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,** **XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services,** **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,** **JANET WOODCOCK, in her official capacity as Acting 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,** **Defendants.**	**CIVIL ACTION NO. 3:21-cv-01211-AW-HTC** **SECOND AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

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

INTRODUCTORY STATEMENT

1. Plaintiffs are a group of service members on active-duty or reserves, including members from each branch of the armed services, who are being subjected to unlawful COVID-19 vaccine mandates under the threat of severe punishment, including dishonorable discharge, the loss of their constitutional rights, and potential imprisonment.[1] Plaintiffs bring this action to challenge the August 24, 2021 Department of Defense ("DOD") COVID-19 vaccine mandate[2] ("DOD Mandate"), and the August 23, 2021 Food and Drug Administration's ("FDA") August 23, 2021 approval of the Pfizer/BioNTech Comirnaty vaccine ("FDA Comirnaty Approval").[3]

---

[1] Plaintiffs include members of key "special populations" that were not studied in the Comirnaty clinical trials, including: (1) individuals with acquired (or "natural") immunity from COVID-19 due to documented prior infection ("Natural Immunity Plaintiffs"); (2) female service members who are pregnant, nursing or are attempting to become pregnant, which the FDA refers to as "Woman of Childbearing Potential" ("WOCBP Plaintiffs"); and (3) other medical conditions or medical history that may put them at additional risk of side effects or adverse reactions to vaccines. Certain Plaintiffs have requested religious exemptions, some of which have been denied or are still pending and are not addressed herein.

[2] *See* Ex. 2, Secretary of Defense Lloyd Austin, III, "Memorandum for Senior Pentagon Leadership, Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members" (Aug. 24, 2021) ("DOD Mandate").

[3] *See* Ex. 3, FDA, BL 125742/0, Comirnaty Vaccine BLA Approval (Aug. 23, 2021) ("Comirnaty Approval Letter"), available at: https://www.fda.gov/media/151710/download (last visited Oct. 4, 2021).

The FDA's approval was granted in record time for the improper purpose of enabling unconstitutional federal vaccine mandates, rather than on findings that the vaccine meets statutory requirements or that the vaccine has demonstrated long-term safety, efficacy, or public health benefits. Plaintiffs seek declaratory and permanent injunctive relief to enjoin implementation of the DOD Mandate and to stay and vacate the FDA Comirnaty Approval.

2. **FDA Vaccine Emergency Use Authorizations ("EUA").** On December 11, 2020, the Food and Drug Administration ("FDA") granted an EUA for the Pfizer-BioNTech COVID-19 vaccine (BNT16b2 or "BioNTech Vaccine"); followed by the December 18, 2020 EUA for the Moderna COVID-19 Vaccine ("Moderna Vaccine") and the February 27, 2021 EUA for the Johnson & Johnson COVID-19 Vaccine ("Janssen Vaccine," and together with the BioNTech Vaccine and the Moderna Vaccine, the "COVID-19 EUA Vaccines").

3. **FDA Comirnaty Approval and EUA Extension.** On August 23, 2021, Defendant FDA conditionally approved the Biologics License Application ("BLA") for the Pfizer/BioNTech Comirnaty Vaccine ("Comirnaty Vaccine") for individuals 16 years or older. *See* Ex. 3, Comirnaty Approval Letter.[4] On the same day, the FDA

[4] *See also* Ex. 4, FDA, *Summary Basis of Regulatory Action*, BLA 125742/0 at 27 (Aug. 23, 2021) ("FDA Comirnaty SBRA"); FDA, *FDA Approves First COVID-19 Vaccine*, (Aug. 23, 2021), *available at* https://www.fda.gov/news-events/press-

re-issued and expanded the EUA for the BioNTech Vaccine for "booster" shots to certain individuals ("BioNTech EUA Extension").[5] According to the FDA, while the BioNTech Vaccine and the Comirnaty Vaccines are "legally distinct," the two products can be used "interchangeably." *Id.* at 2 n.8. The FDA re-issued the EUA because the licensed Comirnaty Vaccine is "not … available" in sufficient quantities for distribution. *Id.* at 5 n.9.

4. **DOD Mandate.** On the very next day, August 24, 2021, Defendant Secretary of Defense Lloyd Austin, III mandated all service members must receive "full vaccination" using only vaccines with "full licensure" from the FDA "in accordance with FDA-approved labeling and guidance." Ex. 2, DOD Mandate at 1. Secretary Austin enacted this mandate despite minimal hospitalization and mortality rates for military members infected with COVID-19.[6] Service members with natural

---

announcements/fda-approves-first-covid-19-vaccine (last visited Oct. 4, 2021) ("FDA Comirnaty Press Release").

[5] *See* Ex. 5, FDA, Pfizer-BioNTech EUA Letter (Aug. 23, 2021) ("BioNTech EUA Expansion Letter"), available at: https://www.fda.gov/media/150386/download (last visited Oct. 4, 2021).

[6] As of September 15, 2021, there have been a total of 238,120 cases among military personnel since the beginning of the pandemic in January 2020 (*i.e.*, approximately 20 months). Of these, 2,175 (or less than one percent) were hospitalized, with a total of 46 deaths (*i.e.*, less than 0.02 percent or less than one per 5,000 cases). *See* U.S. Department of Defense, "Coronavirus: DOD Response," Table "DOD COVID-19 Cumulative Totals," available at: https://www.defense.gov/Explore/Spotlight/Coronavirus-DOD-Response/ (last visited September 19, 2021).

immunity "are not considered fully vaccinated" or exempted, *id.* at 1, nor is there any exemption for female service members who are pregnant, nursing, or wish to become pregnant.

5. **Armed Services Guidance.** Each of the Armed Services has issued implementation guidance. *See* Ex. 6-9 (collectively, "Armed Services Guidance") and Section III.C. The Armed Services Guidance requires that all uniformed service members be fully vaccinated within 90 to 120 days of the issuance of the DOD Mandate (*i.e.*, November 2, 2021, for the Air Force, November 28, 2021, for the Marine Corps and Navy, and December 15, 2021, for the Army).

6. **Consequences for Non-Compliance.** Service members who decline vaccination may face the full range of administrative and disciplinary sanctions under the Uniform Code of Military Justice ("UCMJ") including separation, dishonorable discharge, and imprisonment. If dishonorably discharged, Plaintiffs will also lose the retirement, veterans and other government benefits they have earned through long service to their country, as well as future employment opportunities, civilian civil rights and fundamental constitutional rights, in particular, the Second Amendment right to bear arms. *See infra* Section III.D.

7. **DOD Mandate & Armed Services Guidance Claims.** Contrary to DOD regulations,[7] the DOD Mandate and the Armed Services Guidance do not provide a medical exemption for service members like Plaintiffs who have natural immunity from a previous COVID-19 infection or for female service members who are pregnant, nursing, or who want to become pregnant. The DOD Mandate is not only arbitrary and capricious, and unsupported by substantial evidence, but it violates the Administrative Procedures Act because it modified or partially repealed AR 40-562 without following applicable rules and procedures. Further, the Armed Services Guidance violates the express terms of the DOD Mandate (which permits only licensed vaccines to be mandated) because it permits the EUA BioNTech Vaccine to be administered pursuant to the mandate "as if" it were the licensed Comirnaty Vaccine (which is currently unavailable),[8] as well as the statutes and federal regulations requiring informed consent for experimental treatments. *See* 10 U.S.C. § 1107a and 21 U.S.C. § 360bbb-3.

---

[7] *See* Army Regulation 40-562, "Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases" (7 Oct. 2013) ("AR 40-562"). AR 40-562 applies with equal force to the Active Army, the Army National Guard, the U.S. Army Reserves, as well as the "uniformed Departments of the Navy, Air Force, and Coast Guard (including the active and reserve components of each Service)," as well as selected DOD employees and contractors. *See* AR 40-562, ch. 3 (7 Oct. 2013).

[8] There are reports that there will not be enough doses until 2024. *See Not Enough Covid Vaccine For All Until 2024, Says Biggest Producer,* FINANCIAL TIMES (Sept. 14, 2021), available at: https://www.ft.com/content/a832d5d7-4a7f-42cc-850d-8757f19c3b6b (last visited Oct. 4, 2021).

8. **FDA Comirnaty Approval Claims.** The DOD Mandate relies on the FDA's rushed and fatally flawed Comirnaty approval that is riddled with substantive and procedural deficiencies. It typically takes 10 years or more from discovery of a vaccine to FDA approval,[9] yet the FDA approved Comirnaty in a matter of months on an "unprecedented timeline."[10] It could issue this "approval" only by ignoring or waiving substantive and procedural requirements including: (a) completion of the crucial Phase 3 clinical trial; (b) the use of "well controlled" clinical trials; (c) including in clinical trials "special populations" like those with natural immunity or pregnant or nursing women; (d) review by the Vaccine and Related Biologics Products ("VRBPAC" or "Advisory Committee"); (e) public notice and comment procedures; (f) procedural requirements in FDA regulations and industry guidance; and (g) or any process to ensure it engages in reasoned decision-making supported by substantial evidence and free from improper political interference. The FDA also ignored or dismissed studies demonstrating the superiority of natural immunity to vaccine-induced immunity and evidence of severe adverse reactions.

---

[9] *See, e.g.,* Gail A. Van Norman, MD, Drugs, Devices and the FDA: Part 1: An Overview of Approval Processes for Drugs, JACC: BASIC TO TRANSLATIONAL SCIENCE, Apr. 2016;1(3):170-79.

[10] Justine Coleman, *FDA Grants Full Approval to Pfizer's COVID-19 Vaccine*, The Hill (Aug. 23, 2021) (quoting Defendant FDA Commissioner Woodcock), available at: https://thehill.com/policy/healthcare/568980-fda-grants-full-approval-to-pfizers-covid-19-vaccine (last visited Sept. 22, 2021).

9. **FDA & DOD "Bait and Switch."** The FDA has violated the Food, Drug & Cosmetic Act ("FDCA"), the Public Health Service Act ("PHSA"), and service members' informed consent rights, insofar as it has determined that the Pfizer/BioNTech vaccine may be simultaneously subject to two mutually exclusive and distinct regulatory regimes (*i.e.*, both an EUA vaccine and a licensed vaccine for the same indication); that the EUA BioNTech and the licensed Comirnaty Vaccine can be used "interchangeably;" and that these products may be substituted for each other for the same indication. The Armed Services Guidance is similarly unlawful insofar as it directs providers to treat EUA-labeled or manufactured vaccines "as if" they were the licensed vaccine and to administer EUA products pursuant to the mandate. These intentional misrepresentations of the law by the FDA and the Armed Services are part of an effort to circumvent informed consent requirements, to enable mandates for unlicensed and dangerous products, and to deceive and coerce service members into taking an unlicensed and experimental vaccine that they have every right to refuse. "[T]he United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs." *Doe No. 1 v. Rumsfeld*, 297 F. Supp. 2d 119, 135 (D.D.C. 2003) ("*Rumsfeld I*").

10. **Relief Requested.** Plaintiffs file this action seeking a Temporary Restraining Order, a Permanent Injunction, Administrative Stay and Declaratory Relief requesting that this Court:

(1) Declare the DOD Mandate unlawful, unconstitutional, and in violation of AR 40-562 and federal laws and regulations governing informed consent;

(2) Enjoin any implementation of the DOD Mandate by the Defendant Armed Services or other DOD components, or stay the effective date for any implementation orders pending resolution by this Court;

(3) Declare unlawful and vacate and remand the FDA Comirnaty Approval to the FDA;

(4) Declare unlawful the FDA's orders permitting the BioNTech/Pfizer vaccine to be both an EUA and licensed product simultaneously for the same indication;

(5) Declare unlawful the FDA's findings that the licensed Comirnaty Vaccine and the EUA BioNTech Vaccine can be used "interchangeably" or that they may be "substituted" for each other; and

(6) Declare unlawful and enjoin the administration of any EUA-labeled or manufactured vaccine pursuant to the DOD Mandate.

11. Plaintiffs seek this relief pursuant to the Administrative Procedures Act, 5 U.S.C. §§ 702 and 705, the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 and § 2202, and the All Writs Act, 28 U.S.C. § 1651.

PARTIES

12. Plaintiffs are active-duty or reserve duty Service members who are subject to the DOD Mandate, as implemented through the Armed Services Guidance of the branch in which they serve. Plaintiffs' declarations provide additional information regarding their religious and medical exemption requests; the orders or

guidance that they have received, including orders or guidance that they must take receive EUA-labeled, "non-BLA-compliant"[11] vaccines to comply with the mandate due to unavailability of Comirnaty or BLA-compliant vaccines; threatened, pending or completed administrative and disciplinary actions or duty restrictions; and discriminatory treatment based on vaccination status, in particular, masking, testing requirements (utilizing unlicensed, EUA testing kits), or facilities access restrictions to which vaccinated service members are not subject.[12]

13. Plaintiff BENJAMIN COKER is a Chief in the Navy. He is domiciled and stationed in Washington, D.C. He has received two "Page 13" counseling letter in connection with his vaccination orders. His religious accommodation request has been denied, and his appeal is pending.

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

---

[11] Plaintiffs do not concede that EUA-labeled vaccines that have been designated as "BLA-compliant" by the manufacturer may be mandated, or are otherwise equivalent or interchangeable with Comirnaty for the purposes of the mandate. Certain Plaintiffs have confirmed that, BLA-compliant vaccines are unavailable to them.

[12] Plaintiffs have included, as Attachment 18, the original signed declarations from the John and Jane Doe Plaintiffs included in the October 6, 2021 complaint who have agreed to continue as publicly named plaintiffs. Plaintiffs will separately file supplemental declarations for the initial plaintiffs and new plaintiffs describing any changes in their circumstances since the filing of the complaint.

He has been denied promotion to E-8 for which he is eligible due to vaccination status.

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 requested a religious exemption but was told the command is only entertaining medical exemptions at this time. His command did allow him to submit a request for religious accommodation, which is still pending, but has told him that he will be separated from the Marine Corps as soon as it 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 a request for medical exemption based on a documented previous infection, which was denied. He was also informed that medical exemptions for prior infections are not being considered. He has inquired regarding the availability of Comirnaty or BLA-compliant lots, but he has not received an answer from his base's immunology department. Due to his unvaccinated status, he cannot travel for training or other official purposes and from permanent changes of station.

17. Plaintiff SAMUEL CRAYMER is a Staff Sergeant in the Air Force. He is domiciled and stationed at Eielson Air Force Base, Alaska. When he received his vaccination orders in September, he inquired regarding the availability of

Comirnaty, and was informed that it was unavailable and that he was required to take the EUA vaccine. 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. Upon refusal, he received an Article 15 for Failing to Follow a Lawful Order. The punishment was downgraded though still carried out via Letter of Reprimand to allow for a Religious Accommodation request. This request was submitted September 24, 2021, and is pending review.

18. Plaintiff KACY DIXON is a Major in the Air Force. She is domiciled and stationed in Virginia. 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. On November 24, 2021, she submitted a request for medical waiver from the COVID-19 vaccination order exemption under code MS for "lack of vaccine supply" due to a lack of licensed supply. Her request for medical waiver was denied, and she submitted an appeal on December 2, 2021, which was denied December 3, 2021.

She also submitted a medical exemption request because she is breastfeeding, which was denied.

19. Plaintiff JAMES FURMAN is a Commander in the Navy. He is domiciled and stationed in Arlington, Virginia. He was required to receive the vaccine by October 24, 2021, or else face administrative separation and other adverse employment and disciplinary actions. He submitted a religious accommodation request, which is still pending. Due to the low chances for success (e.g., the Navy has not granted any to date), 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. He faces adverse employment and disciplinary action for vaccine refusal, including removal from his current position, severe duty restrictions which prevent him from performing his role as executive officer, punitive adverse paperwork, withholding of his promotion to LtCol, and administrative separation via a Board of Inquiry. On December 7, 2021, his religious accommodation appeal was denied, and if he does not receive the first dose within the next 48 hours, he will receive a 6105 "negative counseling" statement document his "refusal of a lawful order," which will commence the process for administrative separation or dismissal from the Marine

Corps. MAJOR HARWOOD's unit has already administratively separated or dismissed 11 Marines (with a general discharge), and is in the process of separating an additional 11 Marines.

21. Plaintiff JORDAN KARR is a Captain in the Air Force. She is domiciled in and stationed at Hurlburt Field, Florida. She is a WOCBP and would likely be injured by, and is unwilling to take, the vaccine due to a medical disorder. CAPT KARR has specifically inquired regarding the availability of Comirnaty and BLA-compliant lots, and she has been informed that it is not available; accordingly, she would be required to take an EUA-labeled, non-BLA-compliant vaccine to comply with the mandate.

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 based on a documented previous infection, which was denied. As a result, he was withdrawn from an assignment for which he had trained, received orders, and been processed. While MAJOR KALTRIDER's appeal of the denial of his religious accommodation request is still pending, his Commanding Officer has directed him and all other unvaccinated Marines to commence the involuntary separation process, including completion of their final physical exam and transition readiness seminar classes, while denying these Marines in-person access to these classes.

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 applied for, and been granted, exemptions from other required vaccines. MSGT KUPPER has recovered from a previous COVID infection, and has requested a medical exemption and religious exemption, both of which are still pending. He has confirmed with his base immunologist that his base does not have Comirnaty or any BLA-compliant lots, and thus would be required to take an EUA-labeled, non-BLA-compliant vaccine to comply with the mandate. He also confirmed with a Pfizer representative that Comirnaty is unavailable, Pfizer does not know when Comirnaty would be available, and that any EUA-labeled vials are not fully FDA approved. 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 order to take an EUA vaccine violated 10 U.S.C. § 1107 and the DOD Mandate.

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 based on a document previous infection via a positive serology test, which was denied due to the SECDEF's determination that service members with natural immunity are not considered fully vaccinated. 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 Captain in the Air Force. He is domiciled and stationed in New Mexico. Captain 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. He also challenged the lawfulness of his vaccination order, by submitting a complaint under Article 138 of the UCMJ, because the Air Force proposed to use the EUA BioNTech Vaccine in lieu of the licensed Comirnaty vaccine. His Article 138 complaint was dismissed on November 19, 2021.

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. On September 13, 2021, the day before the issuance of the Army Guidance, *see infra* Section III.C.2, he was relieved and suspended from treating patients for 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. MAJOR SIGOLOFF has received a negative counseling statement, and he is the subject of a pending investigation under UCMJ Article 15-6 due to his refusal to identify recipients of medical exemptions that he granted, consistent with applicable legal and ethical requirements.

28. Plaintiff ANDREW SNOW is a Major in the Air Force Reserve. He is domiciled in and stationed in Delaware. He has requested a religious exemption, despite leadership and the base chaplain telling him that religious exemptions would likely not be granted except for those with previously issued exemptions. On November 16, 2021, his request was denied, and submitted an appeal which is still pending. He has confirmed that his base does not have Comirnaty. Due to his unvaccinated status, he faces severe duty and flight restrictions; currently in the appeals process and will be placed in "no point, no pay" status if his appeal is denied, and will then be dismissed for cause after two months.

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 been threatened with administrative action from non-promotional status to separation from the Army if he does not take the vaccine. His medical records indicate previous COVID-19

infection. He has submitted a complaint, under Article 138 of the UCMJ, challenging the lawfulness of several COVID-related restrictions and orders, including the lawfulness of his vaccination orders requiring him to take EUA products due to the unavailability of the licensed Comirnaty product.

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 inquired as to the availability of both Comirnaty and "BLA-compliant" lots at Marine Corps facilities in North Carolina, including Camp LeJeune and Cherry Point MCAS, and has been informed that neither Comirnaty nor any BLA-compliant lots of EUA vaccines were available (except for some doses from an expired BLA-compliant lot). 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. MSGT THOMPSON is non-deployable due to his vaccination status, and he has received a Page 11 counseling statement for being unvaccinated, which will form the basis for his administrative separation. He has direct knowledge that Marines at MCAS Cherry Point are being processed for involuntary administrative separation for refusal to take EUA vaccines.

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

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 HHS is a Department of the United States Government. It is led by Secretary Xavier Becerra.

36. Defendant FDA is an agency of the United States Government. It is led by Acting Commissioner Janet Woodcock. Defendant FDA issued the EUA for the EUA COVID Vaccines, the FDA Comirnaty Approval, and the BioNTech EUA Extension.

JURISDICTION AND VENUE

37. This case arises under federal law, namely, the FDCA, 21 U.S.C. § 301 et seq.; the PHSA, 42 U.S.C. § 262 et seq.; 10 U.S.C. § 1107a; the Administrative Procedures Act, 5 U.S.C. § 551, et. seq.; and AR 40-562.

38. The DOD Mandate, the FDA Comirnaty Approval, the BioNTech EUA Expansion, and the FDA Citizen Petition denial 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 with respect to the DOD's imposition of a vaccine mandate, and the FDA's approval of the Comirnaty Vaccine. Each has direct and appreciable legal and life-altering consequences for Plaintiffs and millions of other U.S. citizens.

39. Jurisdiction is proper in this Court under the Administrative Procedures Act, 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.

40. 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 at and/or domiciled in this district, and because a substantial part of the act or omissions giving rise to the claim, namely, the actual and imminent injury due to the unlawful and unconstitutional administration of an unwanted, unnecessary, dangerous, and unproven vaccine will occur in this district, unless this Court grants the relief requested herein.

STATEMENT OF FACTS

I. COVID-19 BACKGROUND

A. COVID-19 Discovery and Public Health Emergency

41. On January 29, 2020, the White House Coronavirus Task Force was established to oversee and coordinate the Trump Administration's response to COVID-19. On January 31, 2020, as a result of confirmed cases of COVID-19, HHS Secretary Azar determined that a public health emergency existed as of January 27, 2020, pursuant to §319 of the PHSA, 42 U.S.C. § 247d et seq.

B. COVID-19 Mortality Risks

42. The mortality risk for those infected with SARS-CoV-2 is not the same for all age groups. Older patients are at higher risk of death if infected, while younger and healthier patients face a vanishingly small risk. The CDC's best estimate of the infection fatality rate for people ages 18-49 years is under 0.06% (34,171 deaths out of 60,461,355 cases), meaning that young adults have a 99.94% survivability rate.[13]

C. COVID-19 Risks for DOD Military Personnel

43. As of September 15, 2021, there have been a total of 238,120 documented COVID-19 cases among military personnel since the beginning of the

[13] *See* CDC *Estimated COVID-19 Burden*, Table 1: Preliminary Estimated COVID-19 Cumulative Incidence, by Age Group – United States, February 2020-May 2021, available at: https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html (last visited Sept. 7, 2021). The CDC's best estimate of the infection fatality rate for people aged 50-64 years is under 0.6% (116,284 deaths our of 20,375,641 cases), meaning this age group have a 99.4% survivability rate.

pandemic in January 2020 (*i.e.*, approximately 20 months). Of these, 2,175 (or less than one percent) were hospitalized, with a total of 46 deaths (*i.e.*, less than 0.02 percent or less than one per 5,000 cases).[14] It is important to note that this low rate of hospitalizations and deaths were achieved with essentially no COVID-19 treatment of these service members, which could have dramatically reduced deaths.[15]

II. FEDERAL VACCINE MANDATES

44. On September 9, 2021, President Joseph R. Biden announced a series of measures to impose federal vaccine mandates on nearly the entire U.S. workforce, including executive orders requiring vaccination for all federal employees[16] and federal contractors.[17] He also announced the expansion of existing requirements to

[14] *See* U.S. Department of Defense, "Coronavirus: DOD Response," Table "DOD COVID-19 Cumulative Totals," available at: https://www.defense.gov/Explore/Spotlight/Coronavirus-DOD-Response/ (last visited September 19, 2021). These low mortality and hospitalization rates were achieved largely without any COVID-19 treatments, which can dramatically reduce hospitalizations and mortality. *See supra* Section VI.E.

[15] *See generally* Ex. 16, *The FDA COVID-19 Drug Approval Process* at 11-12 and studies cited therein.

[16] *See* Exec. Order 14,043, 86 Fed. Reg. 50,989, "Requiring Coronavirus Disease 2019 Vaccination for Federal Employees" (Sept. 9, 2021) ("Federal Employee Mandate"). This mandate appears to exempt White House personnel, CDC personnel, Congress, the U.S. Postal Service, and the federal judiciary.

[17] *See* Exec. Order 14,402, 86 Fed. Reg. 50,985, "Ensuring Adequate COVID Safety Protocols for Federal Contractors" (Sept. 9, 2021) ("Federal Contractor Mandate").

cover 17 million healthcare workers, and he directed the Occupational Health & Safety Administration ("OSHA") to take the extraordinary step of issuing a new emergency temporary standard ("ETS") "to require all employers with 100 or more employees . . . to ensure their workforces are fully vaccinated or show a negative test at least once a week" ("OSHA Mandate") that would cover 80 million workers.

45. Any state governors or other elected officials opposed to these plans will be moved "out of the way."[18] It was also announced that the Department of Education ("DOE") will seek to extend vaccine mandates to all school children and employees, and that the DOE will continue to take legal action against states or elected officials that oppose the vaccine mandate and other measures.[19] The Executive Branch also strongly opposes granting exemptions from vaccine mandates or any limits on imposition of the harshest possible penalties.[20] States are undeterred

---

[18] *See* Jon Brown, *Biden declares war on DeSantis and Abbott: 'Get them out of the way,'* FOX NEWS (Sept. 9, 2021), available at: https://www.foxnews.com/politics/get-them-out-of-the-way-biden-declares-war-on-desantis-and-abbott (last visited Sept. 30, 2021).

[19] *See, e.g.,* Collin Binkley, *States banning mask mandates could face civil rights probes*, AP NEWS (Aug. 18, 2021), available at: https://apnews.com/article/joe-biden-health-coronavirus-pandemic-5943b43e54f61861e65d8cb74f3a68f1 (last visited Sept. 30, 2021).

[20] On September 2, 2021, the Executive Office issued a statement opposing a provision in H.R. 4350 – National Defense Authorization Act for Fiscal Year 2022 ("2022 NDAA") that would enact into law an exemption for service members with natural immunity from prior infections. *See* Executive Office, "Statement of Administrative Policy: H.R. 4350 – National Defense Authorization Act for Fiscal Year 2022" at 4 (Sept. 21, 2021) ("2022 NDAA Statement"), available at:

and have successfully challenged the federal vaccine mandates, with courts issuing stays against the OSHA Mandate, the federal contractor COVID-19 vaccine mandate, and the CMS COVID-19 vaccine mandate.[21]

III. THE DOD MANDATE AND ARMED SERVICES GUIDANCE

A. DOD Mandate

46. On August 24, 2021, SECDEF 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." Ex. 2, DOD Mandate at 1.

47. The only service members expressly exempted are those "actively participating" in vaccine trials. *Id.* "Those with previous COVID-19 infection are not considered fully vaccinated," *id.*, nor are they provided a medical exemption. There is no discussion of exemptions for female service members who are pregnant, nursing or wish to become pregnant, or of the heightened risks of myocarditis or pericarditis for young males that account for a substantial portion of service members. SECDEF further directed that mandatory vaccination "will only use

---

https://www.whitehouse.gov/wp-content/uploads/2021/09/SAP-HR-4350.pdf (last visited Sept. 23, 2021).

[21] Brittany Barrientos, et al., *Judicial Holdings Throw Vaccine Mandate Implementation into Disarray*, JD SUPRA (Dec. 2, 2021), available at: https://www.jdsupra.com/legalnews/judicial-holdings-throw-vaccine-mandate-3363371/ (last visited Dec. 2, 2021).

COVID-19 vaccines that receive full licensure from the [FDA], in accordance with FDA labeling and guidance." *Id.*

B. AR 40-562 Exemptions

48. AR 40-562 presumptively exempts from any vaccination requirement a service member that the military knows has had a documented previous infection. AR 40-562, para. 2-6(a)(1)(b).[22] AR 40-562 also provides for exemptions for pregnant women. *Id.*, para. 2-6(a)(1)(a). Pregnant service members "may pursue a temporary medical exemption following vaccine counseling," pursuant to AR 40-562, para. 2.6(a). These exemptions apply both for EUA and licensed vaccines.

C. Armed Services Guidance

1. Air Force Guidance

49. On September 3, 2021, the Air Force issued the Air Force Guidance on implementation of the DOD Mandate for Air Force personnel.[23] The Air Force Secretary directed that all active-duty Air Force must be fully vaccinated by November 2, 2021, and all members of the Air National Guard must be vaccinated

[22] The current version of AR 40-562) was signed on Oct. 7, 2013, went into effect on Nov. 7, 2013, and remains in effect today. It applies to all branches of the military. AR 40-562 is also designated as AFI 48-110 (Air Force), BUMEDINST 6230.15B (Marine Corps and Navy), CG COMDETINST, M6230.4G) (Coast Guard).

[23] *See* Ex. 6 Dept. of the Air Force, Deputy Director of Staff for COVID-19, "COVID-19 Mandatory Vaccination Implementation Guidance for Service Members" (Sept. 3, 2021) ("Air Force Guidance").

by December 2, 2021.[24] There is no exemption for previously infected individuals like Plaintiffs with natural immunity. *See* Air Force Guidance, § 4.5.1.2.

50. While Air Force Guidance states that "[o]nly an FDA-licensed vaccine may be mandated," *i.e.*, the Comirnaty Vaccine, *id.* § 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 (emphasis added); *see also id.*, § 5.3.2.1 (same).

2. Army Guidance

51. On September 14, 2021, the Army announced its implementation guidance.[25] All active-duty Army personnel are required to be fully vaccinated with an FDA-licensed vaccine by December 15, 2021, and all reserve component personnel are required to be fully vaccinated by June 30, 2022. *Id.* There is no exemption for Army personnel with previous infections, nor is there any discussion of exemption for women who are pregnant, nursing or who wish to become pregnant.

---

[24] *See* Secretary of the Air Force Public Affairs, *DAF Announces Mandatory COVID Vaccine Implementation Guidelines for Airmen, Guardians* (Sept. 3, 2021), available at: https://www.af.mil/News/Article-Display/Article/2765008/daf-announces-mandatory-covid-vaccine-implementation-guidelines-for-airmen-guar/ (last visited Oct. 1, 2021).

[25] *See* Ex. 7, U.S. Army Public Affairs, *Army Announces Implementation of Mandatory Vaccines for Soldiers* (Sept. 14, 2021) ("Army Guidance").

Soldiers who refuse the vaccine will face "administrative or non-judicial punishment – to include relief of duties or discharge," while officers, commanders, command sergeant majors and sergeant majors "face suspension and relief" of duties. *Id.*

3. Navy Guidance

52. On August 30, 2021, the Navy issued implementation guidance,[26] which is also applicable to Marine Corps. All active-duty Navy personnel are required to be fully vaccinated with an FDA-licensed vaccine by November 28, 2021, and all reserve component personnel are required to be fully vaccinated by December 28, 2021. *See id.*, para. 4. The Navy Guidance does not grant, or discuss, any medical exemptions.

53. The Navy Guidance provides that the vaccination order "is a lawful order, and any failure to comply is punishable as a violation of a lawful order under Article 92" of the UCMJ. *Id.*, para. 5. Violations "may result in punitive or adverse administrative action," and the Navy has "the authority to exercise the full range of administrative and disciplinary actions" to enforce compliance. *Id.*

4. Marine Corps Guidance

54. On September 1, 2021, the Marine Corps issued implementation

[26] *See* Ex. 9, Secretary of the Navy, "2021-2022 Department of Navy Mandatory COVID-19 Vaccination Policy," ALNAV 062/21 (Aug. 30, 2021) ("Navy Guidance").

guidance,[27] requiring all active-duty Marines to be fully vaccinated with an FDA-licensed vaccine by November 28, 2021, and all reserve component personnel to be fully vaccinated by December 28, 2021. *Id.*, para. 3.a. Individuals with previous COVID-19 infections or positive serology are not exempted. *Id.*, para. 3.j.5. For pregnant women, "[p]er CDC … COVID-19 vaccination is strongly encouraged," although pregnant women may apply for a temporary exemption. *Id.*, para. 3.j.4. The guidance does not authorize exemptions for nursing women or women who wish to become pregnant.

55. The Marine Corps Guidance provides that it "constitutes a lawful general order and any violation of these provisions is punishable as a violation of article 92" of the UCMJ. *Id.*, para. 3.l. The Marine Corps has "the authority to exercise the full range of administrative and disciplinary actions" to enforce compliance. Ex. 9, Navy Guidance, para. 5.

D. Potential Consequences for Non-Compliance

56. 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. This punishment may include "dishonorable discharge, forfeiture of all pay and allowances, and confinement for 2 years." *Id.*

[27] *See* Ex.8, MARADMIN, "Mandatory COVID-19 Vaccination of Marine Corps Active and Reserve Components," MARADMINS Number: 462/21 (Sept. 1, 2021) ("Marine Corps Guidance").

57. Dishonorable discharges are typically given for the most serious offenses such as murder, fraud, desertion, treason, espionage, and sexual assault.[28] A dishonorably discharged veteran may also lose all retirement and veterans' benefits and is ineligible for a wide array of other governmental benefits. *Id.* Those with a dishonorable discharge lose important civil and constitutional rights, including the right to bear arms protected by the Second Amendment of the United States Constitution. *Id.*[29]

IV. FEDERAL REGULATORY REGIME FOR LICENSING AND EMERGENCY USE AUTHORIZATION OF VACCINES

A. FDA Vaccine Licensing and Approval

58. The FDCA generally prohibits anyone from introducing or delivering for introduction into interstate commerce any "new drug" or "biological product" unless and until the FDA has approved the drug or biological product as safe and

[28] *See Manual for Courts-Martial, United States* (2019 ed.), R.C.M. 1003(a)(8) ("A dishonorable discharge should be reserved for those who should be separated under conditions of dishonor, after having been convicted of offenses usually recognized in civilian jurisdictions as felonies, or of offenses of a military nature requiring severe punishment.").

[29] Dishonorable discharge is not merely a theoretical possibility. Plaintiffs have been verbally threatened with court-martial and dishonorable discharge, along with actual imposition of sanctions and restrictions for vaccine refusal. These commanders have the full support of the Executive, which opposes any limitation on the ability to impose sanctions for vaccine refusal, up to and including dishonorable discharge. *See also supra* 2022 NDAA Statement, note 20, at 4.

effective for its intended use. 21 U.S.C. §§ 331(a), 355(a); 42 U.S.C. § 262(a).[30] 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).

59. Pursuant to Section 351(a) of the PHSA, 42 U.S.C. § 262(a), the FDA has the authority to approve the sale and manufacture of vaccines and other biologics like the Comirnaty Vaccine. 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. EUA products are subject to much lower standards, than those required for licensed products, and they are exempt altogether from certain marketing and manufacturing requirements.

B. "Interchangeable" Biological Products under the PHSA

60. "Interchangeable" and "interchangeability" are specifically defined terms in Section 351 of the PHS Act, 42 U.S.C. § 262,[31] in relation to a "reference

[30] *See also* 42 U.S.C. § 262(a)(2)(C)(i)(I) (approval of biological products require demonstration that the product is "safe, potent, and pure"); 21 C.F.R. § 601.2(a) (same). There are no analogous requirements for EUA products.

[31] "Interchangeable" and "interchangeability" are defined as a "biological product" that "may be substituted for the reference product" by health care providers. 42 U.S.C. § 351(i)(3). To meet the standards in 42 U.S.C. § 262(k)(4) ("Safety standards for determining interchangeability"), the "interchangeable" or substitute biological product (i) must be biosimilar to the reference product and (ii) and "can be expected to produce the same clinical result as the reference product in any given patient." 42 U.S.C. § 262(k)(4).

product,"[32] which is a biological product licensed under Section 351(a) of the PHSA. 42 U.S.C. § 262(a).[33] 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 BioNTech, much less reviewed or approved by the FDA.

C. Emergency Use Authorization Laws and FDA Regulations

61. The FDCA authorizes the FDA to issue an EUA for a medical drug, device, or biologic, where certain conditions have been met. As relevant here, these are that HHS Secretary has declared a public health emergency that justifies the use of an EUA, 21 U.S.C. § 360bbb-3(b)(1), and the FDA finds that "there is no [1] adequate, [2] approved, ***and*** [3] available alternative to the product for diagnosing,

---

[32] "Reference product" is defined as "the single biological product licensed" under 42 U.S.C. § 262(a) "against which a biological product is submitted" under 42 U.S.C. § 262(k). 42 U.S.C. § 351(i)(4).

[33] These definitions and related provisions were enacted as part of the Biologics Price Competition Act of 2009, which "amends the PHSA and other statutes to create an abbreviated licensure pathway," under Section 351(k) of the PHSA, 42 U.S.C. § 262(k), "for biological products shown to be interchangeable with an FDA-licensed biological reference product," licensed under Section 351(a) of the PHS Act, 42 U.S.C. § 262(a). *See generally* FDA, et al., *Considerations in Demonstrating Interchangeability with a Reference Product: Guidance for Industry* (May 2019), available at: https://www.fda.gov/media/124907/download (last visited Sept. 15, 2021).

preventing, or treating" the disease in question. 21 U.S.C. § 360bbb-3(c)(3) (emphasis added).

62. There are significant differences between licensed vaccines and those subject to EUA that render them "legally distinct." Ex. 2, BioNTech Expansion Letter, at 2 n.8. First, the requirements for efficacy are 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). Second, the safety requirements are minimal, requiring only that the FDA conclude 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). 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 (subject to the override procedures for service members described below). *See, e.g., Doe v Rumsfeld*, 341 F. Supp. 2d 1, 19 (D.D.C. 2004) ("*Rumsfeld II*") (granting injunction against DOD anthrax vaccine mandate for EUA vaccine).

63. The public health emergency declaration that justifies the use of an EUA for a product "shall terminate upon the earlier of … a change in the approval status" of the EUA product. 21 U.S.C. § 360bbb-3(b)(2)(A)(ii). Thus, the approval,

or licensing, of a vaccine for a given indication terminates the EUA for that vaccine. The requirements for licensing and emergency use authorization are mutually exclusive; the same product—or same vial of vaccine—cannot be concurrently subject to an EUA and licensed for the same indication or use, under distinct regulatory regimes.[34]

D. Informed Consent Requirements for EUA Products

64. 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." FDCA § 564(e)(1)(A)(ii)(III); 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III).[35] 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]."

---

[34] *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 exceeding its statutory authority).

[35] The norm of informed consent has been "firmly embedded" in U.S. law and FDA regulations for nearly 60 years. *Adullahi v. Pfizer, Inc.*, 562 F.3d 163, 182 (2nd Cir. 2009). Congress first enacted this requirement in 1962 drawing on the Nuremberg Code and the Helsinki Declaration, "which suggests the government conceived of these sources' articulation of the norm as a binding legal obligation." *Adullahi*, 562 F.3d at 182 (citation omitted). Informed consent requirements are a cornerstone of FDA rules governing human medical experimentation. *See, e.g.,* 21 C.F.R. §§ 50.20, 50.23-.25, 50.27, 312.20, 312.120 (2008); 45 C.F.R. §§ 46.111, 46.116-117.

65. The DOD may override service members' informed consent rights, provided that it complies with the requirements of 10 U.S.C. § 1107a (EUA products).[36] The procedures to override service members' informed consent rights have not been followed or implemented by the DOD. Neither the DOD nor the Armed Services acknowledge any duty to invoke these procedures because, in their view, Plaintiff service members do not have any rights to informed consent or to refuse vaccination because Comirnaty has been licensed.

E. FDA Emergency Use Authorizations for COVID-19 Vaccines

66. The FDA issued an EUA for the BioNTech Vaccine on December 11, 2020, for the Moderna Vaccine on December 18, 2020, and for the Janssen Vaccine on February 27, 2021. The FDA granted an EUA for the BioNTech Vaccine based on approximately two months of safety and efficacy data.[37]

67. For the three COVID-19 vaccines, FDA implemented the "option to accept or refuse" condition described in Section 564(e)(1)(A)(ii)(III) in each letter granting the EUA by requiring that FDA's "Fact Sheet for Recipients and

[36] *See* DOD Instruction 6200.02, "Application of Food and Drug Administration Rules to Department of Defense Force Health Protection Programs" (Feb. 27, 2008) (override procedures under 10 U.S.C. § 1107a).

[37] *See generally* FDA, *Emergency Use Authorization (EUA) for an Unapproved Product: Review Memorandum* (Dec. 11, 2020), available at: https://www.fda.gov/media/144416/download (last visited Oct. 1, 2021).

Caregivers" be made available to every potential vaccine recipient. Each Fact Sheet includes the statement that it is your choice to receive or not receive the vaccine.

F. BioNTech Vaccine EUA Expansion

68. The requirements for licensing and emergency use authorization are mutually exclusive. The same product—or same vial of vaccine—cannot be concurrently subject to an EUA and licensed for the same indication or use, under distinct regulatory regimes. Yet that is precisely what the FDA has done by: (1) simultaneously licensing Comirnaty Vaccine and re-issuing the EUA for the BioNTech Vaccine for the same indication (individuals 16 years or older); (2) re-issuing and expanding the existing BioNTech Vaccine EUA for children of 12-15 years of age and permitting the licensed Comirnaty Vaccine to be used for this group; and (3) finding that the EUA BioNTech Vaccine and licensed Comirnaty Vaccine can be used "interchangeably" and may be substituted for each other. Ex. 5, BioNTech EUA Expansion Letter at 2 n.8.

69. First, the approval of Comirnaty should have automatically terminated the EUA for that use. *See* 21 U.S.C. 360bbb-3(b)(2)(A)(ii). The FDA chose to ignore this statutory requirement.

70. Second, to grant an EUA, or extend an existing EUA, the FDA must find that there is no alternative that is (1) adequate, (2) approved, and (3) available. 21 U.S.C. § 360bbb-3(c)(3); *see also* Ex. 5, BioNTech Expansion Letter at 5. All

three requirements must be met. Comirnaty is approved and presumably adequate, so the FDA's EUA re-issuance and expansion is based on that fact that the licensed vaccine is "not … available" in sufficient quantities. *Id.* at 5 n.9. "Not available" is a binary requirement; an alternative either is or is not available; there is no room in the statute for the FDA to add a third option – not available in sufficient quantity – for the purpose of enabling vaccine mandates.

71. The FDA licensed a product that is not available, and then informed the general public that the EUA-labeled and manufactured product can be used "interchangeably," or substituted, for the licensed product.[38] The FDA provides no justification for ignoring and nullifying these express statutory requirements of the FDCA, which also has the effect of nullifying Plaintiffs' rights to informed consent and to refuse the administration of an experimental vaccine.

V. FDA COMIRNATY APPROVAL

A. FDA Guidance on Testing and Review of COVID-19 Vaccines

72. In June 2020, HHS, FDA and the Center for Biologics Evaluation and Research ("CBER") issued guidance to vaccine developers on clinical and non-

[38] The FDA BioNTech EUA Expansion letter appears to authorize injection from an EUA-labeled and manufactured vial for the same indications as the licensed product, namely, to individuals 16 years or older pursuant to a mandate; conversely, it would authorize off-label use of Comirnaty Vaccine manufactured and labeled in compliance with the BLA to be administered to a 12-year old, an indication for which Comirnaty is not licensed.

clinical testing and the procedures the FDA intended to apply in evaluating and approving COVID-19 vaccines.[39] The June 2020 Industry Guidance included a number of recommendations that ultimately were not followed, in particular: (1) the inclusion in clinical trials of individuals with previous COVID-19 infections, *id.* at 11; (2) the inclusion of pregnant women, *id.*; and (3) the use of clinical trials lasting "***at least*** one to two years," *id.* at 12 (emphasis added). The FDA also indicated its intent to follow its standard procedure for clinical trial results to be reviewed by the Advisory Committee.

B. Citizen Petition & FDA Response

73. Many of the arguments made by Plaintiffs regarding the need to study special populations, *i.e.,* those with natural immunity, pregnant/nursing women, etc. (or else provide contraindications), and the numerous procedural, scientific, and evidentiary defects in the FDA's review and approval of the Comirnaty Vaccine were made in a Citizen Petition submitted by the Coalition Advocating for Adequately Licensed Medicines on July 23, 2021 in Docket No. FDA-2021-P-0786. *See* Ex. 11 ("Citizen Petition"). The FDA denied the Citizen Petition on August 23, 2021. *See* Ex. 12 ("FDA CP Response"), the same day that it approved Comirnaty.

[39] *See* Ex. 10, HHS, FDA & CBER, Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry (June 2020) ("June 2020 Industry Guidance"), available at: https://www.fda.gov/media/139638/download (last visited Sept. 22, 2021).

C. FDA Comirnaty Approval and BioNTech EUA Expansion Letters

74. On August 23, 2021, the FDA approved the May 18, 2021, Comirnaty application for individuals 16 years or older. Also on August 23, 2021, the FDA re-issued the EUA for the BioNTech Vaccine for individuals 16 years or older and for children aged 12 to 15 years, and expanded the EUA to cover a third "booster" shot for certain groups. The FDA Comirnaty Approval and BioNTech EUA Expansion thus licensed a vaccine and continued an existing EUA for the same indication (individuals 16 years or older).

75. The FDA has incorrectly asserted that the EUA BioNTech Vaccine and the conditionally approved Comirnaty Vaccine can be used "interchangeably" because they have the "same formulation." Ex. 5, BioNTech EUA Expansion Letter at 2 n.8. As explained above, this statement is contradictory and incorrect insofar as it suggests that an EUA Vaccine, manufactured and labeled in accordance with the EUA, may be treated as a licensed product.[40] The fact that other agencies have seized on this language to justify mandates, *see* Ex. 6, Air Force Guidance, § 3.1.1, (authorizing providers to treat an EUA vaccine "as if" it were the licensed product), indicates that this was the intended result. Further, the EUA BioNTech Vaccine and

[40] Conversely, it suggests that the Comirnaty Vaccine can be used for "off-label" uses under the EUA, *e.g.*, for a child under 16 or for a third "booster" dose for which there is no clinical trial data available. *See* Ex. 5, BioNTech EUA Expansion Letter at 2 ("authoriz[ing] use of the Comirnaty (COVID-19, mRNA) under this EUA for certain uses that are not included in the approved BLA" for the licensed product).

the Comirnaty Vaccine do not have the "same formulation" or number of ingredients, and there is no basis in the publicly available record for concluding that the EUA product is manufactured at the same facilities or using the same processes and components as the Comirnaty Vaccine.[41]

76. The FDA appears to acknowledge that the EUA BioNTech Vaccine and the conditionally licensed Comirnaty Vaccine are not in fact "interchangeabl[e]." The Comirnaty Approval Letter approves the sale of Comirnaty Vaccine, as well as the specific manufacturing facilities, processes, ingredients, storage, and distribution requirements that were not addressed in the BioNTech Vaccine EUA. For example, the Comirnaty Approval Letter requires FDA approval for release of Comirnaty lots manufactured in accordance with the terms of the license.[42] Given the differences in manufacturing between EUA and licensed vaccines, the FDA also required BioNTech to identify specific lots of EUA-labeled and manufactured BioNTech

[41] *Cf.* Ex. 4, Comirnaty SBRA at 6-8 and 12-13 (largely redacting "Drug Substance," "major manufacturing process stages," "Drug Product," "critical steps" in manufacturing, and manufacturing facilities, and listing 11 ingredients, including one redacted excipient) *and* Ex. 5, BioNTech EUA Expansion Letter (does not include information on manufacturing process or facilities, and listing 10 ingredients).

[42] *See* Ex. 3, Comirnaty Approval Letter at 2 ("FDA Lot Release;" "You may not distribute any lots of the licensed product [i.e., Comirnaty Vaccine] until you receive a notification of release from the Director [CBER].").

Vaccines that BioNTech deemed BLA-compliant for FDA review and release. *See* Ex. 4, Comirnaty SBRA at 27 (Section 10.a "Identification of BLA Lots").

77. The Comirnaty Vaccine is not widely available due to limited supply. *See* Ex. 5, BioNTech EUA Expansion Letter at 5 n.9. This has been affirmed by recent media reports,[43] and supports the conclusion that the DOD and other employers intend to mandate vaccination using an the EUA vaccine (BioNTech Vaccine), rather than the licensed Comirnaty Vaccine.

D. Procedural and Substantive Deficiencies in FDA Comirnaty Review and Approval Process.

78. The FDA claims that the Comirnaty Vaccine approval followed its "standard process for reviewing the quality, safety, and effectiveness of medical products,"[44] but this statement is belied by its contemporaneous statements and the deficient process it followed. In its August 23, 2021, press conference, the FDA Acting Commissioner Woodcock conceded that the FDA followed an "unprecedented timeline," Coleman, *supra* note 10, in approving the Comirnaty

[43] *See, e.g.,* Zachary Steiber, *Newly Approved COVID-19 Vaccine Not Yet Available in US*, EPOCH TIMES (Sept. 3, 2021), available at: https://www.theepochtimes.com/newly-approved-covid-19-vaccine-not-yet-available-in-us_3976794.html/amp (last visited Sept. 7, 2021).

[44] 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 Sept. 22, 2021).

application in just over three months. It did so by skipping, or failing to require, the procedures and clinical trial data needed to assess Comirnaty's safety and efficacy.

1. The FDA Permitted Exclusion of "Special Populations."

79. Neither the BioNTech Vaccine nor the Comirnaty Vaccine has been tested in clinical trials for its safety and efficacy on individuals who have recovered from COVID-19. Indeed, the trials conducted so far have specifically excluded survivors of previous COVID-19 infections.[45] The clinical trials also did not include any pregnant or lactating women.[46] The FDA instead relied solely on rat studies in its approval of Comirnaty for these populations.[47] The clinical trials also did not include participants from and/or provide sufficient data for other "special populations" such as those with autoimmune disorders or hematological conditions, children, and frail elderly populations. *See* Ex. 17, Ruby Affidavit at ¶ 15.

---

[45] *See* Fabio Angeli, *SARS-CoV-2 vaccines: Lights and Shadows*, EUROPEAN J. OF INTERNAL MEDICINE 2021;88:1-8.

[46] *See* Sandra Kweder, MD, et al., *Global Regulators Envision Paradigm Shift Toward Inclusion of Pregnant and Breastfeeding Women in Clinical Research for Medicines and Vaccines*, FDA News Releases (July 19, 2021), available at: https://www.fda.gov/news-events/fda-voices/global-regulators-envision-paradigm-shift-toward-inclusion-pregnant-and-breastfeeding-women-clinical (noting that no pregnant or lactating women were included in any COVID-19 vaccine trials).

[47] *See* Ex. 13, FDA, "Fact Sheet for Health Care Providers Administering Vaccine (Vaccination Providers)," at 33 (Aug. 23, 2021) (emphasis added) ("BioNTech/Comirnaty Vaccine Fact Sheet").

80. The Comirnaty application also skipped testing for genotoxicity, mutagenicity, teratogenicity, and oncogenicity. *See id.* at ¶ 13. In other words, it is unknown whether or not COVID-19 vaccines will change human genetic material, cause birth defects, reduce fertility, or cause cancer.

2. The FDA Relied on Interim Results for Limited and Self-Selected Sample.

81. While the Phase 3 clinical trials included a large and statistically significant number of participants, the full sample trial was truncated in unprecedented fashion. It was only followed for ***two months*** (*i.e.*, largely the same trials and participants as used to grant the initial EUA for the BioNTech Vaccine) instead of the FDA's recommended period of at least ***one to two years*** set forth in the June 2020 Industry Guidance. Further, the median period that trial participants were followed was four months, and about one-fourth were covered for six months. *See supra* FDA Comirnaty Press Release, note 4. 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," *id.*, and it has conditioned Comirnaty approval on the completion of at least nine additional clinical trials running through 2025 (none of which specifically address previously infected individuals with natural immunity).

82. The FDA fails to acknowledge, however, that the results of the trials beyond the first two months are of questionable (or perhaps negligible) validity due

to fundamental methodological error that infect all results and undermine any conclusions that can be drawn from them. In its May 18, 2021 application,[48] which included interim six-month safety and efficacy data for Phase 3 clinical trials, Pfizer-BioNTech explained that study participants were given the option to be "unblinded" – to learn whether they had taken the experimental BioNTech Vaccine or the placebo – and if they had taken the placebo, to take the BioNTech Vaccine. As a result, only approximately 7% of study participants were blinded after six months. *Id.* at 5. This "unblinding" converted a randomized, controlled clinical trial into a "modified-open label, observational variable dose trial with no informed consent." *See* Ex. 17, Ruby Affidavit at ¶ 12. Accordingly, the FDA's statements that the Comirnaty approval was based on "randomized, controlled, blinded ongoing clinical trial of thousands of individuals," *see supra* FDA Comirnaty Press Release, note 4, is severely and intentionally misleading.

83. The problem with the unblinding is not simply that the data available after two months covers a smaller number of participants. Instead, it introduces a number of methodological errors that cannot be corrected or adjusted *post hoc*; it infects all results. First, the unblinding introduces an incurable self-selection bias.

[48] *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 Sept. 22, 2021).

Second, it effectively eliminates the "control" group, and therefore any randomization. Third, there is no information provided on the demographic characteristics of those who were unblinded vs. those who remained blinded (race, sex, age, membership in "special populations," previous infection status, etc.), whether they received the vaccination or the placebo, or any self-reported reasons for unblinding (e.g., the presence or absence of side effects or adverse reactions). Fourth, it almost certainly unbalanced the 1:1 matching at the heart of the study design and the numbers of participants in the various sub-groups under examination.

3. The FDA Ignored Evidence of Serious Adverse Effects and Failed to Convene Advisory Committee.

84. Despite the thousands of deaths and serious injuries self-reported through VAERS, *see infra* Section VI.C, the FDA chose not to follow its earlier industry guidance, or their standard practice, to refer this BLA for Advisory Committee review and the consequent opportunity for public notice and comment. *See* Ex. 4, Comirnaty SBRA at 27 ("FDA did not refer this application to the [Advisory Committee] because … this BLA did not raise concerns or controversial issues that would have benefitted from an advisory committee action.").

85. The FDA knew that the licensing of the Comirnaty Vaccine would be used to enable vaccine mandates not only by employers, but also that vaccination would become a condition to go to school, worship, travel by air or across state lines, or even to buy groceries in many areas. It is hard to imagine an issue that could be

more "controversial" than the imposition of vaccine mandates that would bar at least a third of Americans from participating in the Nation's economic and social life. The FDA avoided its obligations under the FDCA and the APA to explain its decision, and to provide the public with an opportunity to comment on a matter of such momentous importance to the health and constitutional rights of hundreds of millions of U.S. citizens.

VI. SAFETY AND EFFICACY DATA FOR COVID-19 VACCINES

A. Novel Technology

86. COVID-19 vaccines employ novel technology, namely, mRNA delivered by nanolipids. COVID-19 vaccines are considered gene-based vaccines or vaccines produced from gene therapy molecular platforms, whose safety and efficacy has not been fully assessed. This is unlike all other vaccines where there is a set amount of antigen or a live-attenuated virus in the vaccine.

87. According to the FDA, there is insufficient data to know whether the COVID-19 Vaccines actually prevent asymptomatic infection or prevent

transmission of SARS-CoV-2, the virus that causes COVID-19. Recent data from the U.S.[49] and abroad[50] suggest that they do not prevent either.

88. These vaccines were only tested on humans for a limited period of time. For example, the Comirnaty Vaccine Phase 2 and Phase 3 trials only covered the full sample for approximately two months, and a much smaller sample for up to six months. *See infra* Section V.D. Accordingly, there is absolutely no knowledge whatsoever of the long-term efficacy or long-term safety of these vaccines, which "is not proven." *Klaassen*, 2021 WL 3073926, at *12. Clinical trials for these vaccines are scheduled to continue through 2023 to 2025. *See* Ex. 3. Because these vaccines have only been used by the public for less than a year, it is impossible to

[49] *See* Catherine M. Brown, DVM, et al., *Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts*, CDC MORBIDITY AND MORTALITY WEEKLY REPORT Aug. 2021;70(31): 1059-1062 (Aug. 6, 2021) available at: https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm?s_cid=mm7031e2_w#suggestedcitation (last visited Sept. 30, 2021).

[50] *See* Nathan Jeffay, *Israeli, UK data offer mixed signals on vaccine's potency against Delta strain*, THE TIMES OF ISRAEL (July 22, 2021), available at: https://www.timesofisrael.com/israeli-uk-data-offer-mixed-signals-on-vaccines-potency-against-delta-strain/ (last visited Sept. 2, 2021); Ian Sample, *Scientists back Covid boosters as studyfinds post-jab falls in antibodies*, THE GUARDIAN (July 22, 2021), available at: https://www.theguardian.com/world/2021/jul/22/uk-scientists-back-covid-boosters-as-study-finds-post-jab-falls-in-antibodies (last visited Sept. 2, 2021).

assess or know fully the safety and efficacy of these vaccines, their necessity, and whether their benefits outweigh the risks.

B. Waning Efficacy and Need for "Booster" Shots

89. Recent studies indicate that the efficacy and protection of the BioNTech Vaccine drops off significantly over time, particularly after the six-month period on which the FDA relied in conditionally approving the Comirnaty Vaccine. For example, recent and well-publicized studies from Israel found that the BioNTech Vaccine's effectiveness decreased from over 90% to 39% after six months for infections and 40.5% for symptomatic cases.[51] Plaintiffs are not aware of any studies contradicting the Israeli studies. In fact, these study results are the reason Israel is already requiring a third booster shot (and is considering a fourth).[52]

---

[51] *See* Ex. 14, Israel Ministry of Health Presentation (July 23, 2021), available at: https://www.gov.il/BlobFolder/reports/vaccine-efficacy-safety-follow-up-committee/he/files_publications_corona_two-dose-vaccination-data.pdf (last visited Sept. 23, 2021) (summarizing six-month efficacy data for Pfizer-BioNTech vaccine in Israel); *see also* Rory Jones & Dov Lieber, *Pfizer COVID-19 Vaccine Is Less Effective Against Delta Infections but Still Prevents Serious Illness, Israel Study Suggests*, WALL STREET J. (July 23, 2021), available at: https://www.wsj.com/articles/pfizer-covid-19-vaccine-is-less-effective-against-delta-infections-but-still-prevents-serious-illness-israel-study-shows-11627059395 (last visited Sept. 22, 2021).

[52] *See* Rosella Tercatin & Maayan Jaffe-Hoffman, *COVID-19 Boosters Expanded to 40 Years Old and Up*, JERUSALEM TIMES (Aug. 20, 2021), available at: https://www.jpost.com/health-science/covid-israel-registers-600-serious-patients-3rd-vaccine-to-be-expanded-677144 (last visited Sept. 4, 2021).

90. At the September 17, 2021 FDA Advisory Committee meeting to consider approval of booster shots, Sara Oliver MD, MSPH presented an overview of studies demonstrating the rapidly declining efficacy of the Pfizer-BioNTech vaccine, in the United States and abroad.[53] Several U.S. studies found that the efficacy of COVID-19 vaccines dropped from over 90% to as 42% (with a median of roughly 65%) over an up to six-month period, with the steepest drops found in the studies with the longest study periods; the only study limited to the Pfizer-BioNTech vaccine got the low score of 42%.[54] Dr. Oliver also presented studies finding a steep decline in efficacy 15%-35% for the pre-Delta vs. the Delta variant. *Id.*, Slide 20. She also presented a number of international studies showing even sharper decreases in efficacy in countries such as Qatar where the Delta variant was prevalent at an earlier date. *Id.* at 21.[55]

---

[53] *See* Ex. 15, Sara Oliver MD, MSPH, *Updates to COVID-19 Epidemiology and COVID-19 Vaccines*, Presentation to September 17, 2021 VRBPAC Meeting (Sept. 17, 2021) ("Oliver FDA Presentation"), available at: https://www.fda.gov/media/152243/download (last visited Sept. 22, 2021).

[54] *See id.,* Slide 15 (citing A. Puranik et al., *Comparison of two highly effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence*, medRxiv2021.08.06.21261707).

[55] Despite this information, the CDC is inexplicably not tracking "breakthrough" infections of vaccinated people. *See, e.g.,* Rachel Roubein & David Lim, *CDC Under Fire for Decision to Limit Tracking of COVID-19 Cases in Vaccinated People*, POLITICO (July 30, 2021), available at: https://www.politico.com/news/2021/07/30/pressure-cdc-breakthrough-cases-501821 (last visited Sept. 19, 2021). This would have provided essential information regarding the long-term efficacy of Comirnaty and other COVID-19 vaccines.

91. The Administration announced its intention to make booster shots available to all adult U.S. citizens who are already fully vaccinated by September 20, 2021. In its September 17, 2021 meeting, the FDA Advisory Committee rejected this deadline, and instead recommended booster shots initially for elderly and at-risk individuals; the FDA implemented this recommendation on September 22, 2021.[56] This debate demonstrates that there is no scientific consensus, or certainty, on the long-term efficacy, or even the proper dosage of the Comirnaty Vaccine. Perhaps more importantly, it suggests that, if the FDA had followed normal procedures of convening an Advisory Committee meeting, it may have had the chance to consider a wider range of views and evidence on Comirnaty's safety and efficacy, and delayed its approval, or limited it to groups for which there was clinical trial data required to fulfill its duty to engage in reasoned decision-making.

92. The debate over booster shots and declining efficacy also resulted in the resignation of the two of the FDA's most senior vaccine leaders, purportedly due

---

Several other countries have continued to track breakthrough infections, which has revealed the rapidly declining efficacy of COVID-19 vaccines and enormous increases in infections of the most vaccinated populations, leading many to concern that the vaccines are enhancing the disease instead of protecting against it.

[56] *See* FDA, News Release, *FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations*, FDA News Release (Sept. 22, 2021), available at: https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations (last visited Sept. 22, 2021).

to improper political interference in the accelerated approval of COVID-19 vaccines and for "booster" shot requirements.[57] Further, a former FDA staffer stated that Gruber and Krause are departing because they are frustrated that CDC and the ACIP committee are involved in decisions that they think should be up to the FDA. *Id.*

93. Based on the limited efficacy of the COVID-19 vaccines and their inability to prevent re-transmission, the CDC abandoned any pretense that the COVID-19 vaccines can prevent disease or its spread, and moved the goalposts to merely providing "protection." In fact, the COVID-19 vaccines may be more appropriately classified as therapeutics than vaccines. Proving this point is the recent decision by the CDC to change the definition of "vaccine" from a product that will "produce immunity"[58] (the definition from 2015 – August 2021) to one that will

[57] Marion Gruber, Director of the FDA's Office of Vaccines Research and Review and 32-year veteran of the agency will leave at the end of October, and OVRR deputy director Phil Krause, who has been at the FDA for more than a decade, will leave in November, 2021. *See* Sarah Owermohle, *Biden's Top-Down Booster Plan Sparks Anger at FDA*, POLITICO (Aug. 31, 2021) available at: https://www.politico.com/news/2021/08/31/biden-booster-plan-fda-508149 (last visited Sept. 22, 2021).

[58] 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 Sept. 18, 2021) (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.").

"produce protection" (September 2021).[59]

94. There is simply no data available – nor could there be – that Comirnaty or other COVID EUA Vaccines can produce long-term immunity or prevent transmission, and accordingly, provide the public health (as opposed to individual health) benefits on which the DOD Mandate and other mandates are based. There is no substitute for time when determining the long-term safety and efficacy of vaccines. This Court should not defer to the FDA's procedurally and substantively deficient determination.

95. Finally, some Plaintiffs possess natural immunity, so neither they nor the community would benefit from them receiving the vaccine. Moreover, as discussed, it is evident that the COVID-19 vaccines are less effective at preventing infection (and thereby spread of the disease) than natural immunity is at preventing re-infection. Accordingly, there is no public health justification for the DOD Mandate.

C. VAERS Data on COVID-19 Vaccine Injuries and Side Effects

96. The VAERS data reveal unprecedented levels of death and other adverse events since the FDA issued EUAs for the three COVID vaccines. The

[59] CDC, *Vaccines and Immunizations: Definition of Terms*, available at: https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm (last visited Sept. 18, 2021) (defining "vaccine" as [a] preparation that is used to stimulate the body's immune response against diseases.").

reported death toll is greater than the combined death toll of all other federally-recommended vaccines administered in the United States since 1990 (totaling 5,018).[60] Similarly, according to VAERS, these three vaccines have also caused nearly as many hospitalizations (29,079 vs. 37,747) and severe life-threatening events (8,056 vs. 37,747) as the combined total of all other vaccines administered since they began tracking this information. *Id.* These adverse events include life-threatening anaphylaxis, myocarditis and pericarditis (heart inflammation), blood clotting disorders, cardiac disorders, miscarriages, Bell's Palsy, Guillain-Barré syndrome and death.[61]

97. It is well known that VAERS captures only a fraction of the actual injuries caused by vaccines. In fact, a 2010 federal study commissioned by HHS and performed by Harvard consultants on behalf of the Agency for Healthcare Research and Quality found that "fewer than 1% of vaccine adverse events" are ever reported

[60] *See* VAERS Analysis, *VAERS Summary for COVID-19 Vaccines Through 8/27/2021*, available at: https://vaersanalysis.info/2021/09/03/vaers-summary-for-covid-19-vaccines-through-8-27-2021/ (last visited Sept. 4, 2021).

[61] VAERS also collects data worldwide. As of September 9, 2021, VAERS had collected the following reports of adverse reactions to COVID-19 vaccines: (1) 675,591 total reports; (2) 14,506 deaths; (3) 58,440 hospitalizations; (4) 77,919 urgent care visits; (5) 106,184 office visits; (6) 5,783 anaphylaxis; (7) 7,911 Bell's Palsy; (8) 1,757 Miscarriages; (9) 6,422 Heart Attacks; (10) 5,371 Myocarditis/Pericarditis; (11) 18,439 Permanently Disabled; (12) 2,910 Thrombocytopenia/ Low Platelet; (13) 14,594 Life Threatening; (14) 27,336 Severe Allergic Reaction; and (15) 7,810 Shingles. *See id.*

to VAERS.[62] As a result, the COVID-19 vaccines are likely more dangerous – and more deadly – than reported.

D. Evidence of Natural Immunity for Those with Previous Infections

1. Israeli Study

98. Substantial research establishes that a COVID-19 infection creates immunity to the virus at least as robust, durable, and long-lasting as that achieved through vaccination. A study conducted in Israel (the "Israeli Study"), one of the most vaccinated countries on Earth, is the most recent – with data collected through August 14, 2021 – and the "largest real-world observational study comparing natural immunity," gained from COVID-19 infection, and "vaccine-induced immunity" from the BioNTech Vaccine.[63]

99. The Israeli Study concluded that: "***natural immunity confers longer lasting and stronger protection against infection*****,** symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2" compared to BioNTech vaccine immunity. *Id.* Specifically, fully vaccinated individuals with no previous

---

[62] *See* Ross Lazarus, MBBS, MPH, MMed, GDCompSci, *Electronic Support for Public Health—Vaccine Adverse Event Reporting System*, available at: https://rickjaffeesq.com/wp-content/uploads/2021/02/r18hs017045-lazarus-final-report-20116.pdf.

[63] Sivan Gavit, MD MA, *et al.*, *Comparing SARS-CoV-2 Natural Immunity to Vaccine-Induced Immunity: Reinfections versus Breakthrough Infections* at 15, medRxiv Preprint (Aug. 25, 2021), available at: https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.full.pdf.

infections had a "statistically significant 13.06-fold (95% CI, 8.08 to 21.11) increased risk for breakthrough infection [with the Delta variant] as opposed to reinfection (P<0.001)" of those previously infected. *Id.* at 12.[64] With respect to symptomatic disease, the fully vaccinated had a "27.02-fold risk (95% CI, 12.7 to 57.5) symptomatic breakthrough infection as opposed to reinfection (P<0.001)." *Id.* at 12-13.[65]

2. Cleveland Clinic Study

100. These results are consistent with an earlier study by doctors and researchers from the renowned Cleveland Clinic.[66] The Cleveland Clinic Study included 1,359 previously infected individuals who did not take any COVID-19 vaccine, and found that "[n]ot one of the 1,359 previously infected subjects who

[64] These results were obtained after adjusting for co-morbidities and matching the time of first event (*i.e.*, administration of second dose for those in Group 1 or the time of documented infection for those in Group 2). *Id.* at 9.

[65] The Israeli Study also found that, without matching for time of first event, there was still a statistically significant differences (P<0.001) between Group 1 and Group 2: Group 1 "had a 5.96-fold (95% CI, 4.85 to 7.33) increased risk for breakthrough infection" and "a 7.13-fold (95% CI, 5.51 to 9.21) increased risk for symptomatic disease" compared to the risk of reinfection for those in Group 2. *Id.* at 13.

[66] *See* Nabin K. Shrestha, MD, MPH, *et al.*, *Necessity of COVID-19 Vaccination in Previously Infected Individuals*, medRxiv preprint (June 19, 2021) ("Cleveland Clinic Study"), available at: https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v3.full.pdf. The Cleveland Clinic Study examined 52,238 employees of the Cleveland Clinic Health System for a five-month period beginning in December 2020.

remained unvaccinated had a SARS-CoV-2 infection over the duration of the study." *Id.* at 2.

101. With respect to the benefits of vaccination, the Cleveland Clinic Study found that "vaccination was associated with a significantly lower risk of SARS-CoV-2 infection among those not previously infected (HR 0.031, 95% CI 0.015 to 0.061)," but that vaccination did not lower the risk of re-infection "among those previously infected (HR 0.031, 95% CI 0 to Infinity)." *Id.* The Cleveland Clinic Study concluded that previously infected individuals are therefore "unlikely to benefit from COVID-19 vaccination." *Id.*

3. Longitudinal Study

102. The more robust response of natural immunity to mutated forms of COVID is supported by the results of a longitudinal analysis of 254 patients over eight months.[67] This study found that SARsS-CoV-2 infection produces "broad and effective immunity" that "may persist long-term in recovered COVID-19 patients."

E. Alternative and Effective Treatments for COVID-19

103. There are now well-studied, safe and reliable alternatives to vaccination for prevention and treatment of COVID-19, including, but not limited to Ivermectin,

[67] Kristen W. Cohen, et al., *Longitudinal Analysis Shows Durable and Broad Immune Memory after SARS-CoV-2 Infection with Persisting Antibody Responses and Memory B and T Cells*, CELL REPORTS MEDICINE 2, 100354 (July 20, 2021), available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8253687/ (last visited Sept. 22, 2021).

Methylprednisolone, Fluvoxamine, Hydroxychloroquine, Vitamin C, Vitamin D3, Zinc, Melatonin, Aspirin, corticosteroids, monoclonal antibodies, and other accessible therapies. Merck recently announced a new COVID-19 treatment, an oral antiviral pill that dramatically reduces risks of hospitalization and death.[68]

104. For example, Ivermectin was rejected by the FDA, despite having significantly more peer reviewed studies, forty-four (44) peer reviewed studies, and thirty-two (32) double-blind clinical trials showing substantially higher efficacy than treatments such as Remdesivir.[69] Ivermectin is used over the counter for COVID in many countries and regions with excellent reported treatment success, such as India. The drug's safety has been established with nearly four billion human doses used, and the drug is on the World Health Organization's list of essential drugs.

VII. PLAINTIFFS WILL EXPERIENCE CONCRETE AND PARTICULARIZED HARM AS A DIRECT CONSEQUENCE OF THE DOD VACCINE MANDATE

105. Natural Immunity Plaintiffs, WOBCP Plaintiffs and other Plaintiffs have real, substantial, and legitimate concerns about taking a COVID-19 vaccine in

[68] *See, e.g.,* Robert F. Service, *"Unquestionably a Game Changer!" Antiviral Pill Cuts COVID-19 Hospitalization Risk*, SCIENCE (Oct. 1, 2021), available at: https://www.science.org/content/article/unquestionably-game-changer-antiviral-pill-cuts-covid-19-hospitalization-risk (last visited Oct. 4, 2021).

[69] *See* Ex. 16, *FDA COVID-19 Drug Approval Process Remdesivir vs Ivermectin*.

light of and the potential for short- and long-term side effects as well as potential adverse reactions from the vaccines themselves.

106. All Plaintiffs will face adverse employment or disciplinary actions, up to and including termination, separation, dishonorable discharge, court martial, loss of post-separation benefits, and permanent damage to their reputation and employment prospects resulting from a court martial and/or dishonorable discharge.

107. "[T]he United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs." *Rumsfeld I*, 297 F.Supp.2d at 135. The injury is exacerbated by the fact that the government not only seeks to deprive them of their informed consent rights both through deception and coercion, but also to take their freedom and livelihoods for having the temerity to exercise the rights granted to them by statute and the U.S. Constitution.

FIRST CAUSE OF ACTION
DOD VIOLATIONS OF ADMINISTRATIVE PROCEDURES ACT AND DOD RULES & PROCEDURAL REQUIREMENTS

108. Plaintiffs reallege the facts in Paragraphs 1 through 107 as if fully set forth in this Count.

109. The DOD Mandate and the Armed Services Guidance violates AR 40-562, which expressly provide a presumptive medical exemption for service members with natural immunity gained through previous infections. See AR 40-562, para. 2-6(a)(1)(b). The DOD and the Armed Services have also violated the Administrative

Procedures Act insofar as they have effectively amended, modified, and/or repealed AR 40-562 without following applicable rules and procedures for amending, modifying or repeal the regulation. The DOD Mandate modifies AR 40-562 insofar as it: (1) imposes an entirely new vaccine requirement not found in the regulation; and (2) eliminates a medical exemption for natural immunity to which service members could otherwise qualify.

110. The DOD and Armed Services also failed to follow the applicable procedures for amending, modifying or partially repealing a multi-service regulation like AR 40-562, nor did the DOD and Armed Services comply with the requirements of DOD Instruction 6205.02 ("DOD Immunization Program") and other applicable laws and regulations for adopting a new vaccination requirement and eliminating existing exemptions. Further, by failing to follow the required procedures, the DOD violated the Administrative Procedures Act because its actions were made "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

111. The DOD Mandate and the Armed Services Guidance also must be set aside as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(A), insofar as they impose a sweeping vaccine mandate 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 (in particular, that an EUA product may be

administered "as if" it were the licensed product). The DOD Mandate's sole justification or explanation is a conclusory statement that the SECDEF has "determined that mandatory vaccination against [COVID-19] is necessary to protect the Force and defend the American people." Ex. 2, DOD Mandate at 1. Given that the DOD Mandate was issued on the very next day after the FDA Comirnaty Approval, there could not have been any meaningful consideration or analysis of the Comirnaty, the FDA's analysis, the legal consequences or alternatives to compliance with AR 40-562, nor is there any indication that the DOD and SECDEF engaged in the careful and the reasoned decision-making that the APA requires and that service members deserve. *See, e.g., Bayer Healthcare, LLC v. FDA*, 942 F.Supp.2d 17, 25 (D.D.C. 2013).

112. As a result of Defendants' unlawful actions, Plaintiffs will be required either to take an unwanted, unnecessary and unproven vaccine—pursuant to an unlawful order that is itself based on an invalid FDA approval or EUA—or else face the serious disciplinary consequences outlined above that will result in the loss of their livelihoods, careers, benefits, and fundamental rights.

SECOND CAUSE OF ACTION
VIOLATION OF INFORMED CONSENT RIGHTS
10 U.S.C. § 1107a AND 21 U.S.C. 360bbb-3

113. Plaintiffs reallege the facts in Paragraphs 1 through 107 as if fully set forth in this Count.

114. The DOD Mandate and the Armed Services Guidance violate numerous federal laws and implementing rules and regulations governing EUA products and informed consent rights, *see* 10 U.S.C. § 1107a and 21 U.S.C. § 360bbb-3, to the extent that the DOD or the Armed Services mandate the EUA BioNTech Vaccine, or permit the administration of the EUA vaccine pursuant to the DOD Mandate.

115. While the DOD Mandate itself states that only FDA-licensed vaccines may be mandated, *see* Ex. 2, DOD Mandate at 1, the Armed Services Guidance expressly states that the EUA BioNTech Vaccine may be administered "as if" it were the licensed Comirnaty Vaccine pursuant to the DOD Mandate. *See, e.g.,* Ex. 6, Air Force Guidance, § 3.1.1; *see also* Ex. 5, BioNTech EUA Expansion Letter at 2 n.8. The EUA and the licensed product are, however, "legally distinct" (with different formulations) in that the EUA BioNTech Vaccine is subject to the laws governing EUA products, including the right to informed consent, while the Comirnaty Vaccine is subject to the laws governing FDA-licensed products; these two regimes are mutually exclusive.

116. Defendants' position is based on willful misrepresentations of the law—that a product may simultaneously be both an EUA and licensed vaccine for the same indication, and that an EUA vaccine may be mandated "as if" it were the licensed product—for the purpose of deceiving and coercing service members to forfeit their statutory rights to informed consent and to refuse an unlicensed vaccine.

117. Even assuming that DOD Mandate applies only to the licensed, but unavailable, Comirnaty product, and the FDA's newly invented category of "BLA-compliant" EUA-labeled vials, neither the DOD nor the Armed Services have set forth any procedures or requirements that would ensure that only Comirnaty or EUA-labeled, BLA-compliant products are administered pursuant to the mandate. As discussed above, several Plaintiffs have confirmed that neither Comirnaty, nor any EUA-labeled, BLA-compliant vaccine are available. Accordingly, they will be required to take a EUA-labeled, non-BLA-compliant vaccine to comply with the mandate, or else face adverse employment or disciplinary actions. Thus, notwithstanding the express requirements of the DOD Mandate, the DOD and the Armed Services are mandating that service members be injected with unlicensed EUA-labeled and manufactured (*i.e.*, non-BLA compliant) products, in violation of service members' informed consent rights.

118. As a result of Defendants' unlawful actions, Plaintiffs will be required either to take an unwanted, unnecessary, and unproven vaccine, based on an invalid FDA approval and an unlawful order, or else face the serious disciplinary consequences outlined above that will result in the loss of their livelihoods, careers, benefits, and fundamental rights.

THIRD CAUSE OF ACTION
ARMED SERVICES VIOLATION OF DOD MANDATE

119. Plaintiffs reallege the facts in Paragraphs 1 through 107 as if fully set forth in this Count.

120. While the DOD Mandate itself states that only FDA-licensed vaccines may be mandated, *see* Ex. 2, DOD Mandate at 1, the Armed Services Guidance expressly states that the EUA BioNTech Vaccine may be administered "as if" it were the licensed Comirnaty Vaccine pursuant to the DOD Mandate. *See, e.g.,* Ex. 6, Air Force Guidance, § 3.1.1; *see also* Ex. 5, BioNTech EUA Expansion Letter at 2 n.8.

121. The Armed Services Guidance and implementation of the DOD Mandate violate the express terms of the DOD Mandate. As such, any order received by service members to take the unlicensed EUA vaccine, or to comply with the mandate despite the admitted unavailability of the licensed Comirnaty product, is unlawful and must be enjoined by this Court.

122. As a result of Defendant Armed Services' unlawful actions, Plaintiffs will be required to take an experimental, unlicensed EUA vaccine, or else face the serious disciplinary consequences outlined above that will result in the loss of their livelihoods, careers, benefits, and fundamental rights.

FOURTH CAUSE OF ACTION
FDA VIOLATIONS OF APA, FDCA & PHSA DUE TO FDA IMPROPER APPROVAL OF COMIRNATY VACCINE

123. Plaintiffs reallege the facts in Paragraphs 1 through 107 as if fully set forth in this Count.

124. The FDA Comirnaty Approval must be found unlawful and set aside due to numerous distinct violations of the Administrative Procedures Act, the FDCA and PHSA, and the FDA's own rules, regulations, procedures and policies, as well as the requirements set forth in the June 2020 Industry Guidance.

125. FDA's reliance on fundamentally flawed scientific studies, covering participants for months rather than years, in licensing the Comirnaty is a violation of the Administrative Procedure Act insofar its decision is "unsupported by substantial evidence," 5 U.S.C. § 706(2)(E), as well as the FDCA requirements for approvals to be supported by substantial evidence, which includes data from "well controlled" clinical trials. 21 U.S.C. §§ 355(d)-(e). First, the FDA erred in granting approval of Comirnaty without completion of a Phase III clinical trial, required under its own regulations and the June 2020 Industry Guidance. Second, the FDA Comirnaty Approval relied on interim test results for only two months using the full study sample. Pfizer/BioNTech submitted interim results that followed participants for up to six months, but these results are invalid as they are not the result of a "well controlled" clinical trial due to the fact that 93% of participants had been unblinded.

126. The FDA's approval of Comirnaty is also arbitrary and capricious, and unsupported by substantial evidence, insofar as it permitted Pfizer/BioNTech to exclude important "special populations" from clinical trials, in particular: (1) individuals with previous COVID-19 infections; (2) women who are pregnant or

nursing, and whose results also apply to women who want to become pregnant and their unborn children or infants; and (3) those with various medical conditions or history that may be subject to differing or heightened risks than the general population. Despite the fact that the FDA expressly directed vaccine developers to include these groups in the June 2020 Industry Guidance, the FDA not only approved Comirnaty safety or efficacy data for these groups but refused to provide any contraindication or limitations on administering the vaccines to these groups. The FDA's determinations with respect to those with previous infections, and other excluded special populations, are not supported by ***any*** evidence (instead being merely extrapolations or assumptions), much less the "substantial evidence" required by statute. 21 U.S.C. § 355(h). Further, in failing to collect, or require, any evidence for these key populations, the FDA "entirely failed to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983) ("*State Farm*").

127. The FDA also violated the APA insofar as it failed to follow procedures required by law, 5 U.S.C. § 706(2)(D), as well as 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.

128. 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 of the Comirnaty Vaccine fell woefully short of the substantive and procedural requirement sets forth in the FDCA, the PHSA, the FDA's own rules, regulations and policies, and the Administrative Procedures Act.

129. As a result of Defendant FDA's improper and invalid 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 VIOLATIONS OF ADMINISTRATIVE PROCEDURE ACT DUE TO IMPROPER PURPOSE FOR COMIRNATY APPROVAL

130. Plaintiffs reallege the facts in Paragraphs 1 through 107 as if fully set forth in this Count.

131. The FDA's approval of the Comirnaty Vaccine violated the substantive provisions of the FDCA and PHSA, and it exceeded its "statutory jurisdiction, authority or limitations," 5 U.S.C. §706(2)(C), insofar as it based its decision on impermissible criteria, namely, the desire to enable federal vaccine mandates for nearly all Americans, rather than on whether Comirnaty is safe and effective under the FDCA and "safe, pure, and potent" under the PHSA. 42 U.S.C. § 262(C)(i)(1).

132. The FDA's actions were also "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 702(2)(A). Basing its approval decision on improper, impermissible, and undisclosed reasons violates the APA's fundamental requirement that agencies decision must be "the product of reasoned decision making." *State Farm*, 463 U.S. at 43. Where, as here, there is significant evidence of improper purposes, and significant departures from normal decision-making processes, this constitutes evidence of "the FDA's bad faith that renders its decision arbitrary and capricious." *Tummino v. Torti*, 603 F.Supp.2d 519, 544 (E.D.N.Y. 2009) ("*Tummino*") (citation omitted).

133. The strongest evidence that FDA's actions were driven by improper considerations—to facilitate vaccine mandates—is the timing. The FDA Comirnaty Approval was announced just over two weeks before the issuance of the Federal

Employee and Federal Contractor Mandates, along with the proposed OSHA Mandate affecting 100 million employees. This conclusion is reinforced by SECDEF's decision to issue the DOD Mandate the very next day, in violation of DOD procedural requirements, including those for amending multi-service regulations like AR 40-562 and DOD 6205.02. Further evidence of the FDA's improper purpose is its "unprecedented timeline," *see supra* Coleman, note 10, for approval, combined with skipping required procedures and truncating clinical trials needed to demonstrate safety and efficacy studies, despite widespread evidence of rapidly decreasing effectiveness over time.

134. Where an agency's decisions are driven by improper motives or extra-statutory criteria, rather than its scientific expertise, then the courts do not owe the agency deference, or the "presumption of regularity" to which it would otherwise be due. *Citizens to Pres. Overton Park, Inc. v. Volpe,* 401 U.S. 402, 415, 91 S. Ct. 814, 28 L.Ed.2d 136 (1971), *abrogated on other grounds by Califano v. Sanders,* 430 U.S. 99, 97 S.Ct. 980, 51 L.Ed.2d 192 (1977). Nor are courts required to bury their head in the sand and "defer" to the agency's pretextual explanations for its actions and decision making. *See, e.g., Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2574-76 204 L.Ed.2d 978 (2019).

SIXTH CAUSE OF ACTION
FDA AND DOD VIOLATIONS OF FDCA AND PHSA TREATING SAME PRODUCT AS EUA AND LICENSED VACCINE AND

FINDING THAT THE TWO PRODUCTS ARE INTERCHANGEABLE

135. Plaintiffs reallege the facts in Paragraphs 1 through 107 through as if fully set forth in this Count.

136. FDA violated the substantive terms of the FDCA and PHSA governing EUA vaccines and licensed vaccines, and exceeds its statutory authority in violation of Section 706(2)(C) of the APA, by unlawfully trying to establish equivalence between what are two legally distinct vaccines, with different formulations, subject to distinct, and mutually exclusive approval requirements and regulatory regimes.

137. The same product—or same vial of vaccine—cannot be concurrently subject to an EUA and licensed for the same indication or use under distinct regulatory regimes. Yet that is precisely what the FDA has done by: (1) simultaneously licensing Comirnaty Vaccine and re-issuing the EUA for the BioNTech Vaccine for the same indication (individuals 16 years or older); (2) re-issuing and expanding the existing BioNTech Vaccine EUA for children of 12-15 years of age and permitting the licensed Comirnaty Vaccine to be used for this group; and (3) finding that the EUA BioNTech Vaccine and licensed Comirnaty Vaccine can be used "interchangeably" and may be substituted for each other. *See* Ex. 5, BioNTech EUA Expansion Letter at 2 n.8.

138. 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, vacate the Comirnaty approval, and remand this issue to the FDA for reconsideration with appropriate guidance.

139. The FDA licensed a product that is not available, and then informed the general public that the legally and chemically distinct EUA-labeled and manufactured product can be used "interchangeably," and can be substituted, for the licensed product. The FDA provides no justification for ignoring and nullifying these express statutory requirements of the FDCA, which also has the intended effect of nullifying Plaintiffs' rights to informed consent and to refuse the administration of an experimental EUA vaccine.

140. The FDA erred, and acted contrary to law and the FDA's own rules and policies, where it found that the licensed Comirnaty Vaccine "can be used interchangeably" with the EUA BioNTech Vaccine. "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 BioNTech, much less reviewed or approved by the FDA.

141. The FDA's "interchangeability" determination also reverses the temporal order of the licensed product and the interchangeable product. The licensing of the reference product under 42 U.S.C. § 262(a) is the first licensed product, and therefore the basis for determining the interchangeability of the later product. Here, however, the EUA BioNTech Vaccine is the earlier product that was not manufactured in a BLA-compliant manner by the FDA's own admission. Thus, the "interchangeability" determination appears to be a transparent attempt to ***retroactively license*** non-BLA compliant lots of BioNTech Vaccine, solely for the purpose of enabling the vaccine mandate.

142. The EUA BioNTech Vaccine and the Comirnaty Vaccine are not "interchangeable" because they do not have the "same formulation" or number of ingredients, and there is no basis in the publicly available record for concluding that the EUA product is manufactured at the same facilities or using the same processes and components as the Comirnaty Vaccine. *Cf.* Ex. 4, Comirnaty SBRA at 6-8 and 12-13 (largely redacting "Drug Substance," "major manufacturing process stages," "Drug Product," "critical steps" in manufacturing, and manufacturing facilities, and

listing 11 ingredients, including one redacted excipient) *and* Ex. 5, BioNTech EUA Expansion Letter (does not include information on manufacturing process or facilities, and listing 10 ingredients).

143. 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).

144. The DOD and the Armed Services are similarly violating these statutes insofar as they mandate, or permit pursuant to the mandate, providers to administer the EUA BioNTech Vaccine "as if" it were the licensed Comirnaty Vaccine, based on the FDA's foregoing statutory violations and willful statutory misinterpretations. In addition, the DOD and Armed Services have required the administration of EUA-labeled and manufactured products (*i.e.*, neither Comirnaty nor BLA-compliant, EUA-labeled products), while listing the administered product as "Comirnaty" on service member medical records.

145. 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 (and the 100 million other Americans potentially subjected to these mandates) into believing that they can be forced to take an experimental vaccine that they have statutory and constitutional rights to refuse.

SEVENTH CAUSE OF ACTION
VIOLATIONS OF ADMINISTRATIVE PROCEDURE ACT
DUTY TO INSTITUTE NOTICE AND COMMENT RULEMAKING

146. Plaintiffs reallege the facts in Paragraphs 1 through 107 as if fully set forth in this Count.

147. The FDA's decision to grant the Comirnaty Vaccine BLA was driven by improper and extra-statutory considerations, namely, to enable the imposition of vaccine mandates. The FDA sought to avoid its obligations under the Federal Advisory Committee Act and the Administrative Procedures Act—disingenuously claiming that the Comirnaty Vaccine BLA did not raise any "controversial" issues that would have benefitted from the Advisory Committee process—to provide public notice and opportunity for comment on its decisions, and to engage in reasoned decision making, rather than engaging in politically motivated subterfuge.

148. Defendant FDA was required to provide an opportunity for public review of the data and the FDA's policy arguments supporting its decision to grant the BLA through the Advisory Committee, and the consequent opportunity for public notice and comment. The Comirnaty application met nearly all of the

requirements for "high priority" Advisory Committee review in 21 C.F.R. § 14.171(b) because the Comirnaty "pose[d] significant safety hazards," had "narrow risk-benefit considerations" at least for certain special populations like those with natural immunity, utilizes a "novel delivery system or formulation," is the "subject of major scientific or public controversy," and is "subject to special regulatory requirements," *i.e.*, federal vaccine mandates. The FDA brushed all of this aside in concluding that Comirnaty did not raise any controversial issues. The FDA should be required to institute a notice and comment rulemaking proceeding to address the implications of federal vaccine mandates.

149. In addition, this court should direct the FDA to institute public notice-and-comment rulemaking proceedings to address both the scientific evidence regarding the safety and efficacy of the COVID-19 vaccines, alternatives to vaccination or vaccine mandates, the legal basis for a vaccine mandate, whether vaccine mandates can be crafted in a manner that satisfies the requirements of strict scrutiny, and the proportionality of proposed conditions and sanctions for refusal.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully ask this Court to:

A. Issue a declaratory judgment that the DOD Mandate is unlawful and in violation of AR 40-562, DOD procedural requirements, the APA, and federal laws governing informed consent.

B. Issue a declaratory judgment that, because the DOD Mandate permits only fully licensed COVID vaccines to be mandated (*i.e.*, Comirnaty), that the Armed Services Guidance and implementation of the mandate are unlawful to the extent that they permit or require an EUA product to be administered pursuant to the mandate.

C. Enjoin any implementation of the DOD Mandate by the Armed Services or other DOD components, and to stay the effective date thereof.

D. Declare unlawful, vacate and remand the FDA Comirnaty Approval to the FDA for reconsideration consistent with appliable laws and regulations, and any additional guidance this Court may provide, and stay the effective date thereof.

E. Issue a declaratory judgment that the FDA may not simultaneously treat the same product as an EUA product and licensed product for the same indication and use, and that the licensed Comirnaty Vaccine and the EUA BioNTech Vaccine can be used "interchangeably" or "substituted" for each other is unlawful.

F. Find that all Plaintiffs with natural immunity due to previous infection are entitled to a medical exemption from COVID-19 vaccination under AR 40-562.

G. Declare unlawful and enjoin the DOD and the Armed Services from treating the EUA BioNTech Vaccine "as if" it were the licensed Comirnaty Vaccine, and from administering any EUA vaccine pursuant to the DOD Mandate.

H. Direct the FDA to institute notice-and-comment rulemaking to

consider the legal and constitutional issues raised by federal vaccine mandates.

I. Award any other relief this Court may deem just and proper, including but not limited to an award of plaintiffs' costs and attorneys' fees and any other relief this Court may find appropriate.

Respectfully submitted,

/s/ Ibrahim Reyes
Ibrahim Reyes, Esq.
Florida Bar No. 581798
REYES LAWYERS, P.A.
236 Valencia Avenue
Coral Gables, FL 33134
Tel. 305-445-0011
Fax. 305-445-1181
Email: ireyes@reyeslawyers.com

/s/ Brandon Johnson
DC Bar No. 491370
/s/ Travis Miller
TX Bar No. 24072952
Defending the Republic
2911 Turtle Creek Blvd., Suite 300
Dallas, TX 75219
Tel. 214-707-1775
Email: bcj@defendingtherepublic.org
Email: traviswmiller@gmail.com

CERTIFICATE OF SERVICE

This is to certify that I have on this day e-filed the foregoing Plaintiffs' Complaint for Declaratory and Injunctive Relief using the CM/ECF system.

This 8th day of December, 2021.

Respectfully Submitted,

/s/ Brandon Johnson
Brandon Johnson