UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

HOWARD CROSBY, GARY BODONY, ERIC BURGESS, JESSICA CALDWELL, JEFFREY COMRIE, HOWARD CROSBY, PAUL DEE, BRIAN DUFFY, ALLEN HALL, NICHOLAS HALLMARK, JOHN HYATT, MICHAEL JACOBELLIS, KRYSTLE KAGEYAMA, ERIC MARPLE, BRIAN MOODY, EMILY NANKIVELL, JOSHUA SCHWARTZ, and JEREMY SEVERSON, **Plaintiffs,** **vs.** **LLOYD AUSTIN, III, in his official capacity as Secretary of Defense, U.S. Department of Defense** **FRANK KENDALL, in his official capacity as Secretary of the Air Force, Department of the Air Force,** **KARL SCHULTZ, in his capacity as Commandant of the Coast Guard,** **CARLOS DEL TORO, in his official capacity as Secretary of the Navy, Department of the Navy, and** **CHRISTINE WORMUTH, in her official capacity as Secretary of the Army, Department of the Army,** **Defendants.**	**CASE NO.** **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

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

INTRODUCTORY STATEMENT

1. Plaintiffs are a group of service members, on active duty or in the reserves, from each branch of the armed services. Plaintiffs allege that the August 24, 2021 Department of Defense ("DOD") COVID-19 vaccine mandate[1] ("DOD Mandate") is unconstitutional in that the DOD Mandate: (1) exceeds the Secretary's statutory authority; (2) violates the Administrative Procedures Act ("APA"), 5 U.S.C. § 551 *et seq.*; (3) modifies or partially repeals existing regulations governing immunization and medical and religious exemptions, without constitutional due process or following procedures required by law; and (4) violates the statutes and federal regulations requiring informed consent for treatments subject to an emergency use authorization ("EUA"). *See* 10 U.S.C. § 1107a and 21 U.S.C. § 360bbb-3. Further, the Defendants' exemption procedures and threats of severe punishment, including dishonorable discharge and potential imprisonment, violates Plaintiffs' rights under the First and Fifth Amendments to the U.S. Constitution, the No

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

Religious Test Clause of Article VI, Section 3, as well as the Religious Freedom Restoration Act ("RFRA"). 42 U.S.C. § 2000bbb, *et seq*.

2. **DOD Mandate.** The DOD Mandate, in reliance on the Food and Drug Administration's ("FDA") August 23, 2021 licensure of the Pfizer/BioNTech Comirnaty vaccine,[2] imposes the unprecedented requirement that 100% of service members be "fully vaccinated" with an FDA-licensed vaccine. *See* Ex. 2, DOD Mandate, at 1. Service members with previous infections and other medical conditions eligible for exemption under existing Army Regulation 40-562[3] "are not considered fully vaccinated" or exempted. *Id*.

3. **Armed Services Guidance.** Each of the Armed Services has issued implementation guidance that, among other things, sets forth deadlines, religious and medical exemption procedures, and consequences for vaccine refusal. *See* Section III.B ("Armed Services Guidance"). Service

[2] *See* Ex. 3, FDA, BL 125742/0, Comirnaty Vaccine BLA Approval (Aug. 23, 2021) ("Comirnaty Approval Letter"). *See also* Ex. 4, FDA, Summary Basis of Regulatory Action, BLA 125742/0 (Aug. 23, 2021) ("August 23 Comirnaty SBRA"). On the same day, the FDA re-issued and expanded the EUA for the BioNTech Vaccine for "booster" shots to certain individuals because the licensed product, Comirnaty, is "not … available." *See* Ex. 5, FDA, Pfizer-BioNTech EUA Letter at 5 n.9 (Aug. 23, 2021) ("BioNTech EUA Expansion Letter").

[3] *See* Ex. 6, 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 each of the Armed Services active and reserve components. *See* AR 40-562, ch. 3 (7 Oct. 2013).

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, and fundamental constitutional rights.

4. **Statutory and Regulatory Violations.** The Armed Services' guidance violates the express terms of the DOD Mandate (which permits only licensed vaccines to be mandated) and informed consent laws insofar as the service branches mandate the use of EUA vaccines "as if," or "interchangeably" with, the licensed Comirnaty Vaccine, which is not available.[4] The DOD Mandate and the Armed Services Guidance also violate AR 40-562, the APA, and required DOD procedures, insofar as the services have written out of the regulations existing medical exemptions for service members like Plaintiffs who have natural immunity from a previous COVID-19 infection or other

[4] On September 13, 2021, the National Institutes of Health ("NIH") posted an announcement by Pfizer that Pfizer "does not plan to produce any product with these new [Comirnaty] NDCs and labels over the next few months while the EUA authorized product is still available and being made available for U.S. distribution." *See* Ex. 22, NIH-Pfizer Announcement of Comirnaty Unavailability. *See also See* Ex. 5, BioNTech EUA Expansion Letter at 5 n.9; Ex. 24, Summary Basis of Regulatory Action – Comirnaty at 5 (Nov. 8, 2021) ("November 8 Comirnaty SBRA") ("In the U.S., there are no licensed vaccines or anti-viral drugs for the prevention of COVID-19.").

medical conditions that place them at heightened risk from vaccinations. Defendants' elimination of the natural immunity exemption, and adoption of an unprecedented 100% vaccination target, appears to be based on blind faith in the recommendations of the Centers for Disease Control and Prevention ("CDC"), which just acknowledged that it has no evidence whatsoever that any previously infected and recovered person has subsequently infected another person. *See* Ex. 16, CDC November 5 FOIA Response.

5. **First Amendment & Religious Liberty Violations**. Plaintiffs have a fundamental right to exercise their religion free of coercion, and to participate in the military without discrimination on the basis of religion. On information and belief, Defendants are intentionally refusing to recognize Plaintiffs' rights under both the Free Exercise Clause of the First Amendment and RFRA. Defendants intend to force Plaintiffs to choose between their sincerely held religious beliefs, which require them to refuse the currently available COVID-19 vaccines, and severe punishments for refusing an unlawful and unconstitutional vaccination mandate. On information and belief, Defendants intend to purge from the military those with sincerely held religious objections to this vaccine through, among other things, an invasive and unconstitutional religious accommodation request questionnaire and evaluation criteria intended to identify and exclude those with disfavored

beliefs. Together, these measures constitute a prohibited religious test in violation of the No Religious Test Clause. *See* U.S. CONST. ART. VI, § 3 ("no religious Test shall ever be required as a Qualification to any Office or public Trust under the United States"). The Defendants' actions prove the unlawful and exclusionary intent: zero religious accommodation requests have been granted, while thousands have been denied. *See* Ex. 19, Defendants' Compliance Notice.

6. **Fifth Amendment Equal Protection Violations.** The DOD Mandate is a part of a government-wide program that irrationally creates and maintains two classes of service members: (1) those who are "fully vaccinated," who are presumed to pose no danger to health or readiness; and (2) those who are not "fully vaccinated," who are uniformly presumed to be a danger to everyone (including themselves). Class membership ("fully vaccinated") is defined in vague and fluid terms that may change from one day to the next (*i.e.*, based on FDA or CDC booster shot recommendations) and that is based on an unsupported and demonstrably false presumption that "full" vaccination prevents the spread of COVID-19. *See infra* Section V.E (""Fully Vaccinated" Spread COVID-19 & Lack of Evidence for Public Health Benefits from Vaccination"). The DOD Mandate also serves no rational or legitimate purpose insofar as it threatens expulsion and punishment of tens of thousands of

service members for refusal to take an unproven, ineffective, and ***unavailable*** experimental treatment based on well-established medical grounds (*e.g.,* natural immunity) and/or sincerely-held religious beliefs. Even if it were 100% effective (which it is not), the treatment would save at most dozens of lives per year. *See infra* Section I.C ("COVID-19 Risks for DOD Military Personnel"). Going forward, the DOD Mandate would bifurcate society into those who may serve in the U.S. military, and those who are barred from serving.

7. **Fifth Amendment Due Process Violations.** The DOD Mandate threatens to deprive Plaintiffs of life, liberty and property without the minimal requirements of constitutional due process. The COVID-19 "vaccines" are experimental and carry a non-negligible risk of death or serious injury; conversely, vaccine refusal will end their military careers, bar them from other federal or private employment, and may result in loss of their freedom, as well as retirement and other governmental benefits to which they would otherwise be entitled. The Defendants have also violated Plaintiffs' due process rights insofar as they have added a new vaccination requirement, while eliminating existing exemptions, without notice, procedures required by law, or even bothering to change the text of existing rules.

8. **Fluid & Changing Meanings of "Vaccine" and "Fully Vaccinated."** The DOD has mandated an experimental medical treatment

that, while referred to as a "vaccine," fundamentally differs from traditional vaccines biologically and in its effects; COVID-19 vaccines do not provide immunity or prevent infection or transmission. In response to the widespread public recognition of the differences, the CDC changed its definition of "vaccine" and "vaccination" within a week after FDA's Comirnaty Approval to treatments that provide only "protection" rather than "immunity." *See infra* Section V.D ("Fluid Definition of "Vaccine," "Vaccination" & "Fully Vaccinated""). The DOD is not due any deference for its expertise where it has outsourced decision-making to the willfully blind CDC, which has intentionally refused to collect or consider evidence on "breakthrough infections" or natural immunity that may contradict its preferred policy outcome (*i.e.*, universal vaccination). *See infra* Ex. 16, CDC November 5 FOIA Response. The DOD's definition of "fully vaccinated"—two doses of Pfizer or Moderna or one dose of Johnson & Johnson—relies on the CDC's recommendations that are subject to change at any time. As soon as the FDA determines that full vaccination requires a third dose (as in Israel, and as currently proposed in the U.S.), or additional doses, then all formerly fully vaccinated service members will be deemed unvaccinated and will be compelled to take however many additional doses the FDA or CDC recommend that week.

9. **Relief Requested.** Plaintiffs file this action seeking an Administrative Stay, Preliminary Injunction and Declaratory Judgment requesting that this Court:

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

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

(3) 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;

(4) Declare unlawful and unconstitutional the DOD and Armed Services requirements and criteria for assessing religious accommodation requests;

(5) Order Defendants to cease targeting Plaintiffs for their religious beliefs;

(6) Order Defendants to grant Plaintiffs' requests for medical exemptions and religious accommodations from the DOD Mandate; and

(7) Declare the DOD Mandate and Defendants' implementation thereof as unconstitutional, in violation of the No Religious Test Clause, and the First and Fifth Amendments of the U.S. Constitution.

10. 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, the All Writs Act, 28 U.S.C. § 1651, and 42 U.S.C. § 1983.

PARTIES

11. 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 guidance that they have received (including orders to receive EUA vaccines in place of licensed vaccines), and administrative and disciplinary actions.

12. Plaintiff HOWARD CROSBY is a Sergeant Major ("SGM") in the US Army Reserves. He is domiciled in Brandon, Florida, and currently stationed in Texas. He has honorably served the United States of America for 23 years, and he has been awarded the U.S. Central Command star performer award from General (now SECDEF) Austin, Defense Meritorious Service Medal, Joint Commendation Medal, Army Commendation Medal, the Joint Service Achievement Medal, as well as many others. SGM CROSBY is willing to take the FDA-licensed Comirnaty vaccine, but not the EUA BioNTech Vaccine. Despite the fact that he has never declined immunization with an FDA-licensed Comirnaty vaccine, on October 12, 2021, he received counseling from his commanding officer for vaccine refusal. Subsequently, he has been unlawfully pressured to sign counseling statements and he has been threatened with a letter of reprimand, receiving a less than honorable

discharge, and loss of retirement and veterans benefits to which he is entitled. He has not been on duty since June 2021, and his command's action raise serious questions as to whether he can be counseled or otherwise sanctioned under the UCMJ while not on duty. He has not pursued a religious or medical exemption due to his belief that the vaccine mandate is an unlawful order.

13. Plaintiff GARY BODONY is a Lieutenant Colonel ("LTC") in the Kansas Air National Guard. He is domiciled and currently stationed in Kansas. He has served for 19 years as a Combat Pilot and an Inspector General. He has received numerous commendations including Air Force Commendation Medals, Meritorious Unit Award, AF Outstanding Unit Award, Combat Readiness Medal, National Defense Service Medal, and the Global War on Terrorism Service Medal. LTC BODONY has filed a religious accommodation request, which is still pending. He is being threatened with a dishonorable discharge for his refusal to receive the COVID-19 vaccination. He also has natural immunity from a documented previous COVID infection, including a positive antibody test. Along with the threat of dishonorable discharge after serving his country for 19 years, he also faces the loss of retirement benefits, veterans and other governmental benefits, even though he is eligible for retirement in less than three months on February 22, 2022.

14. Plaintiff ERIC BURGESS is a Logistics Readiness Officer in the Michigan Air National Guard (as well as Department of the Army Civil Service employee). He is domiciled and stationed in Michigan. MR. BURGESS has served for over 16 years. He has deployed to the Middle East twice for Operation Iraqi Freedom/Enduring Freedom and Operation Inherent Resolve, and he has been awarded a Force Commendation Medal, three Air Force Achievement Medals, and five Meritorious Service Medals, among many others. MR. BURGESS has a previous documented COVID-19 infection in June 2020, but due to Air Force policy is not eligible for medical exemption. He has submitted a religious accommodation based on his sincerely held religious beliefs and refusal to participate in the act of evil underlying the vaccines' development. Despite being recommended for approval by his chaplain, he has been informed by his Commander that it will almost certainly be denied, regardless of its contents, merits, or sincerity, and that submission will result in administrative separation. The terms of his separation will likely result in the loss of both the Air Force Time in Service benefits to which he is entitled, as well as the loss of his Civil Service position, pension, and benefits.

15. Plaintiff JESSICA CALDWELL is a Master Sergeant ("MSGT") in the United States Air Force Reserve. She is domiciled in Nevada and currently stationed in Georgia. She has served for 16 years and has received multiple

high-level achievement awards, including the U.S. Air Force Special Recognition Ribbon. On September 28, 2021, MSGT CALDWELL submitted her request for religious accommodation, which was denied on October 27, 2021. MSGT CALDWELL is also in remission from cancer; when she brought up her medical concerns regarding vaccination, she was advised that her history of cancer would not be grounds for medical exemption.

16. Plaintiff JEFFREY COMRIE is a Captain ("CAPT") in the United States Marine Corps. He is domiciled and stationed in North Carolina. CAPT COMRIE has served his country for five years, earning his Marine Corps wings as a MV-22 (Osprey) pilot in November 2019, as well as the Global War on Terror Service Medal and the National Defense Service Medal. CAPT COMRIE tested positive for COVID-19 on March 12, 2021, but due to Marine Corps policy is not eligible for exemption on that ground, nor on the grounds that the experimental vaccines may interfere with a documented fertility condition. He submitted his request for a religious accommodation on September 10, 2021, which was denied. If CAPT COMRIE's appeal is denied, he will face a Board of Inquiry followed by the potential of an Administrative Discharge with a service Characterization of General Under Honorable Conditions, which would result in the denial of veterans and other governmental benefits and damage his future employment prospects. Due to his submission of a religious

accommodation request, he has already been denied the opportunity to deploy with his unit; even if his appeal is granted, he will still likely be ineligible for future deployments or promotion.

17. Plaintiff PAUL DEE is a Captain in the United States Navy. He is domiciled in New Jersey and is currently the Commanding Officer of the New York Navy Reserve Center New York City. CAPT DEE has served honorably for 28 years, and has been awarded the Defense Meritorious Service Medal, three Meritorious Service Medals, the Joint Service Commendation Medal, two Navy Commendation Medals, one Army Commendation Medal, and three Navy Achievement Medals. After release of the SECDEF Memo, he was urged by his command to be vaccinated by September 2, 2021, despite the unavailability of the licensed vaccine. CAPT DEE submitted a religious accommodation request on August 30, 2021, which was recommended for denial on September 17, 2021. He has also submitted a request to resign his command September 7, 2021, with a May 1, 2022 retirement date to ensure that he remained within the 180-day administrative exemption under AR 40-562/BUMEDINST 6230.15B. His Commanding Officer urged him to request a November 28, 2021 retirement date, or else face Detach for Cause ("DFC") proceedings; CAPT DEE has now received a DFC request, which may result in criminal charges and dishonorable discharge.

18. Plaintiff BRIAN R. DUFFY is an Ensign ("ENS") in the United States Navy and a U.S. Navy SEAL. He is domiciled and currently stationed in California. He has honorably served his country for fourteen years. During this time, he has completed two combat deployments in the Middle East; he was selected for the highly competitive commissioning program "Seaman to Admiral" in 2017; and he has received a Joint Commendation Medal, Army Achievement, two Navy Achievement Medals, Campaign medals for Inherent Resolve, Global War on Terror, and Operation Freedom Sentinel. On September 30, 2021, ENS DUFFY requested a religious exemption, which was denied on November 1, 2021. Despite having a documented previous COVID-19 infection, Naval Special Warfare will not grant or consider a medical exemption; and any medical exemption would automatically disqualify ENS DUFFY from being a SEAL.

19. Plaintiff ALLEN HALL is Senior Master Sergeant (SMSGT/E-8) in the United States Air Force Active Guard Reserve ("AGR") program. He is domiciled in Georgia and stationed in Ohio. SMSGT HALL has served honorably for 21 years. His awards and decorations include the Meritorious Service Medal, the Air Force Commendation Medal (with one device), the Air Reserve Forces Meritorious Service Medal (with 5 devices), and the Global War on Terrorism Service Medal. On October 12, 2021, SMSGT HALL submitted a

request for a temporary religious exemption (120 days) that would be valid only long enough for his requested retirement date of May 30, 2022. On October 27, 2021, his request was denied. SMSGT HALL was given 72 hours to submit an appeal, which he did on October 30, 2021; his appeal is still pending

20. Plaintiff NICHOLAS HALLMARK is a Chief Gunners Mate ("CGM") in the United States Coast Guard. He is domiciled and currently stationed in Texas. CGM HALLMARK is a 21-year veteran of the United States Coast Guard, earning four Coast Guard Achievement Medals, seven Coast Guard Good Conduct Medals, the Iraq Campaign Medal, the Global War on Terrorism Medal, the Global War on Terrorism Expeditionary Medal and two Coast Guard Overseas Service Medals. On October 13, 2021, CGM HALLMARK was informed that his request for medical exemption based on a previous documented COVID-19 infection had been denied. Also, on October 13, 2021, he received disciplinary paperwork ordering him to report to his base's clinic to receive the first dose of an FDA-approved vaccine, but he did not receive a vaccine because the FDA-licensed Comirnaty vaccine was not available. He has subsequently received additional written disciplinary actions for vaccine refusal, including 50-mile travel restrictions and denial of promotion, loss of approved retirement date, and a less than Honorable discharge.

21. Plaintiff JOHN HYATT is Chief Warrant Officer-4 ("CWO-4") in the United States Marine Corps. He is domiciled and currently stationed in Hawaii. CWO-4 HYATT has proudly served in the United States Marine Corps for the past 26 years, and has been awarded three Meritorious Service Medals, three Navy and Marine Corps Commendation Medals, one Navy and Marine Corps Achievement Medal, one Global War on Terrorism Service Medal, four Marine Corps Good Conduct Medals, two National Defense Medals, and many other awards and commendations. On September 8, 2021, CWO-4 HYATT was informed that the vaccination deadline was September 9, 2021. After confirming with his base's medical facility that the FDA-licensed Comirnaty vaccine was not available there or anywhere else in Hawaii, he challenged the legality of the order. On October 6, 2021, CWO-4 HYATT submitted a religious accommodation request, which is still pending.

22. Plaintiff MICHAEL JACOBELLIS is a Major ("MAJ") in the United States Marine Corps with twelve years of service currently serving as an Air Defense Officer at Camp Humphreys, South Korea. His professional achievements include the Navy and Marine Corps Achievement Medal, the Navy and Marine Corps Commendation Medal (with one device) and recognition as the Marine Corps Aviation Association Command and Control Officer of the Year in 2017. On September 14, 2021, MAJ JACOBELLIS

submitted a religious accommodation request, which was denied October 7, 2021. When MAJ JACOBELLLIS challenged the legality of the order based on the unavailability of the FDA-licensed Comirnaty vaccine, he was informed that he will be required to take an EUA vaccine if Comirnaty remains unavailable. He is also willing to take a vaccine that uses traditional technology (*e.g.*, Novavax), rather than mRNA technology, as soon as it is available, and FDA approved. As of November 28, 2021, MAJ JACOBELLIS faces administrative separation and loss of veterans, retirement, health and other benefits. This would impose a severe hardship because he has a child who is reliant on his military medical benefits for follow-on care after being born with a congenital heart defect that required open-heart surgery four days after the child was born.

23. Plaintiff KRYSTLE KAGEYAMA is a Lieutenant Commander ("LCDR") in the United States Navy Reserves. She is domiciled in Virginia and currently stationed in Nebraska. LCDR KAGEYAMA has served for over 18 years, and she has been awarded an Afghanistan Campaign Medal, two Armed Forces Reserve Medals with "M" Device, one Global War on Terrorism Expeditionary Medal, two Joint Service Commendation Medals, three Navy and Marine Corps Achievement Medals, as well as many others. She has been selected as Commander for FY22, but due this promotion has been delayed or

denied due to vaccine refusal. On October 17, 2021, LCDR KAGEYAMA submitted her request for religious exemption and accommodation, which is still pending.

24. Plaintiff ERIC MARPLE is a Major in the United States Army. He is domiciled and stationed in Kentucky. MAJ MARPLE has served on active duty, in the reserves and inactive ready reserves since 2000. MAJ MARPLE is Doctor of Osteopathic Medicine, internal medicine residency trained, gastroenterology fellowship trained, and double board certified. He was counseled for vaccine refusal starting on September 20, 2021. He submitted his request for religious exemption on September 24, 2021, which is currently pending. As a physician, he is opposed to vaccination because he believes he has natural immunity from a previous infection; because he is a 40-year old physician in good health with minimal risk factors; and because the risks outweigh the benefits for someone in his age and risk categories.

25. Plaintiff BRIAN MOODY is a Major in the Pennsylvania Air National Guard Major (Active Guard Reserve). He is domiciled and currently stationed in Pennsylvania. MAJ MOODY has exemplary service to the United States as an enlisted airman and Air Force Officer and pilot for almost 20 years, serving in seven combat deployments, including active duty as part of Operation Enduring Freedom. He has been awarded the Meritorious Service

Medal, four Air Medals, the Aerial Achievement Medal, the Air Force Commendation Medal, the National Defense Service Medal, and many other awards and commendations. On October 13, 2021, MAJ MOODY has submitted a religious accommodation request, which is still pending; he has been informed that even if approved, however, he would not be deployable and therefore no longer useful and should leave the service. MAJ MOODY also has a documented previous COVID infection, but he has not submitted a medical exemption due to the Air Force's categorical elimination of this previously available exemption.

26. Plaintiff EMILY NANKIVELL is a Major in the United States Air Force Reserves. She is domiciled and currently stationed in Ohio. MAJ NANKIVELL has served her country in the United States Armed Forces for over 18 years, and she has been a C-17 pilot for the last 12 years. She served a one-year deployment to Iraq, volunteered for the Army Honor Guard, and flew 64 combat sorties in and out of tactical war zones. She has been awarded a Combat Air Medal, Army Achievement Medal, and an Honor Guard Volunteer Service Award. On November 1, 2021, her request for religious exemption was denied. On November 9, 2021, MAJ NANKIVELL subsequently filed an appeal, which is still pending disposition.

27. Plaintiff JOSHUA SCHWARTZ is a Petty Officer First Class ("PO1") in the United States Navy. He is domiciled and is currently stationed in California. PO1 SCHWARTZ has honorably served his country in the United States Navy for the past eight years. He has been awarded a Navy and Marine Corps Achievement Medal, a National Defense Service Medal, two Good Conduct Medals, a Global War on Terrorism Service Medal, and a Sea Service Deployment Ribbon. On September 14, 2021, PO1 SCHWARTZ submitted a request through his chain of command for medical exemption, based on his previous documented COVID-19 infection and positive antibody test, but the application was not submitted or included in his medical records. As a result of declining to take the unlicensed vaccine, he has received a Page 13 counseling statement, will be removed from his duties as an instructor on November 14, 2021, and will begin administrative separation and discharge process on November 28, 2021.

28. Plaintiff JEREMY SEVERSON is an LCDR in the United States Navy. He is domiciled in Milton, Florida, and is currently stationed in Virginia. LCDR SEVERSON has 18 years of honorable and faithful service, after enlisting in 1999 and then as an Officer after graduating from the United States Naval Academy in 2007, earning both Navy and Marine Corps Achievement Medals and the Navy Commendation Medal. LCDR SEVERSON

has a previous documented COVID-19 infection, diagnosed on December 12, 2020, but did not submit a request for medical exemption because his primary care physician advised him that the Navy does not recognize previous infection as a ground for medical waiver. On September 17, 2021, he submitted a religious accommodation request, which was denied November 1, 2021. As of November 28, 2021, he faces dismissal from the Navy and a service characterization less than HONORABLE.

29. 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.

30. 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.

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

32. 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.

33. Defendant United States Coast Guard is under the Department of Homeland Security, which is a Department of the United States Government. It is led by Commandant Admiral Karl L. Schultz.

JURISDICTION AND VENUE

34. This case arises under federal law, namely the First, Fifth, Ninth, and Fourteenth Amendments of the United States Constitution, U.S. CONST. ART VI, § 3; U.S. CONST. AMENDS. I & V; the APA, 5 U.S.C. § 551, *et. seq.*; 10 U.S.C. § 1107a; 21 U.SC. § 360bbb-3; the RFRA, 42 U.S.C. § 2000bb-1, *et seq.*; and AR 40-562.

35. The DOD Mandate and Armed Services Guidance 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.

36. 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.

37. Venue is proper in this Court pursuant to 28 U.S.C. §1402 and 28 U.S.C. § 1391(e) because certain 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, have or 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

38. 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 Section 319 of the PHSA, 42 U.S.C. § 247d *et seq*.

B. COVID-19 Mortality Risks

39. 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.

40. Based on data available through June 27, 2021, for each 18-29 year-old that dies from COVID-19, four (4) 30-39 year old individuals die, ten (10) 40-49-year-olds, thirty-five (35) 50-64-year-olds die, ninety-five (95) 65-74-

year-olds die, 230 75-84-year-olds die, and 610 over 85 years of age die. *See* Ex. 14, McCullough Decl., Table 2.

C. COVID-19 Risks for DOD Military Personnel

41. As of October 27, 2021, there have been a total of 249,858 cases among military personnel since the beginning of the pandemic in January 2020 (*i.e.*, approximately 20 months). Of these, 2,266 (or less than one percent) were hospitalized, with a total of 71 deaths (*i.e.*, less than 0.03 percent or less than one per 3,500 cases).[5] 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. *See infra* Section V.G ("Alternative and Effective Treatments for COVID-19").

II. FEDERAL VACCINE MANDATES

42. On September 9, 2021, President Biden announced a series of executive orders and administrative actions that would impose vaccine mandates on "100 million Americans – two thirds of all workers."[6] First, he

[5] *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 Nov. 1, 2021).

[6] *See* Ex. 12, President Joseph R. Biden, *Remarks by President Biden on Fighting the COVID-19 Pandemic* (Sept. 9, 2021), available at: https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-

issued Executive Order 14,043, which requires vaccination for all federal employees,[7] and Executive Order 14,042, requiring vaccination for all federal contractors.[8] Second, he announced the expansion of an existing vaccination mandate[9] to cover 17 million healthcare workers. *See* Ex. 12, Biden Mandate Statement, at 5.

43. In the same speech, President Biden announced that he had 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. *Id.* at 5. On November 5, 2021, the OSHA Mandate was published in the *Federal Register*,[10] but was stayed one week later by the Fifth Circuit because the OSHA Mandate "runs afoul of the statute from which [OSHA] draws its power and, likely, violates

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by-president-biden-on-fighting-the-covid-19-pandemic-3/ (last visited Nov. 8, 2021) ("Biden Mandate Statement").

[7] *See* Exec. Order 14,043, 86 Fed. Reg. 50,989, "Requiring Coronavirus Disease 2019 Vaccination for Federal Employees" (Sept. 9, 2021) ("Federal Employee Mandate").

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

[9] *See* OSHA, Interim Final Rule, *Occupational Exposure to COVID-19; Emergency Temporary Standard*, 86 Fed. Reg. 32,376 (June 21, 2021).

[10] *See* OSHA, Interim Final Rule, *COVID-19 Vaccination and Testing; Emergency Temporary Standard*, 86 Fed. Reg. 61,402 (Nov. 5, 2021).

the constitutional structure that safeguards our collective liberty." *See BST Holdings, LLC v. OSHA*, --- F.4th ---, 2021 WL 5279381, at *9 (5th Cir. Nov. 12, 2021) ("*OSHA*").

III. THE DOD MANDATE AND ARMED SERVICES GUIDANCE

A. DOD Mandate

44. 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. The Secretary further directed that mandatory vaccination "will only use COVID-19 vaccines that receive full licensure from the [FDA], in accordance with FDA labeling and guidance,"[11] and that vaccination requirements are "to be implemented consistent with DoD Instruction 6205.02." *Id.* The SECDEF Memo does not cite any statute, regulation, executive order, or any other legal basis for the DOD's authority to issue the mandate.

45. The only service members expressly exempted are those "actively participating" in vaccine trials. *Id.* "Those with previous COVID-19 infection

[11] This statement from the SECDEF Memo is consistent with the DOD position reported in the July 6, 2021 Memorandum Opinion for the Deputy Counsel to the President, *Whether Section 564 for the Food, Drug, and Cosmetic Act Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization* (July 6, 2021) ("OLC EUA Opinion") (attached as Ex. 23).

are not considered fully vaccinated," *id.*, nor are they provided a medical exemption. The SECDEF Memo does not mention AR 40-562, the medical exemptions provided thereunder, or the legal basis for SECDEF's action; nor is there any suggestion that the SECDEF Memo repeals, modifies, or waives AR 40-562 or any other currently effective rule, regulation, directive, or instruction.

B. Armed Services Guidance

1. Vaccination Requirements & Deadlines

46. For the Air Force, unless exempted, all active-duty personnel must be fully vaccinated by November 2, 2021, and all reserve and National Guard components must be fully vaccinated by December 2, 2021.[12] All active-duty Army personnel are required to be fully vaccinated by December 15, 2021, and all reserve component personnel are required to be fully vaccinated by June 30, 2022.[13] All active-duty Navy personnel are required to be fully vaccinated by November 28, 2021, and all reserve component personnel are required to be fully vaccinated by December 28, 2021.[14] The same deadlines apply for the

[12] *See* Ex. 7 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"); Secretary of Air Force Memorandum for Air Force Commanders (Sept. 3, 2021).

[13] *See* Ex. 8, Dept. of the Army, *Fragmentary Order 5 to Headquarters Dept. of the Army Executive Order 225-21* (Sept. 14, 2021) ("Army Guidance").

[14] *See* Ex. 10a, Secretary of the Navy, "2021-2022 Department of Navy Mandatory COVID-19 Vaccination Policy," ALNAV 062/21 (Aug. 30, 2021) ("Navy Guidance").

Marine Corps.[15]

2. Interchangeability of EUA and Licensed Vaccines

47. On September 14, 2021, Assistant Secretary of Defense for Health Affairs Terry Adirim directed Armed Services Surgeons General and DOD components that "health care providers ***should*** use doses distributed under the EUA to administer the vaccination as if the doses were the licensed [Comirnaty] vaccine."[16] The Air Force Guidance also expressly directs healthcare providers to use the EUA BioNTech Vaccine "interchangeabl[y]" 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." Ex. 7, Air Force Guidance, ¶ 3.1.1 (emphasis added); *see also id.*, ¶ 5.3.2.1 (same).

See also Ex. 10b, "2021-2022 Navy Mandatory COVID-19 Vaccination and Reporting Policy," NAVADMIN 190/21 (Sept. 1, 2021) ("NAVADMIN 190/21"); Ex. 10c, "COVID-19 Consolidated Disposition Authority," NAVADMIN 225/21 (Oct. 14, 2021) ("NAVADMIN 225/21").

[15] *See* Ex. 9a, MARADMIN, "Mandatory COVID-19 Vaccination of Marine Corps Active and Reserve Components," MARADMINS Number: 462/21 (Sept. 1, 2021) ("Marine Corps Guidance"); *see also* Ex. 9b, MARADMIN, "Supplemental Guidance to Mandatory COVID-19 Vaccination of Marine Corps Active and Reserve Components," MARADMINS Number: 533/21 (Oct. 7, 2021) ("MARADMIN 533/21").

[16] *See* Ex. 11, Terry Adirim, Asst. Sec. of Defense Memo to Surgeons General, *Mandatory Vaccination of Service Members Using the Pfizer-BioNTech COVID-19 and Comirnaty COVID-19 Vaccines* at 1 (Sept. 14, 2021) (emphasis added) ("Surgeons General Guidance"). *Cf.* Ex. 5, FDA BioNTech EUA Expansion Letter, at 2 n.8 (EUA and licensed product "can" be used interchangeably).

3. Medical Exemptions & Previous Infections

48. The Air Force, Navy and Marine Corps categorically deny the AR 40-562 exemption for those with documented previous infections. *See* Air Force Guidance, ¶ 4.5.1.2 ("Previous infection or positive serology do not exempt Service members from full vaccination requirements."); NAVADMIN 190/21, ¶ 3.d.1 ("A history of COVID-19 disease and/or positive serology does not exempt a Navy service member from receiving a COVID-19 vaccine."); MARADMINS 462/21, ¶ 3.a (same). The Army Guidance states that "service members with previous infections or positive serology are not automatically exempt," ¶ 3.D.8.B.6, and the Army has indicated that it will not grant, or even consider, requests for exemptions based on previous documented infection. Further, none of the Armed Services provide exemptions for women who are pregnant or for other medical conditions eligible for exemption under AR 40-562.

4. Religious Accommodation Requests

49. The DOD and Armed Services guidance, procedures, and evaluation criteria for religious accommodation requests are vague at best and have varied greatly over time and by service (or even by unit) since the announcement of the DOD Mandate on August 24, 2021. It would not be possible to provide a meaningful summary of these procedures; instead, Plaintiffs have attached Defendants' filings in a proceeding raising similar religious liberty claims (*Navy Seal 1 v. Biden*, M.D. Fla. Case No. 8:21-cv-2429)

summarizing the procedures in effect as of November 12, 2021. *See* Ex. 19, Defendants Compliance Notice.[17]

50. Whatever guidance the DOD and Armed Services have provided regarding religious accommodation requests and the criteria for grant or denial, the results are unequivocal. The DOD and Armed Services' records indicate that well over ten thousand requests have been submitted, and thousands have been denied, yet to date zero religious accommodation requests have been granted. *See* Ex. 19 & *infra* Section VI.D ("Defendants Have Systematically Denied Religious Accommodation Requests.").

5. Disciplinary Actions for Vaccine Refusal

51. The guidance provided by each of the Armed Services states that the requirement to be vaccinated is a "lawful order" and that any service members who refuses to take the vaccine will be subject to the full range of administrative and disciplinary actions under the UCMJ. *See* Ex. 7, Air Force Guidance, ¶ 5.3; Ex. 8, Army Guidance, ¶ 3.D.8.B & Annex 20; Ex. 9a, Marine Corps Guidance, ¶ 3.1; Ex. 10a, Navy Guidance, ¶ 5.

[17] *See also id.* (*citing* DOD Instruction 1300.17, "Religious Liberty in the Military Services" (Sept. 1, 2020) (DOD generally); DAFI 52-201, "Religious Freedom in the Department of the Air Force" (June, 23, 2021) (Air Force); Army Regulation 600-20, "Army Command Policy" (July 24, 2020) (Army); BUPERSINST 1730.11A (Navy and Marine Corps)).

C. UCMJ Sanctions for Vaccine Refusal

52. 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.*

53. Dishonorable discharges are typically given for the most serious offenses such as murder, fraud, desertion, treason, espionage, and sexual assault. *See Manual for Courts-Martial, United States* (2019 ed.), R.C.M. 1003(a)(8). 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.

IV. FDA EMERGENCY USE AUTHORIZATION AND LICENSING OF COVID-19 TREATMENTS

A. FDA Emergency Use Authorization for COVID-19 Vaccines

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

55. There are significant differences between licensed vaccines and those subject to EUA that render them "legally distinct." Ex. 5, 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.

B. Informed Consent Requirements for EUA Products

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

the product." 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III).[18] 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 Caregivers" be made available to every potential vaccine recipient. Each Fact Sheet includes the statement that the recipient "has the option to accept or refuse" the vaccine. *See, e.g.,* Ex. 13, FDA, "Fact Sheet for Health Care Providers Administering Vaccine (Vaccination Providers)," at 9 (Aug. 23, 2021).

C. FDA Vaccine Licensing and Approval

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

[18] The DOD may override service members' informed consent rights, provided that it complies with the requirements of 10 U.S.C. § 1107 (investigational new drugs) or § 1107a (EUA products), including a Presidential Waiver. The DOD has not requested or obtained a Presidential Waiver.

covers specific labeling and manufacturing requirements, including the manufacturing location, process, and storage requirements.

D. Comirnaty Approval and BioNTech EUA Expansion

58. On August 23, 2021, the FDA approved the May 18, 2021, Comirnaty application for individuals 16 years or older. 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.[19]

59. 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 extended and expanded the existing EUA because Comirnaty is not available. *See* Ex. 5, BioNTech EUA Expansion Letter at 5 n.9.

60. On September 13, 2021, the National Institutes of Health ("NIH") posted an announcement by Pfizer that Pfizer "does not plan to produce any product with these new [Comirnaty] NDCs and labels over the next few months while the EUA authorized product is still available and being made available

[19] 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 Vaccines that BioNTech deemed BLA-compliant for FDA review and release. *See* Ex. 4, August 23 Comirnaty SBRA at 27 (Section 10.a "Identification of BLA Lots").

for U.S. distribution." *See* Ex. 22, NIH-Pfizer Announcement of Comirnaty Unavailability. On November 8, 2021, the FDA confirmed that Comirnaty remains unavailable in the United States. *See* Ex. 24, November 8 Comirnaty SBRA, at 5.

E. Differences Between EUA and Licensed Vaccines

61. The FDA has incorrectly asserted that the EUA BioNTech Vaccine and the conditionally approved Comirnaty Vaccine have the "same formulation" and can be used "interchangeably." Ex. 5, BioNTech EUA Expansion Letter at 2 n.8. However, there is no basis in the public record for the FDA's position that the two products are the "same." Nor is there any basis in the public record that the two admittedly "legally distinct" products are "interchangeable."[20]

62. In any case, there is no evidence in the public record for finding that the EUA and licensed products are the same, and ample evidence for finding that they are not. The most detailed information on Comirnaty's

[20] The only reasonable interpretation of the FDA's use of the term "interchangeable" is that it was intended to constitute a legal determination that the two distinct products were "interchangeable" as defined under the same provision of the PHSA, *see* 42 U.S.C. §§ 262(i) & 262(k). The FDA subsequently admitted that, despite the use of this specific term defined in the same provision of the PHSA pursuant to which it approved Comirnaty, it instead meant to use this term in a "scientific" or "factual" sense, rather than in the "legal" sense. *See* Ex. 20, Marks Declaration ¶¶ 9-11 (submitted in *Doe v. Austin*, Case No. 3:21-cv-1211, ECF No. 31-13 (N.D. Fla. Oct. 21, 2021)).

composition, manufacturing process, manufacturing locations and other matters approved by the FDA is included in the FDA Comirnaty SBRA, nearly all of which is redacted, *see* Ex. 4, August 23 Comirnaty SBRA, at 6-8, while most of this information was never made available in the Pfizer/BioNTech EUA applications or authorizations. To the extent such information is available, it reveals that there are differences in the composition of the EUA and licensed products.[21] There is also no dispute that the FDA EUA addressed manufacturing processes or locations, which are solely addressed in the Comirnaty licensure. *See* Ex. 4, August 23 Comirnaty SBRA, at 12-13.

F. Pfizer/BioNTech Safety & Efficacy Data Reviewed by FDA

63. The DOD expressly relied on the FDA's approval of Comirnaty in issuing the DOD Mandate. The safety and efficacy data provided by Pfizer/BioNTech, and reviewed by FDA, suffers from serious procedural, evidentiary, and methodological defects that are briefly described below. In light of these obvious defects, the FDA opposes the full release of the studies

[21] *See* Ex. 21, *Doe v. Austin*, Case No. 3:21-cv-1211, Order Denying TRO/PI Motion at 7 & n.5 (M.D. Fla. Nov. 12, 2021). *Compare* Ex. 4, August 23 Comirnaty SBRA at 9 (listing 11 components, including .450 ml per vial of a redacted excipient), *with* Ex. 5, BioNTech EUA Expansion Letter, at 7 (listing 10 components, all of which also appear on the Comirnaty SBRA) *and* Ex. 24, November 8 Comirnaty SBRA, at 7-8 (listing 11 components, but removing .450 ml per vial of redacted excipient and replacing with unspecified amount of water as 11th component).

and other safety and efficacy data on which it relied for Comirnaty approval, which was reviewed in a little over three months, until 2076.[22]

64. 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. *See* Ex. 19, McCullough Decl., ¶ 47. The clinical trials also did not include any pregnant or lactating women.[23] 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.

65. While the Phase 3 clinical trials included a large and statistically significant number of participants, the full sample trial was truncated in unprecedented fashion. The original trial participants were followed for only

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[22] *See Pub. Health & Med. Profs. For Transparency v. FDA*, Second Joint Report at 7-8, Case No. 4:21-cv-01058, ECF No. 20 (N.D. Tex. Nov. 15, 2021), available at: https://www.sirillp.com/wp-content/uploads/2021/11/020-Second-Joint-Status-Report-8989f1fed17e2d919391d8df1978006e.pdf (last visited Nov. 17, 2021) (proposing to process 329,000 pages at a rate of 500 pages per month, *i.e.*, 658 months or 55 years).

[23] *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).

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 FDA's June 2020 Industry Guidance.[24] 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."[25]

66. The FDA fails to acknowledge, however, that the results of the trials beyond the first two months are of questionable validity due to fundamental methodological error that infects all results and undermines any conclusions that can be drawn from them. In its May 18, 2021 application,[26] 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

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[24] *See* FDA, *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 Nov. 8, 2021).

[25] *See FDA Approves First COVID-19 Vaccine* (Aug. 23, 2021) ("FDA Comirnaty Press Release"), *available at* https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited Nov. 8, 2021). The FDA 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). *See* Ex. 3, FDA Comirnaty Approval Letter.

[26] *See* Stephen J. Thomas, MD, *Six Month Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine*, medRxiv Preprint (July 28, 2021), available at: https://www.medrxiv.org/content/10.1101/2021.07.28.21261159v1.full.pdf (last visited Nov. 8, 2021).

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 an uncontrolled or partially controlled trial that cannot be used as the basis for approval. *See* 21 C.F.R. § 314.126(e). 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 25, is severely and intentionally misleading.

67. Further, Comirnaty and the other COVID-19 vaccines are "genetic vaccines", "or vaccines produced from gene therapy molecular platforms which according to US FDA regulatory guidance are classified as gene delivery therapies and should be under a 15-year regulatory cycle with annual visits for safety evaluation by the research sponsors."[27]

V. SCIENTIFIC EVIDENCE AND ADMINISTRATIVE ACTIONS FOR COVID-19 MRNA "VACCINES"

A. Novel Technology

68. The Pfizer-BioNTech and Moderna COVID-19 treatments employ novel technology, namely, mRNA delivered by nanolipids. These products are

[27] *Id.*, ¶ 17 (*citing* FDA, Center for Biologics Evaluation and Research, *Long Term Follow-up After Administration of Human Gene Therapy Products: Guidance for Industry*, FDA-2018-D-2173.2020 (Jan. 2020) ("FDA Gene Therapy Guidance")).

considered "genetic vaccines" or "or vaccines produced from gene therapy molecular platforms." Ex. 14, McCullough Decl., ¶ 17. As Dr. McCullough explains, the mRNA "vaccines" "have a dangerous mechanism of action in that they all cause the body to make an uncontrolled quantity of the pathogenic wild-type spike protein from the SARS-CoV-2 …. This is ***unlike all other vaccines*** where there is a set amount of antigen or live-attenuated virus." *Id.* (emphasis added).

69. Because of the novelty of gene therapies like mRNA, and the unknown safety risks, the FDA Gene Therapy Guidance advises "sponsors to observe subjects for delayed adverse events for as long as 15 years following exposure to the investigational gene therapy product." *Id.* (*quoting* FDA Gene Therapy Guidance at 4). The FDA's own guidelines make clear that the long-term safety risks cannot be known with any degree of certainty until recipients have been followed for 10 or more years, rather than six months.

70. These mRNA treatments were only tested on humans for a limited period of time. For example, the Comirnaty 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 supra* Section IV.F, ¶ 65. Accordingly, the long-term efficacy or long-term safety of these vaccines "is not proven."

Klaassen v. Trustees of Ind. Univ., --- F.Supp.3d. ---, 2021 WL 3073926, at *12 (N.D. Ind. July 18, 2021) (*"Klaassen"*).

B. Evidence of Rapidly Decreasing Efficacy

71. The Pfizer Factsheet admits that Comirnaty's "duration of protection against COVID-19 is currently unknown."[28] What is known, however, is that 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.

72. 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.[29] Plaintiffs are not aware of any studies contradicting the Israeli studies. In fact, these

[28] FDA, *Vaccine Information Fact Sheet for Recipients and Caregivers about Comirnaty* at 4 (Sept. 22, 2021), available at: https://www.fda.gov/media/144414/download (last visited Sept. 29, 2021).

[29] *See* 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 Nov. 8, 2021); 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 Nov. 8, 2021).

study results are the reason Israel is already requiring a third booster shot (and is considering a fourth).[30]

73. 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.[31] 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%.[32] 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

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[30] *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 Nov. 8, 2021).

[31] *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 Nov. 8, 2021).

[32] *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).

such as Qatar where the Delta variant was prevalent at an earlier date. *Id.* at 21.[33]

74. Of greatest relevance to Plaintiffs' claims is the November 4, 2021 study published in *Science*, which examined the Veterans Health Administration ("VHA") records 780,000 U.S. veterans[34] (who are older and presumably less healthy than active duty service members). From February 2021 to October 2021, the vaccine effectiveness against infection (VE-I) declined from 87.9% to 48.1% overall (and all the way down to 13.1% for Janssen vaccine vs. 43.3% for the Pfizer-BioNTech vaccine).

75. In any case, "the spike protein produced by the vaccines is obsolete" due to the emergence of other variants, in particular the Delta variant, which now accounts for 99.6% of cases.[35] The vaccines were developed in response to the original Alpha variant, which now accounts for less than

[33] 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 Nov. 8, 2021). This would have provided essential information regarding the long-term efficacy of Comirnaty and other COVID-19 vaccines.

[34] *See* Barbara Cohn, et al., *SARS-CoV-2 Vaccine Protection and Deaths Among Veterans During 2021,* SCIENCE (pre-print) (Nov. 4, 2021) ("VHA Study"), available at: https://www.science.org/doi/epdf/10.1126/science.abm0620 (last visited Nov. 8, 2021).

[35] *See* Ex. 14, McCullough Decl., ¶ 18 (*citing* CDC, *COVID Data Tracker: Variant Proportions* ("CDC Variant Report"), available at: https://covid.cdc.gov/covid-data-tracker/#variant-proportions (last visited Oct. 23, 2021)).

0.1% of cases. *Id.* The current COVID-19 vaccines do not encode RNA or DNA from the Delta variant or other variants of concern. *Id.*, ¶ 21.

76. Vaccination provides limited protection at best, and some studies indicate that the vaccinated may be at greater risk than the vaccinated for new variants like the Delta variant. Dr. McCullough discusses the results of a June 2021 study performed in the UK, which found that: "92,056 cases had the Delta variant and 50/7235 fully vaccinated and 44/53,822 of the unvaccinated died. This indicates that the fully vaccinated who contract the Delta variant have an 8.6-fold increased risk for death, (95% CI 5.73-12.91), $p < 0.0001$, as compared to those who chose to remain unvaccinated." Ex. 14, McCullough Decl., ¶ 24.

77. As a result of declining efficacy, the emergence of new variants, and the obsolescence of the current EUA vaccines, the FDA and CDC have recommended additional rounds of booster shots. The ongoing and unresolved booster shot debate demonstrates that the science is not "settled" as to the duration of protection provided by, or the proper dosage for, mRNA treatments. Further, as soon as the CDC or FDA recommend additional booster shots, all of the "fully vaccinated" will immediately be treated as unvaccinated, and therefore a threat to public health, for the purposes of the DOD and other federal vaccine mandates.

C. Vaccine Injuries and Side Effects

78. The VAERS data reveal unprecedented levels of death and other adverse events since the FDA issued EUAs for the three COVID vaccines. The total safety reports in VAERS for all vaccines per year up to 2019 was 16,320. By comparison, the total VAERS safety reports for COVID-19 Vaccines "alone through October 1, 2021, is 778,683." Ex. 14, McCullough Decl., ¶ 27. Through October 1, 2021, this included "16,310 COVID-19 vaccine deaths … and 75,605 hospitalizations," *id.* and "98% of all vaccine-related AEs from December 2020" through October 1, 2021. *Id.*, ¶ 28. "Thus, the COVID-19 mass vaccinationis associated with at least a 39-fold increase in annualized vaccine deaths reported to VAERS." *Id.*, ¶ 27.

79. COVID-19 vaccines are "especially risky for those 12-29," *id.*, ¶ 30, which are the prime ages for military service. "[M]yocarditis causes injury to heart muscle cells and may result in permanent heart damage resulting in heart failure, arrhythmias, and cardiac death," and can result in "a lifetime need for multiple medications, implantable cardio defibrillators, and heart transplantation." *Id.*, ¶ 31. "Heart failure has a five-year 50% survival and would markedly reduce the lifespan of a child or young adult who develops this complication after vaccine-induced myocarditis." *Id.*[36] Due to these risks, in Dr.

[36] On June 29, 2021, the Defense Health Agency (DHA) published a report in the *Journal of the American Medical Association Cardiology* (JAMA) on vaccine-linked

McCullough's expert medical opinion, "no individual under age 30 under any set of circumstances should feel obliged to take this risk with the current genetic vaccines particularly the Pfizer and Moderna products." *Id.*, ¶ 32.

80. The COVID-19 vaccines are "dangerous for those who have already had COVID-19 and have recovered with inferred robust, complete, and durable immunity." *Id.*, ¶ 47. As noted above, these patients were inexplicably and inexcusably excluded from the FDA-approved clinical trials for the COVID-19 vaccines. Thus, "[t]here has been no study demonstrating clinical benefit with COVID-19 vaccination in those who have well documented or even suspected prior COVID-19 illness." *Id.* There have, however, been numerous studies demonstrating that the those with previous infections have suffered greater risks of adverse reactions from the vaccines, as well as a greater rate and severity of subsequent COVID-19 infections than those with previous infections who remained unvaccinated. *See id.*, ¶¶ 49-51 & studies cited therein.

D. Fluid Definition of "Vaccine," "Vaccination" & "Fully Vaccinated"

81. Based on the limited efficacy of the COVID-19 vaccines and their

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myocarditis among U.S. military service members. "The study reports that previously healthy service members have developed myocarditis, a severe and life-threatening inflammation of the heart, within an average of just four days of receiving their first shot of either the Pfizer-BioNTech or the Moderna vaccine." *Id.*, ¶ 38 (citations omitted).

inability to prevent re-transmission, *see infra* Section V.E.1, 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. This prompted the CDC changes to the definition of "vaccine" on its website, just days after the Comirnaty approval, from a product that will "produce immunity"[37] (August 2021) to one that will "produce protection" (September 2021).[38]

82. In contemporaneous internal emails produced in response to a Freedom of Information Act ("FOIA") request, CDC leadership acknowledged that it changed the definition of "vaccine" and "vaccination" in response to (correct) public criticism and questions that the COVID-19 vaccines did not meet the CDC's then current definitions of "vaccine" and "vaccinations" as providing "immunity." *See id. at* 2 ("The definition of vaccine we have posted is problematic and people are using it to claim that the COVID-19 vaccine is not

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[37] CDC, *Vaccines and Immunizations: Definition of Terms* (Aug. 26, 2021), available at: http://web.archive.org/web/20210826113846/https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm (last visited Nov. 8, 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.").

[38] 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.").

a vaccine based on our own definition."); *id.* at 3 ("these definitions are outdated and being used by some to say COVID-19 vaccines are not vaccines per CDC's own definition.").

83. The CDC's definition of "fully vaccinated" on which the DOD relies is similarly fluid and subject to unannounced changes. CDC Director Rochelle Walensky has stated that the CDC will likely need to "update our definition of fully vaccinated in the future," based on its determinations regarding booster eligibility.[39]

E. "Fully Vaccinated" Spread COVID-19 & Lack of Evidence for Public Health Benefits from Vaccination

1. COVID-19 "Vaccines" Do Not Prevent Infection & Transmission.

84. 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

[39] *See* PBS Newshour, *Watch: CDC Says the Definition of "Fully Vaccinated" May Change as More People Get Boosters* (Oct. 22, 2021), available at: https://www.pbs.org/newshour/health/watch-live-white-house-covid-task-force-holds-briefing-as-more-booster-shots-get-approval (last visited Nov. 15, 2021).

from the U.S.[40] and abroad[41] suggest that they do not prevent either. There is simply no data available – nor could there be – that Comirnaty or other COVID EUA treatments 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.

2. Equal or Greater Risk of Infection by "Fully Vaccinated" Compared to Unvaccinated.

85. A study by the UK National Institute for Health Research, published in *The Lancet* on October 28, 2021, of the rate of household spread of the Delta variant "among household contacts exposed to fully vaccinated index cases was similar to household contacts exposed to unvaccinated index cases (25% [95% CI 15-35] for vaccinated vs. 23% [15-31] for unvaccinated."[42]

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[40] *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).

[41] *See, e.g.,* 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).

[42] *See* Anika Singanayagam, et al., *Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study* (Findings), THE LANCET (Oct. 29, 2021), https://doi.org/10.1016/S1473-3099(21)00648-4, available at: https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00648-4/fulltext#seccestitle160 (last visited Nov. 8, 2021).

Accordingly, "fully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts." *Id.*

86. A September 29, 2021 preliminary report from the University of California, Davis, Genome Center found that "[t]here were no statistically significant differences in mean [cycle threshold] Ct-values of vaccinated … vs. unvaccinated … samples."[43] There were also "no statistically significant differences were found in the mean Ct-values of asymptomatic … vs. symptomatic … samples, overall or stratified by vaccine status." *Id.*

87. A July 2021 CDC study of an outbreak in Massachusetts found that the vast majority of cases were reported among the vaccinated.[44] The VHA Study discussed above also found that, with respect to the Delta variant, viral loads are similar for both vaccinated and unvaccinated. *See supra* VHA Study,

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[43] *See* Charlotte B. Acharya, et al., *No Significant Differences in Viral Load Between Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Groups Infected with SARS-CoV-2 Delta Variant*, medRxiv Pre-Print (Sept. 29, 2021), https://doi.org/10.1101/2021.09.28.21264262, available at: https://www.medrxiv.org/content/10.1101/2021.09.28.21264262v2 (last visited Nov. 8, 2021).

[44] *See* Ex. 14, McCullough Decl., ¶ 25 & Figure 1 (*citing* CDC, *Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021*, CDC Morbidity and Mortality Weekly Report (Aug. 6, 2021), available at: https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7031e2-H.pdf (last visited Oct. 23, 2021)).

note 34, at 3.

88. Accordingly, claims that this is a "pandemic of the unvaccinated," *see* Ex. 12, Biden Federal Mandate Statement at 2, are incorrect and deceptive. As is the CDC's policy, announced May 1, 2021, that community breakthrough cases would no longer be reported to the public. *See supra* Roubein & Lim, note 33. "This overt asymmetric reporting will create the false picture of only unvaccinated individuals developing COVID-19 when in reality patients who are fully vaccinated will be contracting breakthrough infections." Ex. 14, McCullough Decl. ¶ 21.

3. Lack of Evidence That COVID-19 Spread by Unvaccinated Individuals with Natural Immunity

89. Of equal importance is the admission of the CDC—on whose recommendation the DOD and Armed Services expressly relied on in eliminating the natural immunity exemption—that they do not have any:

> Documents reflecting ***any documented case*** of an individual who: (1) never received a COVID-19 vaccine; (2) was infected with COVID-19 once, recovered, and then later became infected again; and (3) transmitted SARS-CoV-2 to another person when reinfected.

Ex. 16, November 5 FOIA Response, at 1 (emphasis added). Of even greater importance is the CDC's admission that "this information is not collected." *Id.*[45]

[45] Plaintiffs do not contend that previously infected individuals with naturally immunity who have recovered can never be reinfected and then reinfect others; instead, Plaintiffs merely highlight that the CDC itself has intentionally refused to

4. Quarantine & Testing Provide Equal or Greater "Protection."

90. In Dr. McCullough's expert medical opinion, "the epidemic spread of COVID-19, like all other respiratory viruses, notably influenza, is driven by symptomatic persons; asymptomatic spread is trivial and inconsequential." Ex. 14, McCullough Decl., ¶ 10. A meta-analysis published in the *American Journal of the American Medical Association* concluded that "asymptomatic spread was negligible at 0.7%."[46] Consequently, "a rational and ethical prevention measure to reduce the spread of COVID-19 is a simple requirement" would be for persons with "active symptomatic, febrile (feverish) respiratory illnesses … to isolate themselves." *Id.*, ¶ 11. Thus quarantine and testing, the previous COVID-19 mitigation strategy, can provide equal or greater protection, at much lower costs to society, the DOD, and the individuals involved, than mass vaccination.

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collect, or even consider, contrary evidence. Such intentional blindness cannot be the basis for deference by this Court to the CDC, nor can it form the foundation for deference to DOD where that decision is based on outsourcing decision-making to an agency that ignored evidence that might contradict its preferred policy outcome.

[46] *Id.*, ¶ 11 (*citing* Zachary J. Madewell, Ph.D., et al., *Household Transmission of SARS-CoV-2: A Systematic Review and Meta-analysis*, JAMA Network Open, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774102 (last visited Oct. 23, 2021)).

F. Natural Immunity Provides Superior Protection to Vaccination.

91. Numerous studies (described below) demonstrate the superiority of natural immunity over vaccine-induced immunity (or "protection" in CDC's new terminology). In Dr. McCullough's expert opinion, "SARS-CoV-2 causes an infection in humans that results in robust, complete, and durable immunity, and is superior to vaccine immunity." *Id.*, ¶ 53. "There are no studies demonstrating the clinical benefit of COVID-19 vaccination in COVID-19 survivors and there are three studies demonstrating harm in such individuals. Thus, it is my opinion that the COVID-19 vaccination is contraindicated in COVID-19 survivors." *Id.*

92. A study conducted in Israel, described as the "largest real-world observational study comparing natural immunity," 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 Pfizer-BioNTech vaccine immunity.[47] After adjusting for co-morbidities and age, fully vaccinated individuals with no previous infections had a "statistically significant 13.06-fold (95% CI, 8.08 to 21.11) increased risk

[47] 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) ("Israeli Study"), available at: https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.full.pdf.

for breakthrough infection [with the Delta variant] as opposed to reinfection (P<0.001)" of those previously infected. *Id.* at 12. 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.

93. The Cleveland Clinic Study[48] 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 remained unvaccinated had a SARS-CoV-2 infection over the duration of the study." *Id.* at 2. The Cleveland Clinic Study found that "vaccination was associated with a significantly lower risk of SARS-CoV-2 infection among those not previously infected," but that vaccination did not lower the risk of re-infection "among those previously infected." *Id.* The Cleveland Clinic Study concluded that previously infected individuals are therefore "unlikely to benefit from COVID-19 vaccination." *Id.*

94. The more robust response of natural immunity to mutated forms of COVID is supported by the results of a longitudinal analysis of 254 patients

[48] *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.

over eight months.[49] This study found that SARsS-CoV-2 infection produces "broad and effective immunity" that "may persist long-term in recovered COVID-19 patients."

95. Dr. McCullough discusses a study of 615,777 previously infected individuals, which found a re-infection rate of less than one percent (<1%) over the long term (including periods where the Delta variant is dominant).[50]

G. Alternative and Effective Treatments for COVID-19

96. There are now well-studied, safe and reliable alternatives to vaccination for prevention and treatment of COVID-19, including, but not limited to Ivermectin, 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.[51]

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[49] 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 Nov. 8, 2021).

[50] *See* Ex. 14, McCullough Decl., ¶ 56 (*discussing* Eamon O Murchu, et al., *Quantifying risk of SARS-CoV-2 reinfection over time,* Reviews in Medical Virology (May 27, 2021), available at: https://onlinelibrary.wiley.com/doi/10.1002/rmv.2260 (last visited Oct. 23, 2021)).

[51] *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).

97. 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. *See generally* Ex. 18, *FDA COVID-19 Drug Approval Process Remdesivir vs Ivermectin*. 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.

98. Dr. McCullough has studied—and developed through his work with the Association of American Physicians and Surgeons—a number of alternative treatments. The treatment approach outlined in his declaration "has resulted in an ~85% reduction in hospitalization and death in high-risk individuals" with COVID-19, and results in "less than 2% change of facing hospitalization or death among high-risk adults (age over 50 with medical problems). Ex. 14, McCullough Decl., ¶¶ 12-13 & Table 3. These hospitalization and death rates would necessarily be lower for younger, healthier service members.

99. Further, in light of the CDC's changing definition of vaccines and vaccination to provide only "protection," rather than "immunity" (*i.e.*, because

COVID-19 vaccines do not provide immunity), the numerous alternative treatments that do provide protection (as well as natural immunity) should be considered as alternative methods to meet the CDC's public health goals, and the DOD's exclusion of these alternatives is irrational and unsupported.

VI. PLAINTIFFS RELIGIOUS ACCOMMODATION REQUESTS

A. Plaintiffs' Sincerely Held Religious Beliefs

100. In their declarations and the religious accommodation requests attached thereto ("RA Requests"), Plaintiffs have set forth the sincerely held religious beliefs that compel them to oppose the mandate. The primary reason cited is the refusal to participate in the abomination of abortion. *See, e.g.,* Ex. 1, Bodony Decl., RA Request, ¶¶ 3-4 ("My sincerely held religious belief is that human life is recognized at the moment of conception and all child sacrifice is condemned by God. …. By participating in an immunization that results from abortion, I would be committing a cardinal sin that can lead to spiritual death."); Dee Decl., RA Request, ¶ 5 ("any support for or acceptance of a product that is produced using aborted human fetal tissue goes against my sincerely held belief that voluntary termination of a pregnancy is murder and a violation of God's commandments."); Duffy Decl., RA Request, ¶ 1 ("cultivation and testing of aborted fetuses in making the mRNA goes against my Christian ethics."); Hyatt Decl., at ¶ 8 ("The use of cells, cellular debris, protein and DNA from willfully aborted human children cell lines used to

develop the Covid-19 vaccine violate the very basic foundations of Exodus 20:13, which instructs us not to murder."); Kayegama Decl., RA Request, ¶ 2 ("My request is based on my sincere belief as a non-denomination Christian that believes God is our Creator and using aborted fetal cells and lining in the vaccine itself or in testing is not acceptable as a Christian."); Nankivell Decl., RA Request, ¶ 4(a) ("I believe abortion is immoral and that these current vaccine options are not morally justifiable. I cannot use any product I have knowledge of that takes its origin in abortion while maintaining a clear conscience"); Severson Decl., RA Request, ¶ 2 ("allowing morally objectionable and/or unsafe substances, including vaccines which utilize cell lines from murdered babies in the development, production, and/or testing processes, is counter to my spiritual convictions. The murder of an unborn child is never justified.").

101. Certain Plaintiffs also object to the use of gene therapies like the COVID-19 treatments that alter God's creation, *i.e.*, their genetic codes or immune system, in violation of God's commandments. *See, e.g.,* Dee Decl., RA Request, ¶ 1 ("God created me perfectly and in His image." Taking the vaccine "would cause me to support the murder of unborn children, which is a violation of His commandments."); Jacobellis Decl., RA Request, ¶ 3 ("My body is a temple of the Holy Spirit and, as such, my cells should not be manipulated by

medical intervention. Covid vaccines deliver a genetic code to host cells in the body, giving those cells instructions, or blueprints for making copies of spike proteins. I believe that the process by which these vaccines send instructions to my cells is undoing God's created order (1 Corinthians 6:19-20).").

102. Plaintiffs also believe that the mandate is forcing them to choose between God and country and/or following an unlawful order. *See, e.g., id.*, Bodony Decl., RA Request, ¶ 7; Duffy Decl., RA Request, ¶ 2 (taking a vaccine developed from a fetal cell line taken from aborted fetuses "would force me to conform and sacrifice my religious freedom and, in return, be subject to the wrath of the Lord (Deuteronomy 7:4)"); Jacobellis Decl., RA Request, ¶ 4 ("By taking the vaccine, he is being ordered to participate in a practice that comes in conflict with God's authority over his life. This violates God's created order (Deuteronomy 11:1)").

B. COVID-19 Vaccines Are Critically Dependent on, and Could Not Exist but for, the Use of Aborted Fetal Cell Tissue.

103. It is undisputed that HEK-293 and PER.C6 fetal cell lines were used in the development and testing of the three (3) available COVID-19 vaccines. As reported by the North Dakota Department of Health, in its handout literature for those considering one of the COVID-19 vaccines, "[t]he non-replicating viral vector vaccine produced by Johnson & Johnson did require the use of fetal cell cultures, specifically PER.C6, in order to produce

and manufacture the vaccine."[52] The Louisiana Department of Health likewise confirms that the Johnson & Johnson COVID-19 vaccine used the PER.C6 fetal cell line, which "is a retinal cell line that was isolated from a terminated fetus in 1985."[53]

104. The same is true of the Moderna and Pfizer-BioNTech mRNA vaccines. The Louisiana Department of Health's publications again confirm that aborted fetal cells lines were used in the "proof of concept" phase of the development of their mRNA vaccines. *See id.* The North Dakota Department of Health likewise confirms: "Early in the development of mRNA vaccine technology, fetal cells were used for 'proof of concept' (to demonstrate how a cell could take up mRNA and produce the SARS- CoV-2 spike protein) or to characterize the SARS-CoV-2 spike protein." *See* NDH FAQ. Multiple Pfizer executives have confirmed both that aborted fetal cells were critical for development, while at the same trying to cover this up this essential fact.[54]

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[52] *See* North Dakota Health, *COVID-19 Vaccines & Fetal Cell Lines* (Oct. 5, 2021) ("NDH FAQ"), available at: https://www.health.nd.gov/sites/www/files/documents/COVID%20Vaccine%20Page/COVID-19_Vaccine_Fetal_Cell_Handout.pdf (last visited Nov. 15, 2021).

[53] La. Dept. of Public Health, *You Have Questions, We Have Answers: COVID-19 Vaccine FAQ* (Dec. 21, 2020), available at: https://ldh.la.gov/assets/oph/Center-PHCH/Center-PH/immunizations/You_Have_Qs_COVID-19_Vaccine_FAQ.pdf (last visited Nov. 15, 2021).

[54] *See* Project Veritas, *PFIZER LEAKS: Whistleblower Goes On Record, Reveals Internal Emails from Chief Scientific Officer & Senior Director of Worldwide Research Discussing COVID Vaccine ... 'We Want to Avoid Having the Information on the Fetal Cells Floating Out There',* (Oct. 6, 2021), available at:

C. Plaintiffs Religious Accommodation Requests Have Been Denied.

105. The following Plaintiffs have had their religious accommodation requests denied or recommended for disapproval: Jessica Caldwell (Caldwell Decl., ¶ 9); Paul Dee (Dee Decl., ¶ 10); Brian Duffy (Duffy Decl., ¶ 7); Allen Hall (Hall Decl., ¶ 7); Michael Jacobellis (Jacobellis Decl., ¶ 9); Emily Nankivell (Nankivell Decl., ¶ 9); and Jeremy Severson (Severson Decl., ¶ 10).

D. Defendants Have Systematically Denied Religious Accommodation Requests.

106. Defendants have systematically denied religious accommodation requests. As demonstrated in the table below, Defendants have granted zero religious accommodation requests, while denying thousands:[55]

Table 1: Statistics on Religious Accommodation Requests as of November 12

Branch	Total	Pending	Denied	Granted
Air Force	11,007	10,319	688	0
Army	114	114	0	0

www.projectveritas.com/news/pfizer-leaks-whistleblower-goes-on-record-reveals-internal-emails-from-chief/ (last visited Nov. 8, 2021).

[55] *See* Ex. 19, Defendants Compliance Notice in *Navy Seal 1 v. Biden*, ECF No. 34, Case No. 8:21-cv-2429 (M.D. Fla.). "Denied" requests includes both "Denied Requests Pending Appeal" and "Initial Requests Denied and Are Not Currently Subject to Appeal." "Pending" includes "Initial Requests Under Review" for Navy and Marine Corps. The filing by the Army (including Army Reserves and presumably Army National Guard), the largest branch by far with over one million soldiers and nearly 50% of total armed services personnel, indicate that only 114 requests have been received by the Surgeon General for the Army ("TSG"); this is presumably a small fraction of the total submitted by Army soldiers.

Coast Guard	818	818	0	0
Marines	2,266	1,202	1,053	0
Navy	2,375	1,897	478	0

107. These statistics demonstrate that (1) submission of religious accommodation requests are futile and (2) that the DOD and Armed Services are systematically denying these requests, in violation of their statutory obligations and the constitutional rights of Plaintiffs.

VII. PLAINTIFFS WILL SUFFER CONCRETE AND PARTICULARIZED HARM AS A DIRECT RESULT OF DEFENDANTS' ACTIONS

108. Plaintiffs have real, substantial, and legitimate concerns about taking experimental COVID-19 treatments in light of and the potential for short- and long-term side effects and adverse reactions. Moreover, several Plaintiffs have been denied medical exemptions to which they are entitled under currently effective regulations for natural immunity and other conditions, while several other Plaintiffs have also been denied religious accommodation requests under new illegal and unconstitutional criteria. *See* Section VI.C ("Plaintiffs Religious Accommodation Requests Have Been Denied.").

109. 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. *See supra* Section III.B.5 ("Disciplinary Actions for Vaccine Refusal") & Section III.C ("UCMJ Sanctions for Vaccine Refusal"). Several already face promotion or duty restrictions as a result of vaccine refusal.

110. Further, Plaintiffs have objected to the mandate based on the unavailability of Comirnaty, but have faced disciplinary action or involuntary separation for their refusal to take an unlicensed experimental treatment. *See, e.g.,* Ex. 1, Dee Decl., ¶ 8; Hallmark Decl., ¶ 12; Jacobellis Decl., ¶ 10; Nankivell Decl., RA Appeal ¶¶ 10-12; Severson, Decl., ¶ 8. "[T]he United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs." *John Doe #1 v. Rumsfeld*, 297 F.Supp.2d 119, 135 (D.D.C. 2003). 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
VIOLATION OF INFORMED CONSENT RIGHTS
10 U.S.C. § 1107a AND 21 U.S.C. 360bbb-3

111. Plaintiffs reallege the facts in Paragraphs 1 through 110 as if fully set forth in this Count.

112. The DOD Mandate and the Armed Services Guidance violate 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 have mandated the unlicensed EUA BioNTech Vaccine, or directed DOD healthcare providers to administer the EUA vaccine pursuant to the DOD Mandate. The DOD Mandate must therefore be declared unlawful and enjoined. *See generally John Doe #1 v Rumsfeld*, 341 F. Supp. 2d 1, 19 (D.D.C. 2004), *modified sub nom.* 2005 WL 774857 (D.D.C. 2005) (expanding injunction against mandated EUA anthrax vaccine).

113. While the DOD Mandate itself states that only FDA-licensed vaccines may be mandated, *see* Ex. 2, DOD Mandate at 1, the Air Force Guidance and DOD Surgeons General Guidance expressly state that the EUA BioNTech Vaccine should be administered "interchangeably" with, and/or "as if" it were, the unavailable licensed Comirnaty Vaccine pursuant to the DOD Mandate. *See, e.g.,* Ex. 7, Air Force Guidance, § 3.1.1; Ex. 11, DOD Surgeon Generals Guidance, at 1. This raises the question of whether it is the Air Force and DOD Surgeons General, rather than Plaintiffs, who are disobeying a direct order.

114. The EUA and the licensed product are "legally distinct" in that the EUA BioNTech Vaccine is subject to the laws governing EUA products, including the right to informed consent, while Comirnaty is subject to the heightened safety and efficacy requirements governing FDA-licensed products, as well as FDA regulation of manufacturing facilities and process. The two products are also chemically distinct because the EUA and licensed products do not have "same formulation." *Compare* Ex. 4, August 23 Comirnaty SBRA at 9 (11 components, including redacted excipient), *with* Ex. 5, BioNTech EUA Expansion Letter, at 7 (listing 10 components) *and* Ex. 24, November 8 Comirnaty SBRA at 7-8 (listing 11 components, but removing redacted excipient).

115. Further, the licensed Comirnaty is unavailable in the United States and will not be available for several months. *See* Ex. 24, November 8 Comirnaty SBRA at 5; Ex. 22, NIH-Pfizer Announce Comirnaty Unavailability. Defendants' compliance deadlines will necessarily require Plaintiffs to receive an unlicensed product, in violation of federal informed consent laws. Further, Plaintiffs have objected to the mandate based on the unavailability of Comirnaty, but have been rejected and even disciplined for their refusal to take an unlicensed experimental treatment. *See, e.g.,* Ex. 1, Dee

Decl., ¶ 8; Hallmark Decl., ¶ 12; Hyatt Decl., ¶ 8; Jacobellis Decl., ¶ 10; Nankivell Decl., RA Appeal ¶¶ 10-12; Severson, Decl., ¶ 8.

116. Defendants' position is based on willful misrepresentations of the law—that the product (or even the same vial) may simultaneously be labeled as EUA but still be a licensed product vaccine for the same indication, and that an EUA-labeled vial 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. 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.

SECOND CAUSE OF ACTION
VIOLATIONS OF APA & PROCEDURAL REQUIREMENTS

118. Plaintiffs reallege the facts in Paragraphs 1 through 110 as if fully set forth in this Count.

119. The DOD Mandate is a two-page memorandum from the Secretary of Defense that cites no statute, regulation, executive order or other legal basis for the imposition of an entirely new mandate on over two million active duty and reserve service members. The Armed Services guidance is just that,

guidance documents, that solely on the SECDEF Memo, without citing any further legal basis for their implementation of the SECDEF Memo.

120. The DOD Mandate exceeds the statutory authority of the Secretary of Defense. The DOD and the Armed Services are departments and agencies of the United States Government. As such, they are agencies created by statute, and "it is axiomatic that an administrative agency's power to promulgate legislative regulations," like the DOD Mandate, "is limited to the authority delegated by Congress." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208, 109 S. Ct. 468, L.Ed.2d 493 (1988); *see also La. Pub. Serv. Comm'n v. FERC*, 476 U.S. 355, 375, 106 S. Ct. 1890, 90 L.Ed.2d 369 (1986) ("an agency literally has no power to act, …, unless and until Congress confers power on it."). Accordingly, the DOD Mandate and Armed Services' guidance are "in excess of statutory jurisdiction [and] authority." 5 U.S.C. § 706(2)(C).

121. The DOD Mandate and the Armed Services Guidance violates the APA and the existing DOD and Armed Services regulations and directives governing immunization, in particular multi-service regulation ("MSR") AR 40-562, DOD Instruction 6500.02, "DOD Immunization Program" (July 23, 2019) ("DODI 6500.02"), and the DOD rules for amending or modifying MSRs.

122. AR 40-562 is the currently effective MSR setting forth immunization requirements and exemptions for service members and DOD

civilians. AR 40-562 is a "legislative rule" insofar as it sets forth service members' rights and obligations regarding immunization and exemptions, and thus has the force of law. MSRs like AR 40-562 must be promulgated and approved by order of each of the Armed Services (*i.e.*, Secretaries of the Army, Navy, Air Force and Coast Guard). *See* Ex. 6, AR 40-562, at i.

123. The DOD Mandate modifies AR 40-562 insofar as it: (1) imposes an entirely new vaccine requirement not found in AR 40-562 or any other statute, MSR, DOD instruction or directive regulation; and (2) eliminates medical exemptions to which service members would otherwise be entitled, including those with previous documented infections. There are nearly 250,000 service members with previous COVID-19 infections that are affected by the elimination of this exemption alone, and several Plaintiffs were either denied medical exemption for previous infections or did not request one because they were informed that this exemption had been eliminated. *See, e.g.,* Ex. 1, Hallmark Decl., ¶ 11; Severson Decl., ¶ 10; Schwartz Decl., ¶ 10; *see also* Caldwell Decl., ¶ 10 (no exemption for cancer).

124. The amendment, modification or repeal of currently effective regulations like AR 40-562 must be performed in accordance with the DOD's procedural requirements for MSRs, including separate review and approval by the Secretaries of each of the Armed Services. The SECDEF and DOD are not

permitted to unilaterally change an existing MSR—by adding an entirely new vaccination requirement and categorically eliminating existing classes of exemptions—and DOD has cited no authority that would allow them to do so. Further, if the DOD intends to change the currently effective governing regulation, it must actually change the regulation; it may not just ignore it, read it out of the regulation, or amend it *sub silentio* as it appears to do have done with respect to its elimination of existing exemptions for COVID-19 only. Finally, the Armed Services' guidance is just that, guidance; guidance documents, or interpretive rules, cannot modify legislative rules like AR 40-562.

125. Where, as here, an agency amends a legislative rule, effecting a substantive change in the regulation, and therefore to service members' legal rights and obligations thereunder, the agency must follow the required procedures—and actually revise the regulations in question—so that regulated persons may ascertain the rules to which they are subject. By failing to follow the required procedures for amending MSRs, the DOD Mandate, and amendments to AR 40-562, were made "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

126. 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 underlying legal basis or authority; any findings of facts or analysis (cost-benefit or otherwise) supporting their determination; and are based on patent misrepresentations of the law (in particular, that an EUA-labeled product may be administered "as if" it were the licensed product, which is not available). The DOD Mandate's sole justification or explanation is a conclusory statement that the Secretary 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 FDA Comirnaty Approval, it is apparent the DOD blindly relied on the FDA approval; there is no indication that the DOD and SECDEF engaged in reasoned decision-making that the APA requires or that the mandate is based on the DOD's independent judgment or expertise.

127. The Defendants' elimination of the exemption for natural immunity is also arbitrary and capricious. "[A] naturally immune unvaccinated [service member] is presumably at less risk than an unvaccinated" service member, but the DOD's elimination of this exemption "fails almost completely to address, or even respond to, much of this reality and common sense." *OSHA*, 2021 WL 5279381, at *6.

128. The DOD's decision to eliminate the exemption for natural immunity appears to be based on CDC guidance. Deference to Defendants' expertise is especially inappropriate where, as here, they have outsourced decision-making to the CDC, which has admitted that it has no evidence of any instance where an individual with a previous infection has recovered, then become reinfected and transmitted the infection to another individual. *See* Ex. 16, November 5 FOIA Response. The CDC not only has no contrary evidence; it has intentionally chosen not to collect evidence that might contradict its preferred policy outcome. The CDC also redefined "vaccine" and "vaccination"—in response to (correct) public criticism that the mRNA vaccines did not qualify under the current definition—after the Comirnaty licensure and issuance of the DOD Mandate, to accommodate this ineffective, unsafe, and experimental treatment that does not provide immunity, or prevent infection or transmission. *See supra* Section V.E (""Fully Vaccinated" Spread COVID-19 & Lack of Evidence for Public Health Benefits from Vaccination"). No deference is due to such an intentionally one-sided and asymmetrical process.

129. Defendants have also violated the APA and applicable regulations insofar as the DOD Mandate and Armed Services implementation thereof permits the vaccination requirements to be met only by the EUA COVID-19

"vaccines" and Comirnaty "vaccine." The CDC definition and guidance that DOD purports to follow permit consideration of a much wider range of available treatments that provide "protection" against COVID-19. *See* Section V.D ("Fluid Definition '") and Section V.G ("Alternative and Effective Treatments for COVID-19"). There is no indication in the record that the DOD considered any other treatments that provide such protection.

130. Finally, the DOD Mandate is arbitrary and capricious because it constitutes an unannounced and unexplained departure from a prior policy insofar as it mandates EUA vaccines. In a July 6, 2021 memorandum from the Office Legal Counsel, the DOD interpreted the informed consent requirements in 10 U.S.C. § 1107a "to mean that DOD may not require service members to take an EUA [vaccine]" without first obtaining a Presidential Waiver under 10 U.S.C. § 1107a." *See* Ex. 23, Office of Legal Counsel, Vaccine Mandate Opinion at 16 (July 6, 2021). There has been no Presidential Waiver, yet the Defendants are mandating use of EUA vaccines. "[A]gencies must typically provide a 'detailed explanation' for contradicting a prior policy;" they may not, as DOD has done here, "depart from a prior policy *sub silentio*." *OSHA*, 2021 WL 5279381, at *5 (*quoting FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515, 129 S. Ct. 1800, 173 L.Ed.2d 738 (2009) ("*Fox*")).

131. As a result of Defendants' unlawful actions, Plaintiffs will be

required either to take an experimental, unlicensed vaccine—pursuant to an unlawful mandate from which many or most would otherwise be exempt—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
VIOLATION OF FIFTH AMENDMENT DUE PROCESS CLAUSE
U.S. CONST. AMEND. V

132. Plaintiffs reallege the facts in Paragraphs 1 through 110 as if fully set forth in this Count.

133. The Fifth Amendment Due Process Clause provides that no person may "be deprived of life, liberty or property without due process of law." U.S. CONST. AMEND. V. The DOD Mandate would deprive Plaintiffs of all three, as well as and does so without providing "fair notice" of the rules to which they are subject.

134. The DOD Mandate requires Plaintiffs to take a vaccine without their consent and thereby exposes them to a non-negligible risk of death or serious injury.

135. The DOD Mandate "threatens to substantially burden the liberty interests" of Plaintiffs "put to a choice between their job(s) and their jab(s)." *OSHA*, 2021 WL 5279381, at *8. Plaintiffs face not only the loss of the current employment, but also will be barred from other federal or private employment due to their vaccination and discharge status. The DOD Mandate, and its

treatment of religious accommodation requests, also burdens other fundamental rights, in particular, the free exercise of religion protected by the First Amendment. *See id.*, at *8 n.21 (citations omitted).

136. Vaccine refusal may also result in deprivation of the protected property interests. Disciplinary action or discharge status may cause Plaintiffs to lose retirement, veterans, and other governmental benefits to which they are entitled.

137. The Defendants have also violated the Due Process Clause insofar as they have modified or amended AR 40-562, the currently effective regulation governing immunization and exemptions—by imposing an entirely new vaccination requirement and categorically eliminated existing exemptions—without any legal authorization or following procedures required by law. By changing the currently effective regulation governing Plaintiffs' vaccination obligations and rights to medical exemption, which remains on the books unchanged, Defendants have failed to provide "fair notice" of the rules to which they are subject. *See, e.g., Fox*, 567 U.S. at 253.

138. Even if Plaintiffs were to become "fully vaccinated," they would be threatened with the loss of this status (and consequent deprivation of protected life, liberty and property interests), at any time and without fair notice, due to changes in the CDC or FDA approval of booster shots and change to the

definition of "fully vaccinated." So would the majority of service members who are currently deemed "fully vaccinated." The rapid decline in efficacy and need for booster shots demonstrates that there is no scientific consensus on Comirnaty's efficacy, protection provided, or even dosage. *See supra* Section V.E.2 ("Equal or Greater Risk of Infection by "Fully Vaccinated" Compared to Unvaccinated."). "As COVID-19 is a new disease, and the vaccines are even newer, the long-term efficacy of immunity derived from vaccination and infection is not proven." *Klaassen*, 2021 WL 3073926, at *12. Accordingly, the term "fully vaccinated" is unconstitutionally void for vagueness, and this fluid and changing classification cannot be used as the benchmark for determining who may serve in the military, or alternatively, for depriving Plaintiffs of their life, liberty, property and other fundamental constitutional rights, including the free exercise of their religion.

139. As a result of the Defendants' unlawful and unconstitutional actions, Plaintiffs face deprivation of their rights to life, liberty and property without due process or fair notice. Plaintiffs seek declaratory and injunctive relief because they have no adequate remedy at law to prevent future injury caused by Defendants' violation of their Fifth Amendment rights to due process.

FOURTH CAUSE OF ACTION

VIOLATION OF FIFTH AMENDMENT EQUAL PROTECTION CLAUSE
U.S. Const. amend. V

140. Plaintiffs reallege the facts in Paragraphs 1 through 110 as if fully set forth in this Count.

141. The Fifth Amendment's Equal Protection Clause requires that "all persons similarly situated should be treated alike." *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 439 (1985); *see also Sessions v. Morales*, 137 S. Ct. 1678, 1686 n.1 (2017) (the Supreme Court's "approach to Fifth Amendment equal protection claims has always been precisely the same as to equal protection claims under the Fourteenth Amendment").

142. The DOD Mandate is a part of a government-wide program that irrationally creates and maintains two classes of service members: (1) those who are "fully vaccinated," who are presumed to pose no threat; and (2) those who are not "fully vaccinated," who are presumed to be a danger to everyone (including themselves). Class membership ("fully vaccinated") is defined in vague and fluid terms that may change from one day to the next (*i.e.*, based on FDA or CDC booster shot recommendations) and that is based on an unsupported and demonstrably false presumption that "full" vaccination prevents the spread of COVID-19. *See infra* Section V.E (""Fully Vaccinated" Spread COVID-19 & Lack of Evidence for Public Health Benefits from Vaccination").

143. The DOD Mandate serves no rational or legitimate purpose insofar as it threatens expulsion and punishment of tens of thousands of service members for refusal to take an unproven, ineffective, and unavailable experimental treatment. As such, the DOD Mandate violates the Equal Protection Clause under the Fifth Amendment of the United States Constitution because it unlawfully discriminates against plaintiffs on the basis of unconstitutionally vague and irrational medical classifications. The constitutional violation is further exacerbated by Defendants' elimination of existing medical exemptions and denial of religious accommodation based on sincerely held religious beliefs.

144. Defendants' actions of adopting, implementing, promulgating, delegating, and enforcing the DOD Mandate have discriminated and continue to discriminate against Plaintiffs and other service members, on the basis of class-based animus, stigma, and irrational and unsupported fears regarding the perceived dangerousness of the unvaccinated. *See, e.g.,* Ex. 12, Biden Mandate Remarks, at 2 (falsely claiming that "[t]his is a pandemic of the unvaccinated"); *id.* at 6 ("We've been patient, but our patience is wearing thin. Any your [vaccine] refusal has cost all of us."); *id.* at 5 (stating that he understands the "anger" at the unvaccinated). These motivations are not permissible bases for differential treatment under any standard of review. But

the DOD Mandate and the other federal vaccine mandates more generally single out and impose a government-created disability on a class that not only bars them from public service and most private employment, but also expressly denies that class the equal protection of the laws. *See Romer v. Evans*, 517 U.S. 620, 116 S. Ct. 1620, 134 L.Ed.2d 855 (1996) (striking down provision that "impos[ed] a broad an undifferentiated disability on single named group" that "seem[ed] inexplicable by anything but animus towards the class it affects.").

145. Apart from the evident animus towards the unvaccinated motivating the Federal Vaccine Mandates, the class definition for those denied equal protection of the laws is fluid, subjective and unconstitutionally vague. The rapidly declining efficacy, inability to prevent infection or transmission, and erroneous presumptions regarding the relative public health threats posed by those who are "fully vaccinated" and those who are not, demonstrate that these class distinctions are not based on any objective or rational basis. *See supra* SectionV.B ("Evidence of Rapidly Decreasing Efficacy") and Section V.E (""Fully Vaccinated" Spread COVID-19 & Lack of Evidence for Public Health Benefits from Vaccination"). Instead, the evident under inclusiveness of the mandate, by exempting the "fully vaccinated" from any requirements like testing that could prevent the spread of COVID-19, demonstrates that the mandate's "true purpose is not to enhance … safety, but instead to ramp up

vaccine uptake by any means necessary." *OSHA*, 2021 WL5279381, at *7 n.19.

146. Further, if and when the FDA approves additional booster shot(s) and the CDC changes its definition of "fully vaccinated" to require additional shot(s), all those who are "fully vaccinated" now will be moved into the unvaccinated class and deprived of the equal protection of the law. America's soldiers, military readiness and constitutional rights cannot be subject to such arbitrary and ever-changing administrative diktats.

147. The DOD Mandate, and its procedures and criteria for evaluating religious accommodation requests, also discriminate on the basis of religion. The Supreme Court has "time and again held that the government generally may not treat people differently based on the God or gods they worship, or do not worship." *Board of Ed. of Kiryas Joel Village School Dist. v. Grument*, 512 U.S. 687, 714 (1994).

148. Plaintiffs' free exercise of their religious beliefs is a fundamental right. Defendants' decisions on whether to approve Plaintiffs' religious exemptions from the available COVID-19 vaccines are subject to strict scrutiny. *See Employment Div., Dept. of Human Resources of Ore. v. Smith*, 494 U.S. 872, 886, n.3 (1990).

149. Defendants have violated the Equal Protection Clause by denying equal treatment to certain Plaintiffs solely for their religious beliefs. *See*

Section VI.C ("Plaintiffs Religious Accommodation Requests Have Been Denied. This is part of a systematic and discriminatory policy implemented by Defendants. Out of the tens of thousands of religious accommodation requests submitted, Defendants have denied thousands while granting zero requests. *See* Section VI.D ("Defendants Have Systematically Denied Religious Accommodation Requests.").

150. Those denied by Defendants are forced to choose between their religion and their profession. Defendants have no rational or compelling interest for this arbitrary division. These types of religious classifications are "presumptively invidious." *Plyler v. Doe*, 457 U.S. 202, 216 (1982).

151. The DOD Mandate deprives Plaintiffs, who have sincerely held religious beliefs, of their ability to freely exercise religion as their sincerely held religious beliefs prohibit compliance with the DOD Mandate. Because of their closely held religious beliefs, Plaintiffs have suffered, and continue to suffer, a deprivation of their constitutional rights because of Defendants' refusal to accommodate their sincerely held religious beliefs, as well as significant stress and psychological harm caused by this impending threat to their military service and employment.

152. Plaintiffs, because of their sincerely held religious beliefs, are also immediately injured by the stigma created by the DOD Mandates. Even if some

religious service members are permitted to remain exempt from the DOD Mandate, they now serve in a military where the Commander-in-Chief has announced that their service or work is unwanted and unwelcome, and that their religion is not respected. Any religious service member that is permitted to remain in their current positions will necessarily be treated as a person with second-class status.

153. Plaintiffs will be harmed due to Defendants' unlawful and unconstitutional vaccination mandates that would deprive them of their livelihoods, liberty, property rights, and fundamental constitutional rights, simply for asserting their statutory and constitutional rights. Plaintiffs seek declaratory and injunctive relief because they have no adequate remedy at law to prevent future injury caused by Defendants' violation of their rights to equal protection.

FIFTH CAUSE OF ACTION
VIOLATION OF NO RELIGIOUS TEST CLAUSE
U.S. CONST. ART. VI, § 3

154. Plaintiffs reallege the facts in Paragraphs 1 through 110 as if fully set forth in this Count.

155. The No Religious Test Clause of the Constitution states that "no religious test shall ever be required as a Qualification to any office or public Trust under the United States." U.S. CONST. ART. VI, § 3. Plaintiffs are members of the United States military and are thus officers or under the public

Trust of the United States.

156. Upon information and belief, Defendants have implemented their religious exemption policy in order to identify, isolate, and ultimately screen-out and/or punish those with sincerely held religious objections to the COVID-19 vaccines. This is demonstrated, in part, by the hostility in which Defendants have addressed Plaintiffs' religious accommodation request and their blanket refusal to grant any requests submitted to date. *See* Section VI.D ("Defendants Have Systematically Denied Religious Accommodation Requests."). The DOD's unprecedented, and medically unjustifiable 100%, vaccination requirement is further proof that Defendants true motivation is to purge the military of people of faith (as well as those who would question the lawfulness of a facially unconstitutional regulation), rather than to promote military readiness or protect the health and welfare of service members.

157. The religious exemption requirement – which Plaintiffs must pass to avoid the vaccine mandate and continue their employment – is itself an unconstitutional religious test in violation of Article IV, § 3 of the U.S. Constitution as applied to those Plaintiffs who have been denied religious exemptions. Moreover, Defendants' denial of Plaintiffs' religious exemption requests, where applicable, is a violation of the No Religious Test Clause.

158. Plaintiffs have no adequate remedy at law for Defendants'

violation of the No Religious Test Clause of the Constitution.

SIXTH CAUSE OF ACTION
VIOLATION OF FIRST AMENDMENT FREE EXERCISE CLAUSE
U.S. CONST. AMEND. I

159. Plaintiffs reallege the facts in Paragraphs 1 through 110 as if fully set forth in this Count.

160. The First Amendment's Free Exercise Clause provides that "Congress shall make no law respecting an establishment of religion or prohibiting the free exercise thereof." U.S. CONST. AMEND. I. Where, as here, a law targets religious practice for disparate treatment inhibiting the free exercise thereof, that law is assessed under the Supreme Court's strict scrutiny rubric, even in a pandemic. *See Roman Catholic Diocese of Brooklyn v. Cuomo*, --- U.S. ---, 141 S. Ct. 63, 67, 208 L.Ed.2d 206 (2020) ("[e]ven in a pandemic, the Constitution cannot be put away and forgotten").

161. Defendants have deprived and will continue to deprive Plaintiffs of their First Amendment rights. Plaintiffs are Christians and hold sincerely held religious beliefs that the Scriptures are the Word of God, and that they must follow God's mandates and instructions. Plaintiffs' religious beliefs require them to abstain from being administered the COVID-19 vaccines that are currently available to the public.

162. Plaintiffs submitted religious accommodation requests, stating that their religious beliefs prohibited them from receiving the available

COVID-19 vaccines because of their sincerely held religious beliefs that abortion is an abomination and because the aborted fetal cells were critical to the development of the vaccines, they refuse to participate or support this evil. *See supra* Section VI.A ("Plaintiffs' Sincerely Held Religious Beliefs") and Section VI.B ("COVID-19 Vaccines Are Critically Dependent on, and Could Not Exist but for, the Use of Aborted Fetal Cell Tissue.").

163. Defendants have not granted any Plaintiffs' religious accommodation requests, and every Plaintiff who has received a decision has been denied. *See* Section VI.C ("Plaintiffs Religious Accommodation Requests Have Been Denied."). In issuing these denials, Defendants are unlawfully denying Plaintiffs their religious liberty to abstain from available COVID-19 "vaccines." Further, the Defendants have confirmed that, as of November 12, 2021, they have denied thousands of religious accommodation requests, while granting zero religious accommodation requests to date. *See supra* Section VI.D ("Defendants Have Systematically Denied Religious Accommodation Requests. This is the unlawful and unconstitutional targeting of Plaintiffs' religious practices.

164. The DOD Mandate, as a policy and as applied to Plaintiffs, fails to accommodate Plaintiffs' sincerely held religious beliefs. There is no interest – rational or otherwise – for Defendants to deny Plaintiffs' religious exemptions

or threaten to not accommodate Plaintiffs' sincerely held religious beliefs. Nor is the least restrictive means of achieving Defendant's alleged interest. Accordingly, the DOD Mandate, and the Defendants' religious accommodation policies and procedures, cannot survive strict scrutiny.

165. Plaintiffs seek declaratory and injunctive relief because they have no adequate remedy at law to prevent future injury caused by Defendants' violation of their First Amendment right to the free exercise of religion.

SEVENTH CAUSE OF ACTION
VIOLATION OF RELIGIOUS FREEDOM RESTORATION ACT
42 U.S.C. § 2000bbb, *et seq.*

166. Plaintiffs reallege the facts in Paragraphs 1 through 110 as if fully set forth in this Count.

167. RFRA states that "Government shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability." 42 U.S.C. § 2000bb-1(a). If the Government substantially burdens a person's exercise of religion, it can only do so if it "demonstrates that application of the burden to the person – (1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest." 42 U.S.C. § 2000bb-1(b).

168. RFRA applies to Defendants, as they constitute a "branch, department, agency, instrumentality, and official of the United States." 42 U.S.C. § 2000bb-2(1).

169. RFRA was enacted "in order to provide very broad protection for religious liberty." *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2760 (2014). RFRA's definition of the term "exercise of religion" includes "any exercise of religion, whether or not compelled by, or central to, a system of religious belief." *Burwell*, 134 S. Ct. at 2761-62 citing § 2000cc-5(7)(A). "Congress mandated that this concept be 'construed in favor of a broad protection of religious exercise, to the maximum extent permitted by the terms of this chapter and the Constitution.'" *Id*. citing § 2000cc-3(g). And "[i]n RFRA's congressional findings, Congress stated that 'governments should not substantially burden religious exercise," a right described by RFRA as 'unalienable.'" *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2383 (2020), citing 42 U.S.C. §§ 2000bb(a)(1), (3).

170. Defendants have substantially burdened Plaintiffs' exercise of religion. Plaintiffs' sincerely held religious beliefs – based on the Word of God – prohibits them from receiving any of the currently available COVID-19 vaccines. Plaintiffs provided explanations of their religious beliefs and requested exemptions to the Vaccine Mandate based on these beliefs. Defendants denied these exemption requests, have threatened to deny these requests, and have otherwise threatened Plaintiffs with professional

retaliation based on the exercise of their religious beliefs.

171. Defendants have no compelling governmental interest to require Plaintiffs receive a COVID-19 vaccine in light of their religious exemptions. Furthermore, even if there is a governmental interest, Defendants' denial of Plaintiffs' religious exemptions are not the least restrictive means of furthering that interest. For example, Plaintiffs could be subject to regular COVID-19 testing, along with isolation or quarantine for positive tests, as they have been for over a year. *See supra* Paragraph 90. There are alternative and effective treatment options for Plaintiffs that provide equivalent and safer "protection" to the "vaccines." *See supra* Section V.G. ("Alternative and Effective Treatments for COVID-19") And several Plaintiffs have natural immunity from previous protections, which provides stronger and longer-lasting protection than the vaccines. *See supra* Section V.F ("Natural Immunity Provides Superior Protection ").

172. Defendants ignore these options in favor of punishing Plaintiffs, singling them out for having the courage to put their religious beliefs over a governmental order. Plaintiffs are asked by Defendants to choose compliance with Defendants' orders and their sincerely held religious beliefs. This puts Plaintiffs into the position of choosing between their religious beliefs or facing discipline, including court martial, termination, and possibly imprisonment.

This substantially burdens Plaintiffs' exercise of religion without having a compelling governmental interest and not pursuing the least restrictive means of furthering its interest.

173. Plaintiffs have no adequate remedy at law for the deprivation of their sincerely held religious beliefs.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully ask this Court to:

A. Issue a declaratory judgment that the DOD Mandate is unlawful and in violation of federal laws governing informed consent, the APA, and AR 40-562, and in excess of Secretary's statutory authority.

B. Enjoin any implementation of the DOD Mandate by the Armed Services or other DOD components, and to stay the effective date thereof pending resolution of Plaintiffs' claims before this Court.

C. Issue a declaratory judgment finding that the DOD and Armed Services may not mandate an EUA product, or use an EUA vaccine "interchangeably" with a licensed product for the purposes of the DOD Mandate.

D. Issue a declaratory judgment Defendants' requirements and criteria for assessing religious accommodation requests are unlawful and unconstitutional.

E. Find that all Plaintiffs who have requested medical exemptions must be granted exemptions pursuant to the terms of AR 40-562, and that Plaintiffs who have submitted religious accommodation requests should be granted such requests pursuant to RFRA and the First Amendment.

F. Issue a declaratory judgment that the DOD Mandate infringes upon Plaintiffs' First Amendment Free Exercise Clause, the No Religious Test Clause of Article VI, § 3 of the U.S. Constitution, the Fifth Amendment's Equal Protection Clause and Due Process Clauses, and RFRA.

G. Award plaintiffs' costs and attorneys' fees and any other relief this Court may find appropriate.

Respectfully submitted,

/s/ Brandon Johnson
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CERTIFICATE OF SERVICE

This is to certify that I have on this day e-filed the foregoing Plaintiffs' Complaint for Declaratory and Injunctive Relief using the CM/ECF system, and that I have delivered the filing to the Defendants, as well as the United States Attorney General and the United States Attorney for the Middle District of Florida, by mail at the following addresses:

This 19th day of November, 2021.

Respectfully Submitted,

/s/ Brandon Johnson
Brandon Johnson

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