medika.life/pfizer-confirms-mrna-vaccine-never-tested-forpreventing-covid-transmission/ (last visited Oct. 31, 2022).

29, 2022), available at: https://www.fda.gov/media/144638/download (last visited Nov. 23, 2022).

107. Less than 60 days after SPIKEVAX® was approved, Moderna sought FDA authorization for "a fourth shot of its Covid-19 vaccine as a booster dose for all adults."[16] On March 29, 2022, the FDA, in recognition of the rapidly waning effectiveness of the licensed two-shot SPIKEVAX®'s, with an additional Moderna EUA booster, approved a fourth Moderna dose.[17]

D. The FDA Continued to Issue Supplemental Approvals of mRNA Products Despite Knowledge That mRNA Products Were Obsolete and Ineffective against Omicron Variant.

108. At the time of the initial approvals, the FDA did not have any evidentiary basis or clinical trial data for concluding that the Mandated mRNA Products provided long-term protection against infection or prevented transmission. Since then, conclusive evidence has emerged that the FDA-licensed mRNA Product do not provide even short-term protection against infection—and may even have negative efficacy—and do not prevent transmission at all. Despite the

[16] NBC NEWS, *Moderna Asks FDA to authorize second booster for adults* (Mar. 17, 2022), available at: www.nbcnews.com/news/us-news/moderna-asks-fda-authorize-second-booster-adults-rcna20558 (last visited Nov. 23, 2022).

[17] Spencer Kimball, CNBC, *CDC recommends fourth Pfizer and Moderna Covid vaccine doses for people age 50 and older* (Mar. 29, 2022), available at: https://www.cnbc.com/2022/03/29/fda-authorizes-fourth-pfizer-covid-vaccine-dose-for-people-age-50-and-older-.html (last visited Nov. 23, 2022).

acknowledgment by manufacturers and expert public health agencies is that the licensed products are ineffective and obsolete against Omicron, *see infra* ¶¶ 136-142, the FDA has granted several supplemental approvals after the Omicron became the predominant strain starting in November-December 2021.

109. The FDA issued multiple supplemental approval letters for Grey Cap COMIRNATY®: (1) December 16, 2021, *see* ECF 120-1 ("December 16 Comirnaty Approval Letter"); (2) July 8, 2022, *see* ECF 120-2 ("July 8 Comirnaty Approval Letter"); and (3) August 25, 2022, *see* ECF 120-3 ("August 25 Comirnaty Approval Letter"). The FDA has granted additional supplemental approvals that were not issued publicly in response to Plaintiffs' filings, including letters issued on January 14, 2022, *see* ECF 118-1 ("January 14 Letter"), and April 14, 2022. *See* ECF 124-2 ("April 14 Letter").

110. For SPIKEVAX®, there are no publicly available FDA supplemental approval letters. On information and belief, however, the FDA has issued non-public supplemental approvals.

E. The FDA Approved the mRNA Products Despite Strong Evidence of Serious Safety Problems.

111. The FDA continued to grant approvals and supplemental approvals long after the FDA's Vaccine Adverse Event Reporting System ("VAERS") data reveal unprecedented levels of death and other adverse events for the mRNA "vaccines". Through April 2022, COVID-19 vaccination "has led to more than

12,000 deaths and more than 13,000 permanently disabled Americans." Ex. 10, McCullough Supp. Decl., ¶ 17

112. The mRNA Products pose a particular risk of myocarditis (heart inflammation) to those who are in the prime ages for military service. Due to these risks, in Dr. McCullough's expert medical opinion, "no individual under age 30 under any set of circumstances should feel obliged to take this risk with the current genetic vaccines particularly the Pfizer and Moderna products." *Id.*, ¶ 12 (discussing FDA myocarditis warnings).

113. Three different military doctors have also testified to the Senate Homeland Security and Governmental Affairs Committee that the Department of Defense's own Defense Medical Epidemiological Database shows alarming trends of medical injuries coinciding with the rollout of the DoD Mandate. This is separate from the VAERS data query that one of the doctors made to the CDC, which reported 300 disabled servicemembers and 119 active-duty deaths as of Feb. 11, 2022, from the vaccines, while the number of deaths from COVID-19 itself for active duty servicemembers since the beginning of the pandemic is a fraction of that number. *See* Ex. 6, Dr. Long Decl., at 13-14.

V. FEDERAL AND STATE REGULATION OF DRUG LABELING, MISBRANDING AND DECEPTIVE MARKETING.

A. FDA Labeling Requirements and Prohibition of Misbranding.

114. 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.

115. 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). The misbranding statute also prohibits false or misleading use of a licensed product's proprietary name, misrepresentations that an unlicensed product is licensed, failure to include required information on the

label, or violations of any FDA regulations thereunder. *See* 21 U.S.C. § 352(e) ("Designation of drugs or devices by established names"), § 352(f) ("Directions for use and warnings on label"), § 352(g) ("Representations as recognized drug"); § 352(i) ("Drug; misleading container; imitation; offer for sale under another name"), and § 352(p) ("Packaging or labeling of drugs in violation of regulations"). *See also* 21 U.S.C. § 379r (non-prescription drugs).

116. 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 U.S.C. § 332(a).

117. 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).

118. The FDA regulations specifically prohibit "[a]ny representation that creates an impression of official approval" of an unapproved product. 21 C.F.R. § 607.39; 21 C.F.R. § 207.77(a); *see also* 21 C.F.R. § 207.77(b) ("Any representation that creates the impression that a drug is approved or is legally marketable … is misleading and constitutes misbranding."). A drug may also be misbranded is a "false or misleading representation with respect to another drug …" 21 C.F.R. § 201.6, such as an unlicensed product claiming to have the "safety" and "efficacy" findings of a licensed drug.

119. FDA regulations further require that any facility where prescription drugs are stored have a separate quarantine area for drugs that are "outdated, … misbranded, or adulterated or that … have been opened." 21 C.F.R. § 205.50.

B. FTC Regulation of OTC Non-Prescription Drug Marketing

120. The FTC and FDA share jurisdiction over the marketing of non-prescription drugs. The FTC has broad authority under the FTCA to address deceptive or unfair advertising of non-prescription, OTC drugs. Under the FTCA, the dissemination of false or deceptive advertising likely to induce the purchase of drugs is unlawful and subject to enforcement by the FTC.

121. In its *Deception Policy Statement*, *appended to Cliffdale Assocs., Inc.*, 103 F.T.C. 110, 174 (1984), the FTC defines false or deceptive advertising broadly to include any "representation or omission of information that is likely to mislead

the consumer," issued by a manufacturer, packer or distributor, that is "likely to affect the consumer's conduct or decisions with regard to a product or service," considered "from the perspective of a consumer acting reasonably in the circumstances." *Id.* at 175. Further, it is irrelevant that an advertiser did not intend to convey a claim, and they "are liable for materially misleading claims or omissions … convey[ed] to reasonable consumers, even if this is done inadvertently." *Kraft, Inc.*, 114 F.T.C. 40, 53 n.33 (1991), *aff'd*, *Kraft, Inc. v. FTC* , 970 F.2d 311 (7th Cir. 1992).

122. The touchstone for the FTC's evaluation of claims is the "substantiation" doctrine pursuant to which any objective claim about a product includes an express or implied representation that the advertiser possesses a "reasonable basis" for the claim. *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1497 (1st Cir. 1989). The FTC applies the six-factor test developed in *Pfizer, Inc.*, 81 F.T.C. 23 (1972) (the "*Pfizer* Test") in determining whether a given health-related claim is substantiated.

123. In evaluating whether an advertiser's substantiation meets the "competent and reliable evidence" standard, the FTC has given great weight to the final *Pfizer* factor: the kind of substantiation that experts in the relevant field believe would be necessary to support the representation. For health-related claims, the FTC has defined "competent and reliable scientific evidence" to require "at least two

adequate and well-controlled, double-blinded clinical studies that conform to acceptable designs and protocols and are conducted by different persons, independently of each other." *Novartis Corp. v. FTC*, 127 F.T.C. 580, 726 (1996), *aff'd*, 223 F.3d 783 (D.C. Cir. 2000).

C. Florida State Law Regulating Drug Misbranding and Deceptive and Unfair Trade Practices.

124. The Florida Deceptive and Unfair Trade Practices Act ("FDUPTA") seeks "[t]o protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." Fla. Stat. § 501.202(2).

125. In interpreting FDUPTA, "great weight shall be given to the interpretations of the [FTC] and the federal courts relating to" analogous provisions of the FTC, Fla. Stat. § 501.204(2), and it must "be construed liberally to promote" the policy of making Florida consumer-protection law "consistent with established policies of federal law relating to consumer protection." Fla. Stat. § 501.202(3).

126. A violation of FDUPTA include violations of the FTCA, §§ 41 *et seq*. and rules promulgated thereunder, as well as any federal or Florida state "law, statute, rule, regulation, or ordinance which proscribes unfair methods of competition, or unfair, deceptive, or unconscionable acts or practices," Fla. Stat. § 501.203(3)(a)-(b), including the FDCA and PHSA for drugs, and Florida's food

and drug laws prohibiting misbranding. These statutory violations are *per se* FDUPTA violations, *see Feheley v. Lai Games Sales, Inc.,* No. 08–23060–civ, 2009 WL 2474061, at *5 (S.D.Fla.2009), which are not subject to the heightened pleading requirements of FRCP Rule 9(b). *See Blair v. Wachovia Mortg. Corp.*, 2012 WL 868878, at *3 (S.D. Fla. Mar. 14, 2012).

127. Florida state law prohibiting misbranding of drugs encompasses a wide range of conduct. As relevant here, this statute prohibits sale, delivery, receipt, distribution, or holding for sale of any drug that is "adulterated or misbranded," Fla. Stat. 499.005(1); "dissemination of any false or misleading advertising," Fla. Stat. 499.005(5); "destruction, obliteration, or removal of the whole or any part of the labeling of a drug" or any other act that "results in the drug … being misbranded," Fla. Stat. 499.005(9); and the "use, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application of the drug is effective when it is not." Fla. Stat. 499.005(11).

128. Florida law defines a drug to be misbranded if: "its labeling is in any way false or misleading," Fla. Stat. 499.007(1); if its "package" does not in include the proprietary name, manufacturer and other information parallel to the FDA's labeling requirements. Fla. Stat. § 499.007(2)-(7); or if it is a prescription drug that is dispensed without a prescription. Fla. Stat. § 499.007(13). In fact, prescription

drugs "not properly 'dispensed' are, per se, misbranded." *Rodriguez v. State*, 67 So.3d 326, 330 (Fla. 3rd DCA 2011).

VI. ALL MILITARY DEFENDENTS' FDA-LICENSED PRODUCTS ARE UNLICENSED, MISBRANDED, EXPIRED, ADULTERATED, AND/OR UNFAIRLY AND DECEPTIVELY MARKETED.

A. The Mandated mRNA Products Are Not Vaccines.

129. COVID-19 vaccines employ novel technology, namely, synthetic mRNA delivered by nanolipids. COVID-19 vaccines are considered gene-based vaccines or vaccines produced from gene therapy molecular platforms. This is unlike all other vaccines where there is a set amount of antigen or a live-attenuated virus in the vaccine.

130. The manufacturers themselves have acknowledged in public filings going back to 2020 that the mRNA products are not "vaccines," but rather "therapeutics." For example, in its 2020 Annual Report to the Securities and Exchange Commission ("SEC"), BioNTech stated:

> Although we expect to submit BLAs [biologics license applications] for our mRNA-based product candidates in the United States, and in the European Union, mRNA therapies have been classified as gene therapy medicinal products, and other jurisdictions may consider our mRNA-based product candidates to be new drugs, not biologics or gene therapy medicinal products, and require different marketing applications.

BioNTech SE Form 20-F, U.S. Securities and Exchange Commission (2020), at 26 (last visited March 1, 2022). Similarly, in its June 30, 2020 Quarterly Report to the

SEC, Moderna acknowledged that "mRNA is considered a gene therapy product by the FDA."[18]

131. The Defendants knew at the time the DOD Mandate was issued that these products were not "vaccines" at all under the DOD's own immunization regulation, DODI 6205.02, the sole legal basis cited by Secretary Austin for issuance of the DOD Mandate. DODI 6205.02 defines "vaccination" and "vaccine" as follows:

> **vaccination**. The administration of a vaccine to an individual for inducing immunity.
>
> **vaccine**. A preparation that [1] contains one or more components of a biological agent or toxin and [2] induces a protective immune response against that agent when administered to an individual.

ECF 65-5, DODI 6205.02 ("Glossary"), at 18-19. The first and second clause establish an identity relationship between the "biological agent" administered (*i.e.*, mRNA) and "that agent" against which the vaccine "induces a protective immune response" (*i.e.*, COVID-19 virus). The identity relationship presents a binary choice—either the agent in [1] the same as "that agent" in [2] or it is not—with no space in between for ambiguity. The mRNA shots do not "contain" a single molecule of the COVID-19 virus, and therefore the mRNA shots are not "vaccines" under

[18] *Moderna SE Form 10-Q* at 70, available at: https://www.sec.gov/Archives/edgar/data/1682852/000168285220000017/mrna-20200630.htm (last visited Nov. 23, 2022).

DODI 6206.02.

132. Due to the general public's recognition that the mRNA Products could not prevent infection or transmission, on September 1, 2021, the CDC changed the definition of "vaccine" from a product that will "produce immunity"[19] (the definition from 2015 – August 2021) to one that will "produce protection" (September 2021).[20]

133. Prior to the issuance of the DOD Mandate, the CDC defined "immunity", "vaccine", and "vaccination" as follows:

> **Immunity**: Protection from an infectious disease. If you are immune to a disease, you can be exposed to it without becoming infected.
>
> **Vaccine**: A product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease. Vaccines are usually administered through needle injections, but can also be administered by mouth or sprayed into the nose.
>
> **Vaccination**: The act of introducing a vaccine into the body to produce immunity to a specific disease.[21]

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[19] CDC, *Vaccines and Immunizations: Definition of Terms* (Aug. 26, 2021), available at: http://web.archive.org/web/20210826113846/https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm (last visited Nov. 23, 2022) (defining "vaccine as "[a] product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease.").

[20] CDC, *Vaccines and Immunizations: Definition of Terms*, available at: https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm (last visited Nov. 23, 2022) (defining "vaccine" as [a] preparation that is used to stimulate the body's immune response against diseases.").

[21] CDC, *Immunization: The Basics* (archived version from Sept. 1, 2021), available at:https://web.archive.org/web/20210901163633/https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm (last visited Nov. 23, 2022).

134. On September 1, 2021, just days after issuance of the mandate, the CDC redefined "vaccine" and "vaccination" as follows:

> **Vaccine**: A preparation that is used to stimulate the body's immune response against diseases. Vaccines are usually administered through needle injections, but some can be administered by mouth or sprayed into the nose.
>
> **Vaccination**: The act of introducing a vaccine into the body to produce protection from a specific disease.[22]

135. Thus, just as Plaintiffs were being ordered by Secretary Austin to take these "vaccines", the CDC eliminated the word "immunity" from its definitions of "Vaccine" and "Vaccination." The CDC did so because the general public recognized that the mRNA injections do not produce immunity or prevent infection or transmission of COVID-19 and therefore did not qualify as "vaccines". So they broadened the definition to cover these ineffective COVID-19 treatments to forestall public doubts about the products, without any scientific basis for doing so.[23]

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[22] *See* CDC, *Immunization: The Basics* (archived version from Sept. 2, 2021), https://web.archive.org/web/20210902194040/https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm (last visited May 4, 2022).

[23] In contemporaneous internal emails produced in response to a Freedom of Information Act ("FOIA") request, CDC leadership acknowledged that it changed the definition of "vaccine" and "vaccination" in response to (correct) public criticism and questions that the COVID-19 vaccines did not meet the CDC's then current definitions of "vaccine" and "vaccinations" as providing "immunity." *See* Ex. 12, CDC FOIA Response Emails (Aug. 13, 2021 - Sept. 1, 2021) at 2 ("The definition of vaccine we have posted is problematic and people are using it to claim that the COVID-19 vaccine is not a vaccine based on our own definition."); *id.* at 3 ("these

B. Defendants Have Long Known That The Mandated mRNA Products Are Not Effective in Preventing COVID-19.

136. On July 21, 2021, in a CNN Town Hall, President Biden informed the American people that "You're not going to get COVID if you have these vaccinations,"[24] suggesting 100% efficacy. On July 21, 2022, exactly one year later, the White House announced that a fully vaccinated and double boosted President Biden had contracted COVID. According to his Press Secretary, the President and his doctors "knew this was going to happen" and that "at some point, everyone is going to get COVID." ECF 106-4, July 21, 2022 White House Press Briefing, at 16.

137. It has long been known that the mandated mRNA vaccines cannot prevent infection or transmission, and at most, can reduce the severity of infections, like other COVID treatments. *See* Ex. 10, McCullough Decl., ¶¶ 8-10. This is not surprising given that Pfizer/BioNTech product was never tested for its ability to prevent transmission, and the FDA did not require it. *See supra* ¶ 103.

138. Despite this knowledge, the FDA licensed COMIRNATY® with an 'indication' "for active immunization to prevent coronavirus disease 2019 (COVID-

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definitions are outdated and being used by some to say COVID-19 vaccines are not vaccines per CDC's own definition.")

[24] *See* Jason Lemon, *Video of Biden Saying Vaccinations Prevent COVID Resurface After Infection,* Newsweek (July 21, 2022), available at: https://www.newsweek.com/joe-biden-2021-video-saying-vaccinations-prevent-covid-resurfaces-1726900 (last visited Nov. 23, 2022).

19).” ECF 1-4, Aug. 23, 2021 Purple Cap COMIRNATY® BLA Approval, at 1.

139. As early as January 10, 2022, Pfizer CEO Albert Bourla acknowledged that the mandated two-dose regimen “offer[s] very limited protection, if any” against Omicron infection.[25]

140. Both Pfizer/BioNTech and Moderna recognized that their licensed mRNA Products were obsolete and ineffective long ago. Based on a review of data on the CDC website, the last lot of FDA-licensed Grey Cap COMIRNATY® was manufactured on February 10, 2022, and the last batch of FDA-licensed SPIKEVAX® was manufactured on April 7, 2022. Ex. 13, Kupper Decl., ¶ 12 & Ex. A. Despite this knowledge of ineffectiveness—reflected in their manufacturing decisions—Pfizer/BioNTech and Moderna continued to distribute and market these products as vaccines for preventing COVID-19 infection and transmission.

141. On August 11, 2022, the CDC issued updated guidance that finally acknowledged that the mandated mRNA Products were not effective. There the CDC stated that the mandated two-dose regimen provides “minimal protection against infection and transmission,” ECF 106-2, Aug. 11, 2021 CDC Summary of Guidance, at 1, and it recommended that COVID-19 mitigation policies should “no longer

[25] *New COVID-19 Vaccine That Covers Omicron ‘Will Be Ready in March,’ Pfizer CEO Says* Yahoo!Finance (Jan. 10, 2022) (transcript of video interview with Pfizer CEO Albert Bourla) (same), available at: https://finance.yahoo.com/video/covid-19-vaccine-covers-omicron-144553437.html (last visited Nov. 23, 2022).

differentiate based on vaccination status." *Id.* at 3.

142. On August 16, 2022, the White House announced that the U.S. government would no longer purchase the current "monovalent" versions of the COVID-19 vaccines.[26] Also on August 16, 2022, the CDC announced that the U.S. government would instead purchase 175 million doses of the new "bivalent" vaccines as part of a fall/winter campaign. *See* ECF 117-2, Aug. 16, 2022 CDC Fall Vaccination Operational Planning Guide, at 1. The U.S. government at that time was the sole paying customer for the licensed mRNA Products, insofar as it directly purchased or reimbursed the costs of all or essentially all mRNA Products distributed in the United States. This policy represents a policy determination by the sole customer and payor that the mandated mRNA Products are obsolete and ineffective.

C. The Mandated mRNA Products Are Misbranded and Deceptively Marketed as Vaccines and as Being Effective Against COVID-19.

143. As set forth above, all of the mandated mRNA Products are misbranded and falsely and deceptively marketed as "vaccines". Accordingly, all mandated mRNA Products are not vaccines, and labeling or marketing them as such is a violation of federal and state laws prohibiting misbranding and deceptive marketing of drugs.

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[26] *See* CNN, *Biden Administration Wil Stop Buying COVID-19 vaccines, treatments and tests as early as this fall, Jha says* (Aug. 16, 2022), available at: https://www.cnn.com/2022/08/16/health/biden-administration-covid-19-vaccines-tests-treatments/index.html (last visited Nov. 18, 2022).

144. All of the mandated mRNA Products are labeled and marketed as being effective against COVID-19. Whether or not they were ever effective in preventing infection by the original variant, they are not effective against the Omicron subvariant that has been prevalent since at least December 2021. Defendants and the manufacturers have acknowledged the lack of efficacy, as shown by the Pfizer CEO's January 10, 2022 admission; Manufacturer Defendants' decision to cease production shortly thereafter; and the decision by the sole customer and payor, the U.S. government, to no longer purchase or provide reimbursement for the costs of these products.

D. Military Defendants Mandated a Product That Did Not Exist and That Was Not Manufactured or Marketed.

145. The DOD Mandate was issued on August 24, 2021, just one day after the FDA approved the original Purple Cap COMIRNATY® on August 23, 2021. The National Drug Code ("NDC") label identifier for the Purple Cap COMIRNATY® is 0069-1000. *See* Ex. 17, August 23, 2021 Purple Cap COMIRNATY® Package Insert at 14-15.

146. This product 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. 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." ECF 120-8, Sept. 13, 2021 Pfizer Announcement, at 1. A review of

the NIH site confirms that there are no active NDCs for the "Purple Cap" formulation; instead, this package insert was obtained from the NIH labeling archives.

E. Defendants Have Mandated Unlicensed, Misbranded Bivalent mRNA Products to Plaintiffs and Other Service Members.

147. The Rans Declaration provides a list of "BLA-approved, Comirnaty-labeled" vaccines, ECF 124-1, Rans Decl., ¶ 4, that are identified as Pfizer Grey Cap COMIRNATY. *Id.*, Ex. A. This list includes vaccines from Lot Numbers GH9667, GH9702, and GH6665 (the "G Lots").

148. On October 20, 2022, Plaintiff Kupper accessed the 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. 13, Kupper Decl., ¶¶ 4-5 & 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,[27] rather than 0069-2025, which is the NDC for Pfizer Grey Cap Comirnaty.

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[27] *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. 14, 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.").

149. This demonstrates that Defendants seek to mandate bivalent EUA products that are unlicensed EUA products misbranded as "Comirnaty-labeled." ECF 124-1, 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* ECF 120, Sept. 26, 2022 PL Mot., at 10-11, 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 appear to be a binding admission in sworn testimony of illegal conduct by all Defendants that necessarily implicates the manufacturers, Pfizer and BioNTech, who misbranded the products.

F. Defendants Have Mandated Unlicensed and Misbranded Monovalent mRNA Products to Plaintiffs and Other Service Members.

150. The Rans Declaration and spreadsheet also includes "BLA-approved Comirnaty-labeled" shots from Lots FW1330, FW1331, and FW1333 (collectively, the "FW Lots").[28] Each of the FW Lots was manufactured at the Pharmacia &

[28] 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." ECF 124-1, 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

Upjohn Kalamazoo, Michigan facility ("Kalamazoo Facility") in January 2022 (FW1330 and FW1331 expiring September 30, 2022) or February 2022 (FW1333 expiring October 31, 2022). *See* Ex. 15, FW1330 Lot Release Letter, at 1; ECF 108-1, Burk Decl., Ex. 1, FW1331 Lot Release Letter, at 1; Ex. 16, FW 1333 Lot Release Letter, at 1. These 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).

151. The August 23, 2021 approval of Purple Cap COMIRNATY® authorized the final formulated product to be "manufactured, filled, labeled and packaged" at the Pfizer facility in Puurs, Belgium and at the Kalamazoo Facility. ECF 1-4, Aug. 23, 2021 Purple Cap COMIRNATY® Approval Letter, at 1.

152. 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" COMIRNATY® to be manufactured at only one facility: Belgium, NV in Puurs, Belgium. *See* ECF 120-1, December 16 Comirnaty Approval Letter, at 1. The December 22, 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., Puurs,

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September 2022), while the DoD had been in possession of the FW Lots for over four months starting in June 2022.

Belgium). *See* ECF 120-4, Dec. 22, 2021 Grey Cap COMIRNATY® Package Insert, at 18. The package insert has a marketing start date of December 22, 2021, with NDC label identifier of 0069-2025. 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 manufactured.

153. Pfizer/BioNTech submitted an updated package insert that the FDA approved on May 19, 2022 (the day before it became orderable by the DoD) with a May 18, 2022 marketing start date and no marketing end date. *See* ECF 120-5, May 19, 2022 Grey Cap COMIRNATY® Package Insert, at 32. Once again, only the Pfizer site in Puurs, Belgium is listed as the 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.

154. All of the Supplemental Approvals expressly approve the manufacture of "COMIRNATY" at specific manufacturing locations. *See* ECF 120-1, December 16 Comirnaty Supp. Approval, at 1; ECF 120-2, July 8 Comirnaty Supp. Approval, at 1; ECF 120-4, August 25 Comirnaty Supp. Approval, at 1. For the January 14 Letter, by contrast, the word "COMIRNATY" is not used, and the letter does not

approve the manufacture of COMIRNATY at the Kalamazoo Facility. The letter uses only the generic name "Covid-19 vaccine (mRNA)." ECF 118-1, Burk Supp. Decl., Ex. 1., January 14 Letter, at 1.

155. 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* ECF 120-1, December 16 Comirnaty Supp. Approval, at 1-2; ECF 120-2, July 8 Comirnaty Supp. Approval, at 1-2; ECF 120-4, August 25 Comirnaty Supp. Approval, 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 …"). 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.

156. Finally, Plaintiffs have presented unrebutted evidence that the CDC identifies the FW Lots as EUA products. 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 9, 2022 response. *See* ECF 120-7, Coppin Decl., at 26 (Bashaw Decl., ¶¶ 10-11). In the attached declaration LT Bashaw reaffirms his August 4, 2022 testimony. *See* Ex. 18, Bashaw Decl., ¶ 8.

G. Defendants Have Mandated Expired and Adulterated Monovalent mRNA Products to Plaintiffs and Other Service Members.

157. The product labels and the Lot Release Letters for the FW Lots both state that the expiration date for Lots FW1330 and FW1331 is September 30, 2022, *see* Ex. 15 & ECF 108-1, and the expiration date for Lot FW 1333 is October 31, 2022. *See* Ex. 16. Further, the currently effective and all previous versions of the package insert state that: "Regardless of storage condition, the vaccine should not be used after the expiration date printed on the vial and cartons."[29]

158. Defendants also submit the April 14 Letter that purports to "extend[]

[29] Aug. 22, 2022 Grey Cap COMIRNATY® 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); ECF 120-4, Dec. 22, 2021 Grey Cap COMIRNATY® Package Insert, at 13; ECF 120-5, May 19, 2022 Grey Cap COMIRNATY® Package Insert, at 27.

the expiration period … from 9 months to 12 months." *See* 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.

159. At most, the April 14 Letter would have permitted Pfizer to modify or replace the expiration date printed on the product labeling or revise the package insert, neither of which was done. 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 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. 16, FW 1333 Lot Release Letter, at 1. All versions of the FDA-approved package inserts, including those from July and August 2022, contain the same directive not to use the product after the expiration date stated on the label.

160. The PHSA and FDA labeling regulations all refer to the requirements that must be stated on the "package", 42 U.S.C. §262(a)(1), or "container", 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 expired at the latest on October 31, 2022.[30]

161. Moreover, most of the FW Lots expired well before the stated expiration date (much less the purported extended date) because these vials were not continuously stored "between -90 ºC and -60 ºC."

162. 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 refrigerated at "2 ºC to 8 ºC" at which point they have a "10-week refrigerated expiry date." Ex. X, 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. 13 Kupper Decl., ¶ 7 & Ex. B, Slide 18.

163. Defendants' filings indicate that they received the FW Lots in early June 2022. These lots were then redistributed from Ft. Detrick, Maryland to military

[30] 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.

facilities at refrigerated temperatures rather than deep freeze, which triggered the 10-week expiration period that ended in August 2022. *See* Ex. 13, Kupper Decl., ¶¶ 9-10. Accordingly, all doses transported from Fort Detrick to other U.S. facilities at refrigerated temperatures, which includes all FW Lots listed in the Rans Declaration, expired after 10 weeks in August 2022.

VII. PLAINTIFFS SATISFY STANDING, RIPENESS, AND EXHAUSTION REQUIREMENTS.

164. All Plaintiffs will face, and have already faced, adverse employment or disciplinary actions, up to and including termination, separation, general discharge, loss of post-separation benefits, and permanent damage to their reputation and employment prospects resulting from a general discharge, as summarized in attached table. *See* Ex. 1, Plaintiffs' November 2022 Status Chart.

165. Plaintiffs Furman, Karr and Snow have been forced into early retirement; Major Harwood has completed his Board of Inquiry, which recommended separation; MSGT Kupper and Captain Cothran had started the separation process and Major Roberts was set to commence the process but was halted by the Air Force class-wide injunction; Plaintiff Connell is in the Medical Evaluation Board process to get his disability rating before separating; and Major Kaltrider was scheduled to commence his Board, when it was halted by the Marine Corps class injunction.

166. Most Plaintiffs have been subject to severe restrictions imposed on them and/or had adverse actions taken against them, that prevented them from performing their duties, attending required schools to maintain qualifications, or had career ending consequences. These restrictions and disciplinary actions include: training, travel and duty restrictions, *see* ECF 68-1, Connell Decl., ¶3; Cossette Decl., ¶5; Craymer Decl., ¶3; Karr Decl., ¶7; Kupper Decl., ¶8; Morgan Decl., ¶5; Roberts Decl., ¶ 6; Snow Decl., ¶4; denial or restriction of promotions, *see id.*, non-deployable status, *see id.*, Connell Decl., ¶3; Cossette Decl., ¶5; negative counseling letters, reprimands, or General Officer Memorandum of Reprimand ("GOMOR"), *see id.*, Sigoloff Decl., ¶15 (GOMOR); Thompson Decl., ¶6. SAC ¶17 (Craymer Letter of Reprimand); ineligibility for change of station or new assignments, *see id.*, Cossette Decl., ¶5; Craymer Decl., ¶3; Dixon Decl., ¶21; denied voluntary separation or early retirement, *see id.*, Dixon Decl., ¶23; Harwood Decl., ¶7; and/or removal from command, *see id.*, Harwood Decl., ¶4 (removed from position as battalion Executive Officer). Sigoloff Decl., ¶16 (removed from position as Medical Director).

167. Three of four Armed Services Defendants are subject to class-wide injunctions based on findings of "systemic" violations of service members' religious

liberties.[31] Accordingly, the only reason that their injuries are not worse—and that most Plaintiffs have not been discharged—is that courts have found that Defendants have engaged in systemic misconduct and taken the nearly unprecedented steps of issuing class-wide injunctions against three branches. All Plaintiffs have suffered the same harms as those enjoined in these and other challenges to the DOD Mandate.

168. This Court has already found that Plaintiffs satisfy ripeness and exhaustion requirements for their claims. *See* ECF 126, Nov. 8, 2022 Order, at 7-8.

169. Exhaustion is not required for Plaintiffs' APA claims. In any case, there are there are no military administrative procedures for challenging generally applicable rules or regulations issued by Secretary Austin or a Service Secretary. *See* ECF 119, Pl. Sept. 26, 2022 Response, at 2-3. Nevertheless, each Plaintiffs has pursued available military remedies by submitting a Religious Accommodation Request; at least nine have had their appeals denied (or in the case of Captain Karr, discharged before they could appeal), and several have appeals pending.[32] Several

[31] *See Navy SEALs 1–26 v. Austin*, No. 4:21-cv-1236, 2022 WL 1025144 (N.D. Tex. Mar. 28, 2022) (Navy class-wide preliminary injunction), *appeal filed* No. 22-10534 (5th Cir. May 27, 2022); *Doster v. Kendall*, 2022 WL 2974733 (S.D. Ohio July 14, 2022) (Air Force class-wide PI); *CFMO*, 2022 WL 3643512 (M.D. Fla. Aug. 18, 2022) (Marine Corps class-wide injunction).

[32] Plaintiffs Connell, Cothran, Craymer, Harwood, Kaltrider, Kupper, and Roberts have had their final appeal denied, while Karr was discharged and not given opportunity to appeal. Plaintiffs Cossette, Dixon, Sigoloff, Stermer, and Thompson have pending RAR appeals.

have had medical exemption requests denied once if not twice.[33] Plaintiffs have also pursued other remedies such as complaints to the Department of Defense's Inspector General ("IG") (Kupper and Craymer) and submitting complaints under Article 138 of the UCMJ (Cossette, Kupper, Roberts, Stermer, Sigoloff). *See* ECF 117, Sept. 26, 2022 PL Supp. Br., at 6. These complaints have been denied or ignored.

FIRST CAUSE OF ACTION
MILITARY MANDATES VIOLATE APA
5 U.S.C. §§ 706(2)(A); DODI 6205.02

170. Plaintiffs reallege the facts in Section I (¶¶ 45-75), Section IV (¶¶ 97-113), and Section VI.A-VI.D (¶¶ 129-146) as if fully set forth in this Count.

171. The DOD Mandate and the Armed Services Mandates must be set aside as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The Military Mandates impose sweeping vaccine mandates without any explanation or justification for their action or the legal basis thereunder; any findings of facts or analysis supporting their determination; and are based on patent misrepresentations of the law. The DOD Mandate's sole justification or explanation is a conclusory statement that the Secretary Austin has "determined that mandatory vaccination against [COVID-19] is necessary to protect the Force and defend the American people." ECF 1-3, DOD Mandate, at 1.

[33] Connnell (denied twice for cancer); Cothran (twice); Craymer (twice); Dixon (twice – nursing and lack of supply); Kaltrider (twice – natural immunity and lack of supply); Karr (fertility); Morgan; Roberts; Sigoloff.

172. First, given that the DOD Mandate was issued on the very next day after the FDA's approval of COMIRNATY®, there could not have been any meaningful consideration or analysis of the FDA's decision or the underlying data; relative risks and benefits based on service members' role, assignment, duty station, medical condition, or other health or demographic factors; or any alternatives to 100% vaccination. There is no indication in the DOD Mandate or the Military Administrative Records that Secretary Austin or the Military Defendants engaged in the careful and reasoned decision-making that the APA requires. *See, e.g., Bayer Healthcare, LLC v. FDA*, 942 F.Supp.2d 17, 25 (D.D.C. 2013).

173. Second, the Military Defendants promulgated a "vaccine" and "vaccination" mandate for a product that cannot be a "vaccine" as that term is defined in the DOD's immunization regulation, DODI 6205.02, ECF 65-6, because the mRNA Products do not include a single molecule of COVID-19. *See supra* ¶ 131. DODI 6205.02 is the sole legal authority cited by Secretary Austin in his August 24, 2021 memorandum promulgating the DOD Mandate. *See* ECF 1-3, DOD Mandate, at 1.

174. Third, the DOD Mandate conflicted with the CDC's definition of "vaccine" and "vaccination" in effect at the time it was promulgated. *See supra* ¶¶ 132-135. While the Military Defendants purport to rely on the expert recommendations of the CDC in implementing their mandates, the Military

Defendants have subsequently repeatedly ignored the CDC's recommendations. Military Defendants ignored the CDC's unanimous recommendation that all eligible adults should receive a third booster shot. *See* CDC, *CDC Expands Eligibility for COVID-19 Booster Shots to All Adults,* CDC Media Statement (Nov. 19, 2021), available at: https://www.cdc.gov/media/releases/2021/s1119-booster-shots.html. They also ignored the CDC's recommendation that the COVID-19 mitigation strategies should "no longer differentiate based on vaccination status," ECF 106-2, Aug. 11, 2022 CDC Guidance, at 3, by continuing to impose numerous arbitrary, discriminatory and punitive restrictions on unvaccinated service members like Plaintiffs. Such selective picking and choosing of which recommendations to follow, without any explanation, is the essence of arbitrary and capricious decision-making.

175. Fourth, the Military Mandates mandated a product that did not exist, in any quantity (*i.e.,* zero doses available, rather than merely "not sufficient" quantities as claimed by FDA). The original Purple Cap COMIRNATY®, the product that was the proximate cause of and provided the sole legal basis for the mandate, apparently was never produced and the FDA withdrew its marketing authorization on the same day it was approved. *See supra* ¶¶ 145-145. The Armed Services implemented a mandate for a product that literally did not and does not exist. The first so-called doses of Grey Cap COMIRNATY® were not even manufactured until at the earliest

January 2022, long after all applicable vaccination deadlines had passed and after Omicron rendered the product obsolete, and were not acquired until June 2022.

176. Fifth, when the Military Mandates were promulgated, there was no scientific evidence, or any clinical trial data, that the mRNA Products could prevent transmission of COVID-19. The manufacturers did not provide it, and the FDA apparently did not require it. *See supra* ¶¶ 103-104. Accordingly, there was never any basis for Military Defendants to conclude that mRNA Products could stop the spread of COVID-19 or "protect the Force", ECF 1-3, DOD Mandate, at 1, the central justification for the Military Mandates and the arbitrary, discriminatory, and punitive treatment of unvaccinated service members.

177. Fifth, both the Manufacturer Defendants (*e.g.,* Pfizer in January 2022) and the expert public health agencies, the CDC and HHS in August 2022, have expressly concluded that the mandated monovalent mRNA Products are obsolete and not effective for preventing infection by or transmission of the Omicron variant. Moreover, the sole customer and payor for the Mandated mRNA Products expressly adopted a policy that it would no longer purchase or provide reimbursement for these products, which Pfizer has not produced since February 2022 and Moderna has not since April 2022. *See supra* Section VI.B. It is therefore necessarily arbitrary and capricious to continue to mandate products that are no longer produced or purchased due to their obsolescence and known ineffectiveness.

178. Seventh, several U.S. district courts have enjoined the Military Mandates, including three that have issued class-wide injunctions for three of the Armed Services Defendants (Air Force, Marine Corps and Navy) for systemic violations of service members' religious liberties. *See supra* note 31. These opinions confirm that Defendants did not consider any alternative to 100% vaccinations. The RFRA cases provide further support for Plaintiffs' claims the DOD Mandate has been implemented by imposing arbitrary sanctions, contrary to CDC recommendations and lacking in scientific support. *See, e.g.*, *CFMO*, 2022 WL 3643512, at *16 (Defendants statistics do not support the mandate and denial of exemptions because they fail "to disaggregate by age, by medical characteristics (for example, BMI, diabetes, high blood pressure, etc.), by assignment and the like," consist of "mostly historical data from the 2020 and 2021 pre-Omicron, pre-vaccine phase of the pandemic," and fail "to address the present state of 'the force'").

179. Defendants' illegal and systematic denials of religious accommodations after the imposition of the mandate are thus entirely consistent with their irrational refusal to consider any alternatives prior to the imposition of the mandate. DOD, "provide[d] little or no explanation for the [its] choices," "omit[ted] explanation for rejecting alternatives," and did "not address alternative (or supplementary) requirements." *Health Freedom Def. Fund v. Biden*, --- F.Supp.3d ---, 2022 WL 1134138, at *18-19 (M.D. Fla. Apr. 18, 2022). While the DOD "did

not need to explore every alternative," it "must consider and explain its rejection of reasonably obvious or significant and viable alternatives." *Id.* at 19 (citations and quotations omitted).

180. As a result of Defendants' unlawful actions, Plaintiffs will be required either to take an unlicensed, obsolete and ineffective product—pursuant to an unlawful order that is itself based on unlawful FDA actions—or else face the serious disciplinary consequences outlined above that will result in the loss of their livelihoods, careers, and retirement benefits.

SECOND CAUSE OF ACTION
MANDATE OF UNLICENSED, MISBRANDED OR EXPIRED PRODUCTS
5 U.S.C. § 706(2)(A) & 5 U.S.C. § 706(2)(C); DODI 6205.02

181. Plaintiffs reallege the facts in Section I (¶¶ 45-75), Section III (¶¶ 87-96), Section V.A (¶¶ 114-119), Section VI (¶¶ 129-163) as if fully set forth in this Count.

182. In June 2022, Military Defendants obtained and mandated that all unvaccinated service members, including Plaintiffs, take the FW Lots they claim are "Comirnaty-labeled, BLA-approved" products. ECF 124-2, Rans Decl., ¶ 4. In September or October, 2022, Military Defendants acquired the G Lots, bivalent Pfizer/BioNTech products, that they also characterize as "Comirnaty-labeled, BLA-approved" products. *Id.*

183. Military Defendants' mandate of these products is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), for all of the reasons set forth in the First Cause of Action. *See supra* ¶¶ 171-179.

184. Military Defendants' mandate of these products is also arbitrary and capricious because it ignores the scientific and clinical evidence that has become available between the issuance of the DOD Mandate and the more recent generally applicable directives to take the FW Lots and the G Lots, The current scientific consensus—by academics, manufacturers, and expert public health agencies—is that the that the Mandated mRNA Products, COMIRNATY® and SPIKEVAX®, are obsolete, ineffective, and cannot prevent infection by or transmission of the Omicron and subsequent variants. The Military Defendants appear to be the sole dissenters and the only organizations that continue to mandate these products (even though neither the DOD nor U.S. Government will no longer purchase these products).

185. In addition, Military Defendants' mandate of the FW Lots and G Lots is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), and "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

186. First, the FW Lots are not licensed products because the Kalamazoo Facility where they were manufactured was not an FDA-approved manufacturing facility for Grey Cap COMIRNATY® on the date when these lots were manufactured, the dates they were released into interstate commerce, or when they were delivered to the DOD. *See supra* ¶¶ 150-156. Consequently, they are necessarily misbranded if they are labeled as FDA-licensed COMIRNATY®. Such misbranded products not only may not be mandated to service member; they may not be sold or administered to anyone. Doing so violates the PHSA express, mandatory labeling requirements, *see* 42 U.S.C. § 262(a); the FDCA's misbranding provisions that make these actions criminal offenses, *see* 21 U.S.C. §§ 352 & 379r; and numerous FDA regulations, *see, e.g.,* 21 C.F.R. § 201.1 - 201.328 (for drugs), and 21 C.F.R. §610.60 - 610.68 (for biologics). *See generally supra* ¶¶ 114-117.

187. Second, the FW Lots all expired no later than October 31, 2022, *i.e.*, the date stated on the FDA-approved product label and package inserts. *See supra* ¶¶ 157-159.

188. Third, most if not all the FW Lots expired earlier than that date stated on the product label. The FDA mandated storage requirements require that, once refrigerated, the expiration date is the earlier of the date stated on the product label or ten weeks. Accordingly, all lots that were shipped refrigerated (*i.e.*, rather than at deep freeze temperatures) from Fort Detrick to the various military facilities around

the United States—which includes all the lots listed in the Rans Declaration—expired after 10 weeks (*i.e.*, August 2022). Defendants have provided no evidence that any FW Lots were continuously stored in deep freeze conditions *See supra* ¶¶ 161-163.

189. Fourth, the G Lots are Bivalent mRNA Products, as confirmed by CDC official records and the NDC numbers assigned to these lots. *See supra* ¶¶ 147-149 & Ex. 13, Kupper Decl., ¶¶ 4-5 & Ex. A. Accordingly, the G Lots are necessarily unlicensed EUA products for which there was no supporting human clinical trial data whatsoever demonstrating safety and efficacy when they were approved on August 31, 2022, just days after the applications were submitted. Labeling the bivalent EUA product as FDA-licensed "Comirnaty" is practically a *per se* violation of the PHSA's express, mandatory labeling requirements, *see* 42 U.S.C. § 262(a); the FDCA's misbranding provisions that make these actions criminal offenses, *see* 21 U.S.C. §§ 352 & 379r; and numerous FDA regulations, *see, e.g.,* 21 C.F.R. § 201.1 - 201.328 (for drugs), and 21 C.F.R. §610.60 - 610.68 (for biologics).

190. As a result of Defendants' violations of numerous federal laws and regulations, Plaintiffs will be required either to take an unlicensed, misbranded, expired, and/or adulterated product, or else face the serious disciplinary consequences outlined above that will result in the loss of their livelihoods, careers, and retirement benefits.

THIRD CAUSE OF ACTION
MILITARY MANDATES AND INTERCHANGEABILITY DIRECTIVES
5 U.S.C. § 706(2)(C); 10 U.S.C. § 1107a; DODI 6200.02

191. Plaintiffs reallege the facts in Section I (¶¶ 45-75), Section II (¶¶ 76-86), Section III (¶¶ 87-96), Section V.A (¶¶ 114-119), Section VI.E-VI.G (¶¶147-163) as if fully set forth in this Count.

192. The Military Mandates and Interchangeability Directives are *ultra vires* actions "in excess of statutory jurisdiction [and] authority," 5 U.S.C. § 706(2)(C), insofar as Military Defendants have from the outset mandated unlicensed EUA products. While Congress and the President have delegated the Secretary of Defense broad authority, they have expressly withheld in 10 U.S.C. § 1107a the authority to mandate an EUA vaccine without Presidential waiver, which Secretary Austin has neither received nor requested.

193. The DOD and the Armed Services are departments and agencies of the United States Government. As such, they are agencies created by statute, and "it is axiomatic that an administrative agency's power to promulgate legislative regulations," like the DOD Mandate, "is limited to the authority delegated by Congress." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208, 109 S. Ct. 468 (1988); *see also La. Pub. Serv. Comm'n v. FERC*, 476 U.S. 355, 375, 106 S. Ct. 1890, 90 L.Ed.2d 369 (1986) ("an agency literally has no power to act, ..., unless and until Congress confers power on it.").

194. While the DOD Mandate itself states that only FDA-licensed vaccines may be mandated, *see* ECF1-3, SECDEF Memo, at 1, the DOD Interchangeability Directives—Ex. 3, September 14, 2021 Pfizer/BioNTech Interchangeability Directive and Ex. 4, May 3, 2022 Moderna Interchangeability Directive—direct each Armed Service to mandate EUA products "as if" they were FDA-licensed products. The Armed Services Mandates also "authorize the forced administration of EUA vaccines," ECF 126, November 8 Order, at 17, "as if" they were the FDA-licensed product. ECF 1-7, Air Force Mandate, §§ 3.1.1 & 5.3.2.1; *see also* Navy AR, DON AR 27, BUMED 6300, at 1. *See generally supra* ¶¶ 55-61.

195. It is undisputed that the EUA and the licensed product are "legally distinct". The EUA mRNA Products are subject to the laws governing EUA products, including 10 U.S.C. § 1107a, the right to informed consent, mandatory statutory labeling requirements for unlicensed products, and numerous federal and state laws that prohibit misbranding and unfair and deceptive trade practices such as misrepresenting an unlicensed product as one licensed by the FDA.

196. The licensed products, COMIRNATY® and SPIKEVAX®, are subject to the laws governing FDA-licensed products, including entirely distinct mandatory (*i.e.*, non-waivable) statutory requirements for FDA licensure and distinct statutory regimes governing labeling, misbranding, marketing, and patient disclosures. *See generally supra* Section II ("Federal Regulatory Regime for Licensing and

Emergency Use Authorization of Drugs and Biologics") & Section V ("Federal and State Regulation of Labeling, Misbranding and Unfair and Deceptive Trade Practices").

197. These two regulatory and labeling regimes are mutually exclusive and prohibit an unlicensed, EUA-labeled product from being an FDA-licensed product. An FDA-licensed biologic product must be labeled as such for the approved indications. *See* 42 U.S.C. § 262(a). The FDCA, PHSA, and FDA regulations all address the requirements stated on the product "package", "container" or "label" of the licensed product. In particular, the PHSA directs that "each package" of the licensed product must state the "proper name" of the licensed product "contained in the package" and the "license number of the manufacturer." 42 U.S.C. § 262(a)(1)(B)(i)-(ii). *See also* 21 U.S.C. § 352 (misbranding requirements defined in terms of contents of "label" or "package"); 21 C.F.R. Pt. 610, Subpt. G ("Labeling Standards"). In the extensive briefing presented in this proceeding, Defendants have cited no statute or any other legal authority that would allow a footnote in an FDA letter that merely grants emergency use authorization—and that is not part of the product labeling—to override these mandatory statutory labeling requirements, much less granting that authority to the DOD or Armed Services to override mandatory statutory FDA labeling requirements in memoranda or orders.

198. It is further undisputed that Defendants are in fact "mandating vaccines from EUA-labeled vials," *Doe #1-#14 v. Austin*, 2021 WL 5816632, at *5 (N.D. Fla. Nov. 12, 2021), as this Court found in its November 12, 2021 Order. Military Defendants could not have implemented the mandates without using EUA products because Military Defendants did not possess any FDA-licensed products.

199. This was not because there was "not sufficient approved vaccine available" for the entire U.S. adult population, or even service members. ECF 1-6, Aug. 23, 2021 Pfizer/BioNTech EUA Reissuance, at 5 n.9. It was because there was no FDA-approved product at all.

200. The original FDA-licensed Purple Cap COMIRNATY®, which provided the legal basis for the DOD Mandate apparently was never manufactured and the FDA withdrew its marketing authorization on the same day that it was approved. *See supra* ¶¶ 145-146. The Military Defendants have further acknowledged that they did not have any FDA-licensed product, which they refer to as "Comirnaty-labeled", until at the earliest June 2022, and even these products are unlicensed, misbranded, expired and/or adulterated. *See supra* ¶¶ 143-163.

201. Military Defendants' administrative records filings, statements in oral arguments, and confirm that they have violated 10 U.S.C. § 1107a by mandating EUA products and treating all EUA products as legally interchangeable with the FDA-licensed product.

202. In the Military Administrative Records, all references to interchangeability in the record indicate that all unlicensed EUA-labeled COVID-19 products are interchangeable with the FDA-licensed product. *See* ECF 79, Apr. 22, 2022 PL Supp. Brief, at 2 & ECF 79-1 (table listing all occurrences of "interchangeable" and "interchangeability"). In their response to Plaintiffs' supplemental brief on the administrative record, Defendants acknowledged that "Plaintiffs are correct that Defendants consider the Pfizer EUA and BLA labelled vaccines" [*i.e.,* "Comirnaty-labeled, BLA-approved" products] to be interchangeable." ECF 82, DF May 2, 2022 Supp. Br., at 3.

203. In the November 3, 2022 hearing before this Court, Defendants' counsel acknowledged that EUA product cannot lawfully be mandated, but insisted that "we're only mandating the fully approved" product. ECF 45, Nov. 3, 2021 Hearing Tr., 52:18-19. This could not have been the case because the FDA-licensed Purple Cap COMIRNATY® was not only not available, but did not exist because it was never made. *See supra* ¶ 145; *see also John DOE #1-#14 v. Austin* , 572 F.Supp.3d 1224, 1233 (N.D. Fla. 2021) ("Indeed, defense counsel could not even say whether vaccines labeled "Comirnaty" exist at all.").

204. In the August 29, 2022 hearing, Defendants' counsel acknowledged that they had mandated the Pfizer/BioNTech EUA product "even before the Comirnaty vaccine was available," ECF 115, Aug. 29, 2022 Hearing Tr., at 27:20-

21, and that "even the non-BLA compliant doses were interchangeable with Comirnaty." *Id.* at 31:11-12.

205. The DOD Interchangeability Directives and Military Mandates are also arbitrary and capricious because they constitute an unannounced and unexplained departure from a prior policy. The consistent policy of the Military Defendants since the enactment of the EUA statute and 10 U.S.C. § 1107a in 2004 through at least July 2021 (*i.e.*, the month before the DOD Mandate was issued) was that EUA products may not be mandated, a position that is reflected in currently effective DOD regulations, namely, DODI 6200.02.

206. The first vaccine that Defendant FDA ever granted EUA status to was the anthrax vaccine during the course of litigation over the DOD's anthrax vaccine mandate, where the Defendants DoD and FDA took the exact *opposite* legal position. The D.C. District Court preliminarily enjoined the anthrax mandate in 2003, *see Doe v. Rumsfeld*, 297 F. Supp. 2d 119 (D.D.C. 2003) ("*Rumsfeld I*"), and then granted summary judgment and a permanent injunction in 2004. *See Doe v. Rumsfeld*, 341 F.Supp.2d 1 (D.D.C. 2004) ("*Rumsfeld II*").

207. The FDA granted the EUA for the anthrax vaccine subject to several conditions:

> the AVIP will be revised to give personnel the option to refuse vaccination. Individuals who refuse anthrax vaccination will not be punished. Refusal may not be grounds for any disciplinary action under

> the Uniform Code of Military Justice. Refusal may not be grounds for any adverse personnel action. Nor would either military or civilian personnel be considered non-deployable or processed for separation based on refusal of anthrax vaccination. There may be no penalty or loss of entitlement for refusing anthrax vaccination.

70 Fed Reg. 5452, 5455 (Feb.2, 2005). Defendant DOD then filed an emergency motion to modify the permanent injunction to permit the anthrax vaccine program to proceed subject to these conditions, which was granted. *See Doe #1 v. Rumsfeld*, 2005 WL 774857 (D.D.C. 2005) ("*Rumsfeld III*").

208. This was the Military Defendants' consistent position through at least July 6, 2021, as set forth a July 6, 2021 memorandum from the Office Legal Counsel, ECF 33-4, the DOD interpreted the informed consent requirements in 10 U.S.C. § 1107a "to mean that DOD may not require service members to take an EUA [vaccine]" without first obtaining a Presidential Waiver under 10 U.S.C. § 1107a. *See* ECF 33-4, OLC Memo, at 16. Currently effective DOD regulations continue to provide a right of refusal for EUA products. *See* DOD Instruction 6200.02, § E3.4 (Feb. 27, 2008) (under the EUA statute, "potential recipients are provided an option to refuse administration," but "the President may . . . waive the option to refuse"). There has been no Presidential Waiver, yet the Defendants are mandating use of EUA vaccines.

209. "[A]gencies must typically provide a 'detailed explanation' for contradicting a prior policy;" they may not, as DOD has done here, "depart from a

prior policy *sub silentio*." *BST Holdings, LLC v. OSHA*, 17 F.4th 604, 614 (5th Cir. 2021) (*quoting FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515, 129 S. Ct. 1800, 173 L.Ed.2d 738 (2009)). The Military Defendants' "established practices" on informed consent are due greater deference than sudden, unexplained reversals because the long-standing and consistent refusal to exercise a claimed power (*i.e.*, to mandate an EUA product) is "significant in determining whether such a power was actually conferred." *W. Va. v. EPA*, 142 S. Ct. 2587, 2610 (2022) (citation and quotation marks omitted).

210. Military Defendants have previously asserted the affirmative defense that the DOD Mandate is limited to EUA-labeled, (but) "BLA-compliant" vaccines (*i.e.*, vaccines manufactured in accordance with the Comirnaty BLA). None of the Military Mandates, the DOD Interchangeability Directives, or the Military Administrative Records use the term "BLA-compliant," or suggest any such limitation. The publicly available documents refer only to "EUA" vaccines, without any limitation to "BLA-compliant" lots.

211. The purported limitation of the mandate to "BLA-compliant" lots was announced in the first instance by agency defense counsel in court filings and is entirely unsupported in the record. Courts may not accept "post hoc rationalization by counsel as prime authority for agency decision[s]." *Harrison v. Ocean Bank*, 2011 WL 2607086, at *4 (S.D. Fla. June 30, 2011). In any case, Military Defendants

appear to have abandoned this defense and confirmed that there is no legal significance to so-called "BLA-compliant" lots. *See, e.g.,* ECF 115, Aug. 29, 2022 Hearing Tr., at 31:11-12 (acknowledging that Military Defendants' policy was that "even the non-BLA compliant doses were interchangeable with Comirnaty").

212. Moreover, the Military Administrative Records submitted in the this proceeding confirm that: (1) all references to interchangeability in the record indicate that all unlicensed EUA-labeled COVID-19 vaccines (*i.e.*, without limitation to EUA-labeled, BLA-compliant lots) are deemed to be interchangeable with the licensed version; and (2) that there is no discussion of interchangeability with respect to "BLA-compliant" lots, nor is there any policy, directive, or guidance limiting the DoD Mandate to EUA-labeled, "BLA-compliant" lots. *See generally* ECF 79, Apr. 22, 2022 PL Supp. Br., at 1-3. In its November 3, 2021 Hearing "the DoD concede[d] that … its current [EUA-labeled] vials are not BLA-compliant, and that there is no policy to ensure that servicemembers get only BLA-compliant vaccines." *DOE #1-#14*, 572 F.Supp.3d at 1233. Accordingly, Defendants are barred by the "record rule" from asserting any defense for which there is no support in the record and that was asserted only by agency defense counsel.

213. As a result of Defendants' unlawful actions, Plaintiffs will be required either to take an unlicensed, obsolete, ineffective and/or misbranded product, or else face the serious disciplinary consequences outlined above that will result in the loss

of their livelihoods, careers, and retirement benefits.

FOURTH CAUSE OF ACTION
FDA UNLAWFUL APPROVALS OF COMIRNATY AND SPIKEVAX
5 U.S.C. §§ 706(2)(A) & (C); 42 U.S.C. § 262; 21 USC §§ 355(d)-(e)

214. Plaintiffs reallege the facts in Section II.A (¶¶ 76-78), Section IV (¶¶ 97-113), and Section VI.A-VI.B (¶¶ 129-142) as if fully set forth in this Count.

215. The FDA's initial and supplemental approvals of the Mandated mRNA Products, COMIRNATY® and SPIKEVAX®, must be set aside as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), and "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

216. First, the FDA approved COMIRNATY® and SPIKEVAX® without substantial evidence of safety and effectiveness and by failing to require adequate, "well controlled" trials expressly required by law. 21 U.S.C. §§ 355(d)-(E); 21 C.F.R. § 314.126. For both products, the manufacturers "unblinded" participants, which eliminated the control group required for a "well controlled" study.

217. The trials and studies also were not adequate. The FDA did not require completion of Phase III studies, required under its own regulations and the June 2020 Industry Guidance. Instead, the FDA approvals of COMIRNATY® and SPIKEVAX® relied on interim test results for only two months using the full study

sample, following roughly only half of participants for four months and less than a fourth for six months. *See supra* ¶¶ 105-107.

218. Second, the Mandated mRNA Products, Comirnaty and Spikevax, are not vaccines. It is undisputed that Pfizer and BioNTech did not submit evidence demonstrating that COMIRNATY® prevents transmission of COVID-19—the defining feature of a vaccine—and the FDA did not require them to do so. *See supra* ¶ 103.

219. Upon information and belief, the FDA approved the Moderna mRNA treatment without any clinical trial data or other evidence demonstrating that it prevented transmission of COVID-19.

220. Third, the FDA approved COMIRNATY® and SPIKEVAX® without any showing that they provide long-term immunity or durable protection against infection for the original COVID-19 variants. At the time of approval, the FDA explicitly acknowledged that the trials that "[i]nformation is not yet available about potential long-term health outcomes" for COMIRNATY® or SPIKEVAX®. FDA Comirnaty Press Release, *supra* note 9; FDA SPIKEVAX® Press Release, *supra* note 10 (same).

221. Fourth, the FDA granted SPIKEVAX®'s initial approval and granted the initial and supplemental approvals for Grey Cap COMIRNATY® after Omicron became prevalent and rendered these vaccines obsolete. On January 31, 2022, the

FDA approved the two-dose SPIKEVAX® regimen more than two months after it approved a third booster dose (implicitly acknowledging ineffectiveness of two-dose regimen) and two months before it authorized a fourth dose.

222. The FDA granted a non-public supplemental approval for Grey Cap COMIRNATY® on January 14, 2022, just days after Pfizer's CEO publicly admitted that the licensed product provided little, if any, protection against Omicron. The FDA continued to grant supplement approvals as late as August 25, 2022, several months after Pfizer/BioNTech produced the last lot in February 2022 and after the sole customer and payor, the U.S. government, decided that it would no longer purchase or provide any reimbursement for the obsolete, FDA-licensed products. *See supra* ¶¶ 108-109.

223. Fifth, the FDA approvals contradicted its own policies and guidance, in particular the June 2020 Industry Guidance, and therefore constitutes an unexplained and unannounced departure from previous policy that must be reversed. *See, e.g., Manin v. National Transp. Safety Bd.*, 627 F.3d 1239, 1243 (D.C. Cir. 2011). The FDA skipped altogether key procedural protections such as standard Advisory Committee review process, which entails public notice and comment procedures for controversial issues. Moreover, as the FDA itself acknowledges, its approval timeline was "unprecedented," because it skipped or waived important procedural requirements, in particular, the completion of well controlled clinical trials covering

the "special populations" required in the June 2020 Industry Guidance.

224. As in *Rumsfeld II* regarding mandatory anthrax vaccinations, "[t]his Court has an obligation to ensure that FDA follow the law in order to carry out its vital role in protecting the public's health and safety." *Rumsfeld II*, 341 F.Supp.2d at 19. Unfortunately, the FDA's review and approval fell woefully short of the substantive and procedural requirement set forth in the FDCA, the PHSA, the FDA's own rules, regulations and policies, and the Administrative Procedures Act.

225. As a result of Defendant FDA's unlawful approvals of COMIRNATY® and SPIKEVAX®, and its supplemental approval of COMIRNATY®, Plaintiff service members will be forced to take what amounts to an experimental vaccine, or else face the serious disciplinary consequences outlined above that will result in the loss of their livelihoods, careers, benefits, and fundamental rights.

FIFTH CAUSE OF ACTION
FDA LABELING AND MISBRANDING VIOLATIONS
5 U.S.C. §§ 706(2)(A) & (C); 21 U.S.C. §§ 352 & 379r; 42 U.S.C. § 262; 21 U.S.C. § 360bbb-3; FDA Labeling Regulations

226. Plaintiffs reallege the facts in Section II (¶¶ 76-86), Section III (¶¶ 87-96), Section V.A (¶¶ 114-119), and Section VI.A-VI.C (¶¶ 129-144) as if fully set forth in this Count.

227. The FDA's Interchangeability Determinations, its purported waiver of non-waivable mandatory statutory labeling and informed consent requirements

("FDA Waiver"), and its approval of false, misleading and deceptive product labeling must be set aside as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), and "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

228. The FDA: (1) violated the substantive terms of the FDCA and PHSA governing EUA vaccines and licensed vaccines; (2) unlawfully treated two "legally distinct" products, subject to distinct, and mutually exclusive approval/authorization requirements and labeling requirements as "interchangeable"; (3) waived mandatory, non-waivable statutory requirements and prohibitions, that deprived service members like Plaintiffs of their statutory rights to informed consent and product labeling detailing the risks of these products; and (4) caused these products to be misbranded.

229. First, the FDA erred, and acted contrary to law and the FDA's own rules and policies, where it found that the EUA and FDA-licensed mRNA Products Comirnaty Vaccine "can be used interchangeably." ECF 1-6, Aug. 23, 2021 Pfizer/BioNTech EUA Reissuance; Ex. 11, Jan. 31, 2022 Moderna EUA Reissuance, at 3 & n.9.

230. "Interchangeable" and "interchangeability" are specifically defined terms in Section 351 of the PHS Act, 42 U.S.C. § 262, in relation to a "reference

product," which is a biological product licensed under Section 351(a) of the PHS Act, 42 U.S.C. § 262(a). For the purposes of determining "interchangeability," the "reference product" must be an FDA-licensed product; in this case, the FDA-licensed Comirnaty Vaccine. But the "interchangeable" product, the EUA BioNTech Vaccine, must be the subject of a later filed "abbreviated" application under 42 U.S.C. § 262(k), and there is no indication that any such application was ever filed by Pfizer/BioNTech or Moderna, much less reviewed or approved by the FDA.

231. The FDA's interchangeability determination is illegal, or else it is of no legal consequence. The FDA acknowledges that it has never made a "statutory interchangeability determination" because the PHSA's requirements have not been satisfied, and instead describes its actions as finding that the two are "medically interchangeable", ECF 65-14, Marks Decl., ¶ 11, an invented term that either has no legal significance, or if it does, explicitly contradicts the requirements of the PHSA.

232. The PHSA grants the FDA the authority only to make "statutory" interchangeability determinations, which is governed by an "intricate process," *Texas v. U.S.*, 809 F.3d 134, 179 (5th Cir. 2015) ("*Texas*"), *aff'd* 136 S.Ct. 2271 (2016), set forth by Congress in the PHSA. The PHSA does not authorize the FDA to create new, alternative categories or criteria for "interchangeable" products. As such, the FDA's action must be held unlawful and *ultra vires.* Because the FDA has not made a "statutory" determination, then the two products are not legally

interchangeable and the FDA's footnote cannot be the basis for the Military Defendants' position that the EUA and licensed products are legally interchangeable.

233. The FDA simply has not explained what "interchangeable" means in this context, nor could it because its use of these terms is incompatible with the PHSA's statutory framework and the publicly available record. Accordingly, this Court must remand the matter to the FDA to explain its decisions. *See, e.g., A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1492 (D.C. Cir. 1995) (remanding to the FDA to explain what "bioequivalency" means in the animal drug context and how the evidence relied on by the FDA satisfied the standard).

234. Second, the FDA unlawfully treated as equivalent, or "interchangeable", "legally distinct" products subject to distinct and mutually exclusive regulatory regimes.

235. The EUA mRNA Products are subject to the laws governing EUA products, including the right to informed consent in 21 U.S.C. §§ 360bbb-3, mandatory statutory labeling requirements for unlicensed products, and numerous federal and state laws that prohibit misbranding and unfair and deceptive trade practices, in particular, misrepresenting an unlicensed product as one licensed by the FDA. These requirements include the mandatory, non-waivable directive that the FDA "shall … ensure that the individuals to whom the product is administered are

informed … of the option to accept or refuse administration of the product …" 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III). The statutory directive does not provide for any exceptions, nor does it make any distinctions based on the prescription or non-prescription status of the drug.

236. The licensed products, COMIRNATY® and SPIKEVAX®, are subject to the laws governing FDA-licensed products, including entirely distinct mandatory (*i.e.*, non-waivable) statutory requirements for FDA licensure and distinct statutory regimes governing labeling, misbranding, marketing, and patient disclosures. *See generally supra* Section II ("Federal Regulatory Regime for Licensing and Emergency Use Authorization of Drugs and Biologics") & Section V ("Federal and State Regulation of Labeling, Misbranding and Unfair and Deceptive Trade Practices").

237. These two regulatory and labeling regimes are mutually exclusive and prohibit an unlicensed, EUA-labeled product from being an FDA-licensed product. An FDA-licensed biologic product must be labeled as such for the approved indications. *See* 42 U.S.C. § 262(a). The FDCA, PHSA, and FDA regulations all address the requirements stated on the product "package", "container" or "label" of the licensed product. In particular, the PHSA directs that "each package" of the licensed product must state the "proper name" of the licensed product "contained in the package" and the "license number of the manufacturer." 42 U.S.C.

§ 262(a)(1)(B)(i)-(ii). *See also* 21 U.S.C. § 352 (misbranding requirements defined in terms of contents of "label" or "package"); 21 C.F.R. Pt. 610, Subpt. G ("Labeling Standards"). In the extensive briefing presented in this proceeding, Defendants have cited no statute or any other legal authority that would allow a footnote in an FDA letter that grants emergency use authorization—and that is not part of the product labeling—to override these mandatory statutory labeling requirements, much less granting that authority to the DOD or Armed Services to override mandatory statutory FDA labeling requirements in memoranda or orders.

238. The FDA exceeds its statutory authority, and abuses its discretion, when it applies two distinct regulatory regimes to the same product. *See, e.g., Genus Med. Techs. LLC v. FDA*, 994 F.3d 631 (D.C. Cir. 2020) (holding that the FDA's determination that it could choose to regulate a product as either a drug or a device, or both, as arbitrary and capricious and in excess of statutory authority). This Court must do the same here and remand this issue to the FDA for reconsideration with appropriate guidance.

239. Third, the FDA Waiver unlawfully waived nonwaivable mandatory statutory requirements and prohibitions. To justify the FDA Waiver, the FDA has stated that it has exercised its "enforcement discretion", ECF 65-14, Marks Decl., ¶ 13, not to enforce labeling requirements—or the requirement to provide the EUA factsheet that includes the "option to accept or refuse" the EUA vaccine—so that

unlicensed, EUA vaccines may be treated "as if" they were licensed vaccines and eliminating the statutory right to refuse the unwanted treatment.

240. In doing so, the FDA went far beyond permissible agency enforcement discretion, which pertains to enforcement priorities and agency inaction. Instead, the FDA's decision is an affirmative and unlawful agency action—granting a license to an unlicensed EUA product—that violates the express terms of the statute it enforces. *See, e.g., Texas*, 809 F.3d at 166-69 (5th Cir. 2015) (agency action was not immune from review as exercise of enforcement discretion where it adopted general policy conferring legal status and benefits); *see also id.* at 166-67 (agency action "need not directly confer … benefits" to be "more than nonenforcement"; instead "removing a categorical bar on receipt of [governmental] benefits and thereby making a class … newly eligible" for such benefits is sufficient).

241. It is not within the FDA's discretion to confer a legal benefit for a product (*i.e.*, licensure), or to exempt unlicensed products from labeling requirements applicable to them, when Congress has already established an "intricate process," *Texas*, 809 F.3d at 179, governing licensure and the benefits thereof in the PHSA.

242. The FDA's mix of actions and inactions are similar to the FDA "enforcement discretion" policy that the D.C. Circuit found to have violated mandatory provisions of the FDCA, as well as the APA. *See Beaty v. FDA,* 853

F.Supp.2d 30, 36 (D.D.C. 2012), *aff'd in part, vacated in part sub. nom. Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013). There, the court emphasized that the FDCA provision in question, like 42 U.S.C. § 262(a) here ("no person shall …"), used mandatory language "shall," which "generally indicates a command that admits of ***no*** discretion." *Beaty*, 853 F.Supp.2d at 37 (citation omitted). As with 42 U.S.C. § 262(a), the FDCA provision did not provide for exceptions or other language suggesting FDA enforcement discretion. The FDA's purported nonenforcement decision amounted to "affirmative acts of approval"—treating unlicensed, misbranded products as if they were licensed and labeled in accordance with FDA regulations—"rather than refusal to take enforcement action." *Cook*, 733 F.3d at 7.

243. The same conclusion applies to the FDA's waiver of the requirement to include the EUA Factsheet advising recipients of their right to refuse the EUA product. The requirement to provide the EUA Factsheet is mandatory: the FDA "shall … ensure that the individuals to whom the product is administered are informed … of the option to accept or refuse administration of the product …" 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III). The FDA cannot waive this requirement, nor may it authorize a third party—like the Military Defendants—to destroy, remove or refuse to provide to recipients the product labeling required by statute.

244. Fourth, the FDA's actions, including its approval of false, misleading and deceptive product labeling, caused these mRNA Products to be misbranded in

violation of 21 U.S.C. § 352 and applicable FDA labeling regulations. *See, e.g.,* 21 C.F.R. § 201.1 - 201.328 (for drugs), and 21 C.F.R. §610.60 - 610.68 (for biologics).

245. The FDA's unlawful approvals of COMIRNATY® and SPIKEVAX®, and its supplemental approvals of Grey Cap COMIRNATY® render the products misbranded, *i.e.*, the product labeling is "false or misleading," 21 U.S.C. § 352(a)(1), for largely the same reasons that the approvals themselves were unlawful. These products are not "vaccines" and the product labeling statements regarding safety and efficacy would mislead a reasonable consumer to believe that the products prevent transmission of and prevent infection by COVID-19, including the Omicron variant that has been the predominant variant since late 2021.

246. The FDA-approved product labeling required to be included with every package is misleading and deceptive insofar as it unlawfully asserts that the EUA and FDA-licensed products are equivalent in terms of both safety and efficacy. The EUA Factsheets for both products state that the products "can be used interchangeably … without presenting any safety or effectiveness concerns." ECF 1-14, Aug. 23, 2021 Pfizer/BioNTech EUA Factsheet, at 1 n.1; Ex. 19, Jan. 31, 2022 Moderna EUA Factsheet, at 1 n.1. This would lead the reasonable consumer to believe that the unlicensed product is equivalent to the licensed product, or that it is the licensed product, which is practically a *per se* violation of statutes and regulations prohibiting misbranding.

247. Moreover, the FDA knew that Military Defendants expressly relied on these false and misleading statements in the FDA-approved misbranding and deceptive product labeling to mislead service members regarding the legal status of the EUA products to deprive them of their statutory rights and to punish them for non-compliance with a facially unlawful mandate.

248. Even if the Military Defendants' position that the EUA-labeled products are in fact licensed products were correct, then these EUA-labeled products would still be misbranded for non-compliance with the PHSA and FDCA mandatory labeling requirements, in particular, the requirement that the product label include the proprietary name (*i.e.*, COMIRNATY® or SPIKEVAX®) and license number. *See* 42 U.S.C. § 262(a)(1)(B)(i)-(ii); 21 U.S.C. §§ 352(b), (e), (f); 21 C.F.R. §§ 610.61-610.62.

249. Plaintiffs are harmed by Defendants' unlawful actions which are an improper maneuver conducted to override federal statutory rights to informed medical consent, to coerce and deceive service members into believing that they can be forced to take an experimental vaccine that they have statutory right to refuse.

SIXTH CAUSE OF ACTION
MANUFACTURERS UNFAIR & DECEPTIVE TRADE PRACTICES
Fla. Stat. 501.201, *et seq.*; Fla. State. § 499.005 & 499.007; 21 U.S.C. §§ 352 & 379r; 42 U.S.C. § 262 & FDA Regulations; 15 U.S.C. §§ 41, *et seq*. & FTC Regulations

250. Plaintiffs reallege the facts in Sections I-VI (¶¶ 45-163) as if fully set

forth in this Count.

251. Manufacturer Defendants have engaged in unfair and deceptive trade practices in violation of FDUPTA.

252. "To plead a FDUTPA claim for injunctive relief, a party must allege 1.) a deceptive act or unfair practice; and 2.) that the party was aggrieved by the act practice." *CareerFairs.com v. United Business Media LLC*, 838 F.Supp.2d 1316, 1324 (S.D. Fla. 2011) (*citing Kelly v. Palmer, Reifler, & Assoc., P.A.,* 681 F.Supp.2d 1356, 1366 (S.D.Fla.2010)).

253. Each Florida Plaintiff is a "person" and "interested person or party" within the meaning of FDUPTA.

254. Each Manufacturing Defendant is a "person" within the meaning of FDUPTA.

255. Each Florida Plaintiff is a consumer, potential consumer, foreseeable user, and/or a member of the "consuming public" that FDUPTA seeks to protect. Fla. Stat. § 501.202(2).

256. Each Manufacturing Defendant is engaged in "trade or commerce" in the State of Florida, and the alleged FDUPTA violations were committed as part of their advertising, soliciting, providing, offering, or distributing for sale the mRNA Products in Florida. Fla. Stat. § 501.203(8).

257. Under FDUPTA a deceptive act or unfair practice may be found when

"there is a representation, omission, or practice that is likely to mislead the consumer acting reasonably in the circumstances, to the consumer's detriment." *Economakis v. Butler & Hosch, P.A.*, No. 2:13-CV-832-FTM-38DN, 2014 WL 820623, at *2 (M.D. Fla. Mar. 3, 2014). Unfair or deceptive trade practices also include *per se* violations of the FDCA, PHSA, FTCA and applicable FTC and FDA regulations thereunder prohibiting misbranding and unfair and deceptive trade practices, as well as violations of Florida's state misbranding statutes, Fla. Stat. §§ 499.005 & 499.007, which provide the standard for FDUPTA violations. *See* Fla. Stat. § 501.203(3)(a)-(c). Plaintiffs allege *per se* statutory violations.

258. Manufacturers' FDUPTA violations occurred in and had the required nexus to the State of Florida. The Manufacturer Defendants' misbranded mRNA products were advertised, solicited, marketed, sold, distributed in, shipped to, and stored in Florida. *See* ECF 124-1, Rans Decl. Ex. A (listing doses stored at Florida facilities, including the Jacksonville Naval Hospital in Jacksonville, Florida; the 6th Medical Group at MacDill Air Force Base, Tampa, Florida; and the 96th Medical Group at Eglin Air Force Base, Fort Walton, Florida).

259. **Unfair or Deceptive Trade Practices.** Each of Manufacturing Defendant is engaged in one or more of the following unfair or deceptive trade practices in violation of FDUPTA.

260. First, all of the Manufacturer Defendants falsely and deceptively

labeled, marketed and advertised non-vaccine mRNA Products as "vaccines". "Vaccines" have been understood for centuries by courts, regulators, the judiciary, and the general public—and were defined by the DOD and CDC at the time the DOD Mandate was issued—as biological products that provide immunity and thus long-term protection from infection and that prevent transmission of the underlying virus.

261. A Pfizer executive has admitted in sworn testimony that their clinical trials did not study whether the mRNA products prevent transmission. *See supra* ¶ 103. The FDA did not evaluate whether the mRNA products provided "long-term" protection from infection for the original variant. As early as January 10, 2022, Pfizer's CEO acknowledged that the mandated two-dose regimen "offer[s] very limited protection, if any" against Omicron infection. The last lot of Pfizer/BioNTech COMIRNATY® was manufactured in February 2022, and the last lot of Moderna SPIKEVAX® was manufactured in April 2022. The CDC finally acknowledged that the "monovalent" mRNA Products were obsolete in August 2022, and the U.S. Government stated that it would no longer purchase or provide reimbursement for the monovalent vaccines. *See supra* ¶¶ 129-142.

262. Yet the Manufacturer Defendants continued to label, market and advertise these products as "vaccines" and continue to do so through the present. Such a patently misleading statement would cause a reasonable consumer to believe that these non-vaccine products are vaccines that prevent infection and transmission

of COVID-19 Omicron variant, which has been predominant for the last year.

263. Second, all Manufacturer Defendants falsely and deceptively misrepresent their unlicensed EUA mRNA Products as being equivalent to FDA-licensed vaccines. For example, their EUA Factsheets state that the products "can be used interchangeably … without presenting any safety or effectiveness concerns." ECF 1-14, Aug. 23, 2021 Pfizer/BioNTech EUA Factsheet, at 1 n.1; Ex. 19, Jan. 31, 2022 Moderna EUA Factsheet, at 1 n.1. This would mislead a reasonable consumer to believe that the unlicensed product is equivalent to the licensed product; that the EUA product is in fact FDA-licensed; that the product had met the safety and efficacy (or "potency") requirements under the PHSA; and/or that it met the PHSA's "purity" and manufacturing requirements.

264. Third, all Manufacturer Defendants have failed to provide service member consumers or "foreseeable users" like the Florida Plaintiffs with product labeling including information on risks, benefits, and other required information by statute. Military Defendants appear to have adopted a generally applicable policy of removing, destroying or refusing to provide the statutorily required EUA Factsheet that must be given to all consumers or potential recipients. Manufacturer Defendants have either actively participated in these violations, *e.g.,* by removing the EUA Factsheet from product packaging prior to shipment to Military Defendants, or they knew or should have known that the Military Defendants were implementing this

policy. Either way, the Manufacturer Defendants are violating their duty under state and federal law not to engage in unfair or deceptive trade practices.

265. Fourth, official records and sworn testimony submitted by Military Defendants assert that Pfizer and BioNTech are unlawfully and deceptively labeling Pfizer/BioNTech Bivalent mRNA Products (the G Lots) as "Comirnaty-labeled, BLA-approved" vaccines. *See* ECF 124-1, Rans Decl., ¶ 4 & Ex. A. Mislabeling an unlicensed EUA product, which was authorized without any human clinical trials whatsoever, would mislead a reasonable consumer and cause them to believe that the product is in fact FDA-licensed and that the product had met the safety and efficacy requirements of the FDCA or the "safety," "purity," and "potency" requirements under the PHSA.

266. Fifth, Pfizer and BioNTech unlawfully and deceptively labeled the FW Lots as FDA-licensed COMIRNATY®, despite the fact that they were manufactured at facility that was not FDA-licensed at the time of manufacture, lot release or delivery to Military Defendants. Mislabeling an unlicensed EUA product would mislead a reasonable consumer and cause them to believe that the product is in fact FDA-licensed; that the product had met the safety and efficacy (or "potency") requirements under the PHSA; and/or that it met the PHSA's "purity" and manufacturing requirements.

267. Sixth, Pfizer and BioNTech knew or should have known that the

Military Defendants have sought to unlawfully mandate expired and/or adulterated products from the FW Lots. Pfizer and BioNTech requested authorization from the FDA to extend the expiration dates for Comirnaty-labeled vaccines, but Pfizer and BioNTech did not change or extend the expiration date stated on the product label and other labeling materials. They did not do so despite the fact that this authorization was granted on April 14, 2022, and they were in Pfizer's possession for between 1-2 months until they were delivered to Military Defendants in June 2022.

268. Under the PHSA and FDA regulations, "each package" or "container" of FDA-licensed product must include the "expiration date". *See, e.g.,* 42 U.S.C. § 262(a)(1)(B)(iii); 21 C.F.R. § 610.60(a)(4). Defendants have cited no authority for their contention that the expiration date on the label can be overridden by a previously non-public FDA letter. Further, Pfizer and BioNTech obtained FDA approval for multiple package inserts after that date, all of which state that: "Regardless of storage condition, the vaccine should not be used after the expiration date printed on the vial and cartons." *See supra* ¶ 162. This statement is consistent with the statute and contradicts Defendants' position.

269. Further, Pfizer and BioNTech knew or should have known that the Military Defendants were systematically violating the required storage conditions and that consequently these products expired before the date stated on the label and

well before the purportedly extended expiration date. Beginning in June 2022, when the Military Defendants received the FW Lots at Fort Detrick, they were shipped at refrigerated temperatures to U.S. facilities.

270. 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 refrigerated at "2 ºC to 8 ºC" at which point they have a "10-week refrigerated expiry date." ECF 120-5, May 19, 2022 Grey Cap COMIRNATY® 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. 13, Kupper Decl., ¶ 7 & Ex. B, Slide 18.

271. Under this generally applicable policy, all FW Lots would have been shipped from Fort Detrick to U.S. facilities at refrigerated temperatures and would have expired 10 weeks after the shipment date (*i.e.*, during August 2022). This applies to all of the doses stored at U.S. facilities listed in the Rans Declaration. *See* ECF 124-1, Rans Decl., Ex. A.

272. The misbranded mRNA Products then expired while in Florida in August 2022 due to Military Defendants' systematic violations of FDA storage

requirements. The Florida Plaintiffs were subject to the Military Mandate, Interchangeability Directives, and other challenged agency actions and the Military Defendants continued to enforce the DOD Mandate against Florida Plaintiffs by misrepresenting the misbranded and/or expired mRNA Products as FDA-licensed that Florida Plaintiffs were required to take. Defendants further repeatedly misrepresented the legal status of these misbranded and/or expired mRNA Products in filings with this Court, most recently in their October 18, 2022 Response. ECF 124.

273. Each of the foregoing deceptive and unfair trade practices is also a violation Florida state misbranding laws. Fla. Stat. §§ 499.005 & 499.007. First, labeling and advertising of a non-vaccine as a vaccine is false and misleading in violation of Fla. Stat. § 499.005(4) and § 499.007(1). Second, labeling and advertising the EUA mRNA Product as being as being equivalent to the FDA-licensed product, and advertising and labeling these products to mislead consumers that they are effective at preventing infection by or transmission of Omicron violates Fla. Stat. § 499.005(11) and § 499.007(1). Third, mislabeling the unlicensed FW Lots and G Lots as FDA-licensed COMIRNATY® violates Fla. Stat. § 499.005(1). Fourth, the removal or destruction of the FDA-approved product labeling, such as the EUA factsheet, violates Fla. Stat. § 499.005(9). Fifth, permitting these prescription only products to be dispensed without a prescription in mass

inoculations and "vaccine rodeos" violates Fla. Stat. § 499.007(13).

274. **Florida Plaintiffs Aggrieved by Unfair or Deceptive Practices.** FDUPTA permits "anyone aggrieved by a [FDUPTA] violation … [to] bring an action to obtain a declaratory judgment that an act or practice violates [FDUPTA] and to enjoin a person who has violated, is violating, or is otherwise likely to violate [FDUPTA]." Fla. Stat. § 501.211(1). Florida courts have recognized that the "aggrieved" standard is extraordinarily broad and does not require Plaintiffs to show actual, monetary damages, or to have even been harmed or suffered a loss of any kind, *see, e.g., Ahearn v. Mayo Clinic*, 180 So.3d 165, 171-72 (Fla. 1st DCA 2015) (defining "aggrieved" as any person "angry or sad on grounds of perceived unfair treatment") (*quoting Black's Law Dictionary* (10th ed. 2014)). *See also Davis v. Powertel, Inc.*, 776 So.2d 971, 975 (Fla. 1st DCA 2000) (claim by aggrieved person can seek injunctive or declaratory relief for "the protection of consumers who have not yet been harmed by the unlawful trade practice"). The only limitation is that the injury claimed cannot be merely speculative. *Ahearn*, 180 So.3d at 173.

275. Florida Plaintiffs easily satisfy the exceedingly low bar to be "aggrieved" by Manufacturer Defendants' FDUPTA violations for purposes of standing. Manufacturer Defendants' unfair and deceptive practices are the proximate cause and but for cause of all or nearly all of Plaintiffs' injuries. *See supra* ¶¶ 164-166 & Ex. 1, November 2022 Plaintiffs Status Chart. In the absence of the unfair

and deceptive labeling, marketing, and advertising of the mRNA Products—and the fact that they knew or should have known of Military Defendants unfair and deceptive practices to coerce and deceive service members—Florida Plaintiffs would have not suffered the injuries to their careers and face discharge and separation for their refusal to take unlicensed, obsolete, and ineffective products.

276. Florida Plaintiffs "need not show actual reliance on the representations or omissions at issue." *Costa v. Kerzner Int'l Resorts, Inc.,* No. 11–60663–Civ, 2011 WL 2519244, at *2 (S.D.Fla. June 23, 2011).

277. **mRNA Products Dispensed as Non-Prescription Drugs.** While the mRNA Products are labeled and classified as prescription drugs, Manufacturers knew or should have known that these products were not being dispensed as prescription drugs and were instead being administered through mass inoculations and "vaccine rodeos" by Military Defendants. *See supra* ¶ 68. Where manufacturers know or should have known that their prescription drugs are being dispensed without a prescription as non-prescription OTC drugs they have a duty to warn consumers of the risks, among other things, by providing the FDA-approved labeling and package inserts. Florida Plaintiffs' claims are not merely speculative, and they identify specific past and ongoing violations by Manufacturing Defendants that are the proximate and but for cause of their injuries.

278. Both the EUA and FDA-licensed version of the mRNA Products were

authorized/approved and labeled as prescription drugs and all product labeling stated "Rx only". Despite the prescription-only requirement, Military Defendants administered these products in "'assembly line' fashion" mass immunizations and "vaccine rodeos", *see supra* ¶ 68, without prescriptions and without any "individualized balancing of risks to the vaccine that is contemplated by the prescription drug exception" to manufacturers duty to warn and provide required product labeling to consumers, potential recipients, and "foreseeable users". *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1277 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096 (1974). Military Defendants eliminated any possibility for treating physicians or base medical personnel to provide any individualized balancing or risks regarding COVID-19 treatments or medical exemptions by elevating such decisions to the Service Surgeon General or medical flag officers who did not evaluate or see individual service members. *See, e.g.,* ECF 31-6, U.S. Army FRAGO 5 (Army Mandate), ¶ 3.D.8.B.6.A.1 (approval authority for medical exemption is the Army Surgeon General); ECF 65-9, U.S. Navy ALNAV 190/21, ¶ 3.d (medical exemptions require approval by medical Flag Officer).

279. Manufacturers are presumed to know or have expertise in how their drugs are distributed and administered, *id.*, a presumption that should be conclusive where Pfizer and Moderna are both among the top 10 defense contractors in 2021, each with sales in the billions. Manufacturer Defendants knew, or should have

known, that Military Defendants were systematically refusing to provide the required warnings and the FDA-approved product labeling information. Manufacturers therefore violated their duties to inform Florida consumers, like Florida Plaintiffs, and the failure to provide required product labeling information rendered their marketing of mRNA Products a deceptive and unfair trade practice.

280. Because the mRNA Products were marketed and administered through "vaccine rodeos" and without regard to the prescription requirement, these practices are subject to regulation as non-prescription drugs subject to the FDA non-prescription labeling requirements and the FTCA and FTC regulations governing non-prescription OTC drugs. The unfair and deceptive practices violated the FTCA and FTC requirements, which establish the standard for FDUPTA violations. *See* Fla. Stat. 501.203(3).

281. Florida state misbranding law expressly prohibits the prescription drugs to be dispensed without a prescription. *See* Fla. Stat. § 499.007(13). In fact, prescription drugs "not properly 'dispensed' are, per se, misbranded." *Rodriguez v. State*, 67 So.3d 326, 330 (Fla. 3rd DCA 2011).

282. **FTCA Violations as Predicate for FDUPTA Violations.** Manufacturer Defendants' unfair or deceptive trade practices violate the FTCA and FTC requirements, as set forth in the *Deceptive Practices Policy*, the *Pfizer* Test, and the *Substantiation Policy Statement*.

283. Manufacturer Defendants' advertising, including statements on their websites, is false and misleading and would mislead a reasonable consumer insofar as: (1) Manufacturers' non-vaccine mRNA Products were in fact vaccines; (2) Manufacturers' unlicensed products were in fact FDA-licensed; (3) misrepresenting the FDA-licensed mRNA products as "vaccines" that could prevent infection and/or transmission, long after Pfizer and the CDC had acknowledged that they provided little, if any, protection against Omicron and long after Manufacturer Defendants had ceased to produce the mandated mRNA Products; (4) that Manufacturers' mRNA products were prescription drugs, when the Manufacturers knew or should have known that these products were not being dispensed by Military Defendants as prescription drugs. Even if the wording of these advertisement were literally truthful, the advertisements making these claims, through representations or omissions, whether express or implied, would still violate the FTCA because "[t]he impression created by the advertising, not its literal truth or falsity, is the desideratum." *FTC v. Cyberspace.com LLC*, 453 F.3d 1196, 1200 (9th Cir. 2006) (citation omitted).

284. Manufacturer Defendants violate the core requirements of the FTC's policies and requirements, in particular, that any objective claim about a product carries with it an express or implied representation that the advertiser possesses a "reasonable basis" for the claim (*i.e.*, substantiation). For health-related claims, the FTC has defined "competent and reliable scientific evidence" to require "at least two

adequate and well-controlled double-blinded clinical studies that conform to acceptable designs and protocols and are conducted by different persons, independently of each other." *Novartis Corp. v. FTC*, 127 F.T.C. 580, 726 (1996), *aff'd*, 223 F.3d 783 (D.C. Cir. 2000). Neither COMIRNATY® nor SPIKEVAX® approvals were based on any adequate, well-controlled studies due to the unblinding that eliminated the control group, the short duration, and other procedural and substantive defects described above. *See supra* ¶¶ 97-113.

285. **Unfair and Deceptive Practices Not Permitted by Federal Law.** Plaintiffs' FDUPTA claims are not subject to the exception for actions required or permitted by federal law. Fla. Stat. § 501.212(6). This exception applies to actions required or permitted by federal law, not to actions that are expressly prohibited by federal law that the FDA unlawfully authorizes or permits. The Manufacturer Defendants' actions are expressly unfair and deceptive trade practices prohibited by federal law, namely, the FDCA, PHSA and FTCA, as set forth above. Further, Plaintiffs expressly challenge the lawfulness of the FDA actions purporting to authorize or permit these illegal actions in the Fourth and Fifth Causes of Action. *See supra* ¶¶ 214-249. The FDA cannot waive mandatory statutory requirements, nor cannot it permit or authorize actions by regulated entities that the statutes it administers expressly prohibit. *See, e.g., Cook; Beaty; Texas.*

286. **FDUPTA Claims Are Not Preempted by Federal Law.** Plaintiffs'

FDUPTA claims are not preempted by federal law because they are parallel traditional state tort actions that use violations of federal laws and regulations as the standard for the FDUPTA violations, Fla. Stat. 501.203(3)(a)-(c) (definition of "violations of this part"), but are not solely premised on violations of federal laws or duties to federal regulators. As such, they are within the "narrow gap" for state tort law claims "for conduct that violates a federal requirement (avoiding express preemption), but cannot sue only because the conduct violated that federal requirement (avoiding implied preemption)." *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017).

287. All of the Florida Plaintiffs' claims are "generally equivalent" to federal claims, *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296 (11th Cir. 2001), and allege the "breach of a well-recognized duty owed to her under state law" and that they were "harmed by a violation of applicable federal law." *Mink*, 860 F.3d at 1327 (citation and quotation marks omitted). All of the alleged violations of are violations of traditional state law duties of manufacturers not to engage in unfair or deceptive trade practices and similar state law claims for misbranding, false advertising, or failure to warn, that are not preempted. *See, e.g., In re Zantac (Ranitidine) Prod. Liability Litig.,* 2021 WL 4593961 (S.D. Fla. Oct. 6, 2021) (misbranding); *Godelia v. Doe 1*, 881 F.3d 1309 (11th Cir. 2018) (false advertising); *Wyeth v. Levine*, 129 S.Ct. 1187 (2009) (failure to warn).

288. Manufacturer Defendants are not immune from suit under FDUPTA, nor are Florida Plaintiffs' FDUPTA claims preempted by the Public Readiness and Emergency Preparedness Act ("PREP Act"). 42 U.S.C.A. §§ 247d-6d, 247-6e. The PREP Act provides immunity and preempts state laws "claims of loss connected to the *use* of covered countermeasures," *i.e.*, drug, biological product or device for treatment or prevention of COVID-19. *Sherod v. Comprehensive Healthcare Mgmt. Servs.*, 2020 WL 6140474, at *7 (W.D. Pa. Oct. 16, 2020). "The PREP Act is inapplicable" where, as here, Plaintiffs do not raise a claim that loss "was causally connected to the administration or use of any drug, biological product, or device." *Gunter v. CCRC OPCO-Freedom Square, LLC*, 2020 WL 8461513, at *4 (M.D. Fla. Oct. 29, 2020) (FDUPTA claim not preempted by PREP Act). Moreover, any products that are misbranded, expired or adulterated are not "covered countermeasures" within the meaning of the PREP Act.

289. Plaintiffs are harmed by Manufacturer Defendants' unlawful, unfair and deceptive trade practices that have been employed to enable the unlawful Military Mandates and to enable Military Defendants to circumvent Plaintiffs' rights to informed consent and to receive adequate warnings of product risks required by federal and Florida state law.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully ask this Court to:

(1) Declare unlawful, vacate and enjoin the Military Mandates because they are arbitrary, capricious, an abuse of discretion, otherwise contrary to law;

(2) Declare unlawful, vacate and enjoin the DOD Interchangeability Directives and Armed Services Mandates for violations of federal laws and regulations governing informed consent, drug labeling and misbranding;

(3) Declare unlawful and vacate the FDA approvals of COMIRNATY® and SPIKEVAX® and the supplemental approvals of COMIRNATY®;

(4) Declare unlawful, vacate and enjoin the FDA's Interchangeability Directives and its purported waiver of mandatory statutory requirements ("FDA Waiver") as arbitrary and capricious and for violations for federal statutes and regulations governing drug labeling and prohibiting misbranding and unfair and deceptive trade practices;

(5) Declare unlawful and enjoin the administration of any EUA-labeled or manufactured vaccine pursuant to the Armed Services Mandates or the DOD Interchangeability Directives;

(6) Declare unlawful and enjoin the Manufacturer Defendants in violation of Florida state law prohibiting misbranding and unfair and deceptive trade practices;

(7) Enjoin all Defendants from the marketing, sale, distribution, and administration of unlicensed, misbranded, expired and/or adulterated mRNA Product, in particular, the G Lots and FW Lots; and

(8) Direct the Manufacturing Defendants to recall and destroy all misbranded, expired, or adulterated mRNA Products.

Dated: November 29, 2022

Respectfully submitted,

/s/ Brandon Johnson

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CERTIFICATE OF SERVICE

This is to certify that I have on this day e-filed the foregoing Plaintiffs' Third Amended and Supplemental Complaint for Declaratory and Injunctive Relief using the CM/ECF system providing service to all counsel of record.

This 29th day of November, 2022.

Respectfully Submitted,

/s/ Brandon Johnson
Brandon Johnson