IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS

JOSHUA WILSON, MICHAEL GROOTHOUSEN, RYAN MADIGAN, DERRICK GIBSON, STEVEN BROWN, BENJAMIN WALKER, SCOTT WELLS, BRITTANY PUCKETT, KARYN CHRISTEN, MICHAEL DOUGHTY, CARLEY GROSS, SUMMER FIELDS, JUSTIN KING, THOMAS BLANKENSHIP, for themselves and all others similarly situated,	§	
and	§	
MEMBERS OF THE ARMED FORCES FOR LIBERTY, an unincorporated association,	§	**Civil Action No. _____**
Plaintiffs	§	
v.	§	**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF; DEMAND FOR JURY TRIAL**
LLOYD AUSTIN, in his official capacity as Secretary of the U.S. DEPARTMENT OF DEFENSE,	§	
U.S. DEPARTMENT OF DEFENSE,	§	
JANET WOODCOCK, in her official capacity as Acting Commissioner of the U.S. FOOD AND DRUG ADMINISTRATION, and	§	
XAVIER BECERRA, in his official capacity as Secretary U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,	§	
Defendants	§	

INTRODUCTION

1. Plaintiffs comprise a group of servicemen and women, active duty, Reserve,

and guardsmen, all subject to the Department of Defense ("DoD") COVID-19 "vaccine" mandate issued by Defendant Secretary of Defense Lloyd Austin, III on August 24, 2021. Plaintiffs allege that the order to receive these non-vaccines is unconstitutional and unlawful *ab initio* because it mandates the injection of unlicensed, experimental products without informed consent, namely, the mRNA COVID-19 therapeutics developed by Pfizer/BioNTech and Moderna. This right to be free from being experimented upon against one's will has been codified in multiple federal statutes requiring informed consent for any mandated use of an "unlicensed product." *See* 10 U.S.C. § 1107a, and 21 U.S.C. § 360bbb-3 (collectively, the "Informed Consent Laws").[1] The Supreme Court has also long held that the right to refuse unwanted medical treatment is a fundamental human right.

2. All plaintiffs seek declaratory and injunctive relief against the Department of Defense ("DOD") and the Food and Drug Administration ("FDA"), who are both in gross violation of the Informed Consent Laws and the applicable provisions of the Public Health Service Act governing the regulation of biologics, ("PHSA"), 42 U.S.C. § 262, the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 et seq., as well as both the FDA's and DoD's own rules, regulations, and procedures. Plaintiffs also seek injunctive relief

[1] The Informed Consent Laws embody the long-standing U.S. and international consensus and legal norms prohibiting human medical experimentation, which were adopted after the revelations of Nazi Germany's war crimes. For example, Institutional Review Board (IRB) procedures for experiments involving human subjects are derived from the Helsinki Declaration, which followed directly from the Nuremburg Nazi Doctor Trials of 1947. *See* 45 C.F.R., Part 690, "Protection of Human Subjects"; *see also* George Annas (JD, MPH), *Beyond Nazi War Crimes Experiments: The Voluntary Consent Requirement of the Nuremberg Code at 70*, Am. J. of Public Health, 2018 Jan;108(1):42-46. ("The Code was a product of a war crimes trial, and a summary version of the Code was quickly adopted as an explicit requirement of the Geneva Conventions of 1949 and the International Covenant on Civil and Political Rights (ICCPR) in 1966; it is a norm of customary international law.")

against the DHHS and its sub-agencies, including the CDC's, declaration of emergency for these plaintiffs. Plaintiffs seek a jury trial on any and all claims or issues triable to a jury.

3. In short, the plaintiffs are being forced to take unlicensed, experimental biologics upon threat of discharge from the military under dishonor and being branded with less than fully honorable discharges for exercising their inalienable, God-given rights by the interlinked, co-dependent, and unlawful actions and inactions of all of these agencies, as detailed in the paragraphs that follow.

4. The named Plaintiffs, including the unincorporated association formed for this litigation, "Members of the Armed Forces for Liberty" (hereinafter "MAFL"), file this lawsuit on behalf of themselves, the members of MAFL, and of the class and sub-classes of similarly situated persons that they represent.

5. The class of plaintiffs includes all members of the United States Armed Forces* (*i.e.*, Air Force, Army, Marine Corps and Navy), Active, Reserve, and Guard, who are and have been subject to Defendant Secretary Austin's unlawful COVID-19 vaccine mandate ("DOD Mandate Class" or "DOD Mandate Plaintiffs"). (*It does not include the members of the Coast Guard because of the different defendants and authorities involved).

6. This class also includes the sub-class of servicemembers who have taken any of these series of shots and been injured as a result (the "Vaccine Injury Sub-Class" or the "Vaccine Injured Plaintiffs") or those who have documented medical contraindications and medical opinions advising against the shots who are being denied exemptions. In light of the recommendation of the Centers for Disease Control & Prevention ("CDC") Advisory Committee on Immunization Practices ("ACIP"), on whose recommendations Defendant

DOD purports to rely, for "boosters" for all adults,[2] the Vaccine Injury Plaintiffs may be ordered to take one or more possible "boosters" in the face of documented adverse reactions because of compromised military medical authorities who downplay or refuse to report vaccine adverse event information from military members.

7. The second sub-class consists of Armed Forces members who have already been infected with, and recovered from, SARS-CoV2 ("Covid-19"), and therefore have documented and demonstrable immunity to the virus (the "Natural Immunity Sub-Class" or "Natural Immunity Plaintiffs"). Plaintiffs who have already had Covid-19 are being denied Equal Protection of the laws under the Fifth and Fourteenth Amendments of the U.S. Constitution. These servicemembers are being treated less favorably than their identically situated peers in the military who took the shots, even though the shots do not provide sterilizing immunity from Covid-19 and do not prevent transmission of the virus by the "vaccinated."

8. The Natural Immunity Plaintiffs who have already had the virus have the most durable, robust, and long-lasting immunity that exists through exposure and recovery from the original SARS-CoV-2 virus. Moreover, many if not most of the members of this sub-class obtained this immunity quite recently during the December 2021-February 2022 spike in infections due to Omicron (including over 150,000 on active-duty, accounting for over 40% of total infections for active-duty personnel).[3] Thus, their natural immunity is at its strongest both due to its recency and because it was acquired due to infection of the

[2] *See CDC Expands Eligibility for COVID-19 Booster Shots to All Adults,* CDC Media Statement (Nov. 19, 2021), available at: https://www.cdc.gov/media/releases/2021/s1119-booster-shots.html.

[3] *See* Exhibit 1, March 28, 2022 Declaration of Colonel Tanya Rans (submitted as ECF 31-5 in *Bongiovanni v. Austin*, No. 3:22-cv-237-MMH-MCR (M.D. Fla.), ¶11 & Table.

currently prevalent Omicron variant. Vaccination not only would not provide any added protection, but in fact poses even greater risks of adverse effects for them than to those lacking natural immunity. Due to the serious risk of side effects, and the lack of any randomized, placebo-controlled studies showing any clinical benefit for those with previous infections, Dr. McCullough has concluded that vaccination is contraindicated for servicemembers with natural immunity.[4] Yet this medical fact is being intentionally ignored, and these servicemembers have been or will be punished by the Defendant DOD's willful actions and inactions.

9. Finally, there is no longer even a qualified "pandemic" or "emergency" under any current scientific standard that would justify *any* of the Defendants' actions, including, *inter alia*, the continued re-issuance of EUAs by the FDA for unlicensed, mRNA "vaccines" that are in fact genetic therapeutics and that are then mandated in violation of 10 U.S.C. § 1107a's express statutory prohibition. Additionally, whatever may have been the state of affairs with regards to the so-called "original" or Alpha variant of Covid-19 at the beginning of this pandemic, the current Pfizer/BioNTech and Moderna mRNA vaccines were rendered "obsolete" by the Delta and Omicron variants.[5] Thus, the current status cannot possibly justify mandating a vaccine known to be ineffective in preventing infection or transmission of the Omicron variant, much less illegally mandating the experimental, EUA versions of those vaccines.

10. Plaintiffs also challenge the lawfulness of the Department of Health and Human Services ("HHS") Secretary Xavier Becerra's continued re-issuance of Emergency

[4] *See* Exhibit 2, Nov. 15, 2021, Declaration of Dr. Peter McCullough, ¶12 (submitted as ECF 1-14 in *Crosby et al. v. Austin et al.*, 8:21-cv-02730-TPB-CPT, (M.D. FL))
[5] Exhibit 3, Apr. 23, 2022 Supplemental Decl. of Dr. McCullough, ¶10

Declarations that have been used to justify the FDA's EUA Reissuances. Defendant HHS Secretary Becerra has unlawfully perpetuated a state of emergency that mathematically doesn't exist for these plaintiffs anymore – if it ever did. HHS was required to terminate the EUAs for these vaccines after the emergency ended, and then again failed to terminate the EUA after the "vaccines" received FDA approval. *See* 21 U.S.C. § 360bbb-3(b)(2)(A).

11. All plaintiffs seek a declaratory judgment under the Declaratory Judgment Act, which authorizes federal courts to declare the rights of litigants. 28 U.S.C. §2201. The issuance of a declaratory judgment can also serve as the basis for an injunction to give effect to the declaratory judgment. *Steffel v. Thompson*, 415 U.S. 452, 461 n. 11 (1974). Plaintiffs also seek relief pursuant to 10 U.S.C. §1107 and/or §1107a, Administrative Procedures Act review (5 U.S.C. §702, et seq.), and the All Writs Act, 28 U.S.C. §1651. Plaintiffs seek temporary and permanent injunctive relief, and vacatur of the applicable Agency decisions, attendant to their claims for declaratory judgment and APA violations, as well as mandamus to compel the Defendant FDA to comply with the Public Health Service Act – all as detailed in the following paragraphs.

12. The respective service branches have notified the Plaintiffs that they must take the mRNA shot or they will be discharged for "misconduct," in addition to all of the various disciplinary and other administrative actions that have already been taken against them. Unlike all other citizens, Plaintiffs – as members of the military – are barred from suing under the Federal Tort Claims Act for damages if they are harmed by this medical experiment. *Feres v. United States*, 340 U.S. 135 (1950). Plaintiffs cannot sue their superiors for tort damages incident to military service, even when the underlying actions constitute criminal battery from medical experiments conducted without the

servicemember's consent or knowledge. *United States. v. Stanley*, 483 U.S. 669 (1987). There are no other adequate remedies available for these Plaintiffs, as Boards for Records Correction are neither statutorily empowered to grant the requested relief and have only limited discretionary authority for correction of records. *See* 10 U.S.C. §1552.

PARTIES

13. Defendant DOD is an agency of the United States Government. It is led by Secretary Lloyd Austin, III who is sued in his official capacity as the Secretary of Defense ("SecDef").

14. Defendant FDA is an agency of the United States Government. It is led by acting Commissioner Janet Woodcock who is sued in her official capacity as head of the FDA.

15. Defendant Department HHS is an agency of the United States Government and oversees many of the sub-agencies that are the subject of litigation in this action. It is led by Secretary Xavier Becerra who is sued in his official capacity as head of HHS.

16. Plaintiff Staff Sergeant (SSG)[6] Steven Brown is a cryptolinguist in the U.S. Army on active duty with the 173rd Infantry Brigade Combat Team (Airborne) at Caserma Del Din, Vicenza, Italy. His domicile is Plymouth, MA. SSG Brown enlisted in the Army in June 2013 and graduated from the Defense Language Institute (DLI) twice, once for Levantine Arabic in 2015 and once for Russian in 2019, subsequently earning an Associates of Arts degree in both languages. After graduating the Levantine Arabic course, he served as a Special Operations Team-Alpha (SOT-A) Team Member from 2016 – 2018.

[6] The abbreviations for military ranks are different across some branches of the armed services. Counsel has used the abbreviation of the respective plaintiffs' military branch. Differences in rank abbreviation are therefore intentional and not typographical errors.

During this time, he deployed once to Africa in an E-7 billeted position leading a SOT-A Team in support of an Operational Detachment Alpha (ODA) in a combat environment.

17. SSG Brown has not requested any exemption from the mandate; he has, however, insisted that he receive only a "fully" FDA approved shot. For refusing an EUA vaccine and explicitly asking for the FDA approved vaccine, he has been categorized as a "vaccine refusal" and received adverse action. SSG Brown has been negatively counseled and flagged on Sep. 29, 2021, for "refusing" to become "fully vaccinated," effectively barring him from both reenlistment and any favorable action to include awards, tuition assistance, and Army schools. He received a General Officer Memorandum of Reprimand (GOMOR) from the USAG Commanding General, Major General Andrew Rohling, on Nov 4, 2021 and filed a rebuttal reiterating his position on Nov. 9, 2021. Major General Rohling ordered the permanent placement of the GOMOR in my Army Military Human Resource Record on Jan. 19, 2022, effectively ending any hope for SSG Brown's continued career in the Army. Despite this, SSG Brown continues to support operations in Ukraine as a Russian cryptolinguist while he awaits discharge.[7]

18. Plaintiff Major Joshua Wilson was an F-16 pilot in the Air National Guard, but now flies the T-38 trainer as an instructor pilot at the 192d Fighter Wing at Langley AFB, VA. He is domiciled in McKinney, TX, because in his day job, Major Wilson is a pilot for American Airlines. He was commissioned in December 2002 and has served honorably for over 19 years in 3 combat coded airframes, with nearly 500 combat hours and 2 tours to Iraq. For the last 5 years in the Guard, he has served as a mission commander and instructor pilot training the next generation of American fighter pilots.

[7] Exhibit 4, Declaration of Plaintiff SSG Steven Brown, U.S. Army

19. Major Wilson submitted a medical exemption request in response to the COVID shot mandate because he has a documented allergy to the contents of the shots, a prior asymptomatic infection for Covid-19 with documented antibodies, and potential for clotting due to vein anatomy and a prior surgery. Two different medical doctors have recommended Major Wilson *not* get an mRNA shot. Notwithstanding all of this, he has been told that he will likely be separated for declining to take the mRNA "vaccines." Major Wilson is currently coded as a "refusal" even though his medical exemption paperwork is still being "processed." Major Wilson's allergy waiver has usually been handled "in-house" and renewed annually without issue, but because it involves the Covid Vaccine, it has higher visibility and can no longer be handled locally. Major Wilson has been told he needs to enter a medical evaluation for suitability for service, quit, or be forced out. There were no other options given.[8]

20. LCDR Michael Groothousen, U.S. Navy Reserve, originally enlisted in December 1998 in the VA Army National Guard as an Air Defense Artilleryman. He is domiciled in Portsmouth, VA. In May of 2000, LCdr Groothousen was discharged from the VA NG to attend the U.S. Naval Academy. After graduation in 2004, LCDR Groothousen was commissioned, attended flight training, and became a rotary-wing naval aviator. LCDR Groothousen was assigned to his fleet squadron, HSL-42, where he deployed to Operation Iraqi Freedom and received an Air Medal (Individual Award) for combat missions in theater. He was later selected to be a company officer at the Naval Academy and completed his Master's in Leadership Education and Development in 2011, serving 3 years as a Company Officer at Annapolis.

[8] Exhibit 5, Declaration of Plaintiff MAJ Joshua Wilson, VA Air National Guard

21. LCDR Groothousen left active duty and transitioned to the Naval Reserve in 2016 and has honorably served in the military a total of 19+ years. He currently is assigned to Naval Warfare Development Center, Detachment 101, as the Assistant Operations Officer and Training Officer. LCDR Groothousen is a cancer survivor and has had a medical history of Bell's Palsy, migraines, and elevated blood pressure, so he submitted a *permanent* Medical Exemption (ME) request to the Covid-19 mRNA vaccines in coordination with his civilian flight surgeon, Dr. Mimi Peak. LCDR Groothousen concurrently submitted a *temporary* ME request because he is also a member of a clinical study being conducted by the Uniformed Services University of Health Sciences (USUHS). In Nov. 2021, LCDR Groothousen and his Commander were told by Naval Operation Support Center staff that his *temporary* ME request was approved until the USUHS study's end (in Sep. 2022). In Jan. 2022, however, he learned that his *permanent* ME had never been submitted and he was subsequently ordered in writing to be vaccinated by a local Navy doctor, CDR Alband, USN, who has never even met, much less treated, LCDR Groothousen. When LCDR Groothousen asked about his *temporary* ME approval (for being in the USUHS study) he was told that it was "no longer in effect" and would need to be resubmitted. LCDR Groothousen has also had a documented case of Covid-19 in January 2021. He was informed that none of this would affect his requirement to receive the Covid-19 shot.[9]

22. Plaintiff Capt. Ryan Madigan is a C-5 instructor pilot in the U.S. Air Force Reserve, is a C-5 Galaxy pilot serving at the 68th Airlift Squadron at Joint Base San Antonio (JBSA), Lackland, TX. Captain Madigan serves as both a traditional Reservist and a full-

[9] Exhibit 6, Declaration of Plaintiff LCDR Michael Groothousen, USNR

time Air Reserve Technician. Captain Madigan is domiciled in southern Texas. In his "other" job, Captain Madigan flies the Boeing B777 for Federal Express. Captain Madigan was commissioned in the Air Force in 2011, graduated from pilot training in 2013, and has more than 1500 hours in the C-5 Galaxy since. He has twice been named Operations Group Flight Commander of the Quarter (Q1 and Q4 of 2021).

23. In Oct. 2021, Capt. Madigan submitted a Religious Accommodation Request (RAR) from the Covid-19 mandate. He was notified it was denied on Nov. 18, 2021, and given 72 hours to appeal, despite the fact that he was not on any kind of military orders or status at the time. Nevertheless, he submitted his appeal on time and has not had a response. In the meantime, despite being the Group Flight Commander of the Quarter for Q4 and having an RAR appeal pending, Captain Madigan was grounded from all flying by his command on Dec. 3, 2021 – to include flying simulators. As a result, Captain Madigan is no longer current in the C-5, although he has continued to fly the B777 for FedEx all over the world, without regard to his vaccination status. Captain Madigan has asked for his grounding in writing, but his command refuses to put the grounding order to paper. Capt. Madigan also caught Covid-19 in Jan. 2022 and returned to work a few weeks after his quarantine period.[10]

24. Plaintiff Major Benjamin D. Walker is an F-16 Fighter Pilot, currently serving as a T-38C Instructor Pilot in the United States Air Force. Major Walker is stationed in Wichita Falls, Texas, on his final expected assignment in the Air Force after 21 years and 9 months of service. Major Walker was commissioned in the USAF in June 2004 from the United States Air Force Academy. He was deployed to Iraq for Operation

[10] Exhibit 7, Declaration of Plaintiff Capt. Ryan Madigan, USAFR

Iraqi Freedom, where he flew 56 combat missions. He was subsequently hand-picked by his command to deploy to Afghanistan for Operation Enduring Freedom for the first USAF F-16 deployment to that theater. Following that assignment, Major Walker spent one-year unaccompanied tour in Korea as an F-16 pilot patrolling the Korean DMZ and supporting U.S. military operations in the Pacific Theater.

25. In 2015, wanting to reunite with his family, Major Walker was selected for orders to Sheppard Air Force Base in Wichita Falls, Texas, as part of the 14-nation Euro-NATO Joint Jet Pilot Training Program (ENJJPT), where he eventually came to be in charge of – the "chief" of – the "check" section, responsible for ensuring all students meet the standards for the supersonic jet trainer, the T-38C Talon. On September 17, 2021, in response to the DoD Vaccine Mandate, Major Walker submitted a Religious Accommodation Request in accordance with his strongly held Christian beliefs. Since then, he has received a designation in his personnel file as restricted from receiving Permanent Change of Station (PCS) orders, as well as his medical records marked that he has "refused" the vaccine. He has been grounded from flight duties and had his local security clearance suspended. Major Walker was ordered and had to undergo a command-directed urinalysis and mental health evaluation after his RAR submission. Major Walker was also ordered out of the operations building in order to keep "good order and discipline" by keeping away "dissenting opinion" from the general training population of ENJJPT. In January 2022, Major Walker tested positive for antibodies and in February 2022 tested for T-cells that recognize COVID-19 vital proteins. Major Walker's RAR was denied on Feb. 9, 2022, and he appealed within the 5-day window on Feb. 14, 2022. He received his RAR appeal denial from the Air Force Surgeon General's office on March 21, 2022, and ordered to take the

vaccine within 5 days.[11]

26. Plaintiff LtCol Scot M. Wells, TX Air National Guard, is currently a Maintenance Squadron Commander serving at Fort Worth Joint Reserve Base (JRB), Texas. LtCol Wells first enlisted in the U.S. Air Force in 1992 as a C-130 Crew Chief for 4 years in the Air Force and then in the NC Air National Guard working on F-16s. In 2003, he was commissioned as a C-130H Navigator. In 2011 he transferred to the Texas Air National Guard where he still is. LtCol Wells was promoted to Chief Navigator, then promoted again to Chief of Current Operations for the 16th Air Wing at JRB Ft. Worth. LtCol Wells has deployed three times to Afghanistan and Kuwait as a Company Grade Officer, and three times to Kuwait as a Field Grade Officer in support of Operation Enduring Freedom, Operation Freedom Sentinel, and Operation Resolute Support. He has amassed over 3300 flight hours, including 663 combat and 121 combat support hours, and been awarded the Meritorious Service Medal, 6 Air Medals, and other awards for distinguished service. On October 26, 2021, he submitted a Religious Accommodation request in response to the mandate. Despite having traveled throughout the height of the pandemic in 2020 and through 2021 unvaccinated without incident, Colonel Wells' accommodation request has gone unanswered. LtCol Wells has served honorably for over 30 years.

27. Plaintiff Staff Sergeant (SSgt) Brittany N. Puckett is a Survival Evasion Rescue Escape (SERE) instructor for pilots and other "high-risk" military members. She is currently stationed at Cannon AFB, New Mexico, but she grew up in, and her Home of Record (HOR) is Sanger, Denton County, TX. SSgt Puckett enlisted in 2014 and has

[11] Exhibit 8, Declaration of Plaintiff Major Benjamin Walker, USAF

completed 29 jump missions and led thousands of hours of instructions for aircrew. SSgt Puckett's work requires her to attend continuation training, observation trips, hands-on schooling, and other trainings, but since she submitted her Religious Accommodation Request (RAR) on September 15, 2021, she has prohibited from attending any training. She contracted COVID-19 in December of 2019 and when tested for antibodies, her results showed substantial immunity to the virus. She has since not contracted the virus despite being in close contact with positive cases. On January 28, 2022, SSgt Puckett's RAR was denied in a "drop-down menu" format with several grammatical mistakes. She appealed and is still waiting for a response. SSgt Puckett visited her base clinic immunization section to determine if there was any Comirnaty or other "fully licensed" products and was informed by the medical staff that there are no fully licensed products available, that the staff is aware that all of the products they have in stock are conspicuously labeled EUA, and that the staff are not providing the appropriate informed consent in compliance with C.F.R. Title 21 50.23 because they fear their careers and medical licenses are at risk if they do not follow through on the mandate to vaccinate everyone. SSgt Puckett is at risk of losing her retirement and having to pay back her $55,000 selective reenlistment pay because she won't take the mRNA shot.[12]

28. Plaintiff COL Karyn L. Christen is a command pilot in the U.S. Air Force Reserve with a TS/SCI clearance and over 2,300 flight hours in multiple aircrafts. She currently serves as the Deputy, Commander's Action Group, JRB Fort Worth, Texas. Colonel Christen is domiciled in Flower Mound, Denton County, TX. She was a distinguished graduate out of the U.S. Air Force Academy in 1995. After earning her

[12] Exhibit 9, Declaration of Plaintiff SSG Brittany Puckett, USAF

Master of Science in Environmental Science Engineering and completing Undergraduate Pilot Training, Colonel Christen was sent to Travis Air Force Base and became Aircraft Commander, deploying in support of Operations Southern Watch, Desert Fox, Phoenix Scorpion I and II, and Allied Force. Colonel Christen became a certified flight instructor and evaluator and transitioned to the Air Force Reserve in 2005 at the U.S. Air Force Academy. In her last five performance evaluations, Colonel Christen was rated #1 out of 13 Operations Group Commanders, #1 out of 24 Operations Group Commanders, #1 out of 5 Wing Colonels, #1 out of 297 Wing Field Grade Officers, and #1 out of 13 Wing Squadron Commanders. In 2018, COL Christen was promoted to her current rank and commanded the 726th Operations Group, Creech AFB, NV. In August 2021, after a successful command tour, Col Christen moved to her current billet with the 10th AF.[13]

29. In response to the COVID shot mandate, COL Christen was tasked to lead the 10th Air Force COVID-19 Operational Planning Team. While in that role, COL Christen raised concerns about the legality of the mandate to her Commander, to the 10 AF Staff Judge Advocate, the Air Force Reserve Command Operational Planning Team, AFRC Staff Judge Advocate and others. COL Christen's concerns were not only dismissed but resulted in her removal from the Operational Planning Team to "eliminate the noise coming from 10 AF." Major General Scobee stated in several virtual meetings attended by Christen that he, "did not see a continued path to serve for anyone unvaccinated" prior to the Air Force guidance on religious accommodation being released. Colonel Christen submitted a Religious Accommodation Request which was denied. She was given 72 hours to submit an appeal, however, her leadership refused to provide Colonel Christen with her

[13] Exhibit 10, Declaration of Plaintiff Col Karyn Christen, USAFR

RAR appeal denial package in order to draft her response. Colonel Christen's leadership were told by the Air Force to not give the Colonel her paperwork and if she wanted it that she would have to submit a FOIA request. Colonel Christen attempted to request her package under the Privacy Act, but was told it would take several months, therefore Colonel Christen was forced to write an appeal letter that did not address her own particular situation because she was not granted access to her own RAR packet. Colonel Christen's request under the Privacy Act was denied because of "pending litigation" and she never received a formal reply. Eventually, the Colonel received a FOIA response in February 2022 that was heavily redacted. Despite having 72 hours to draft her appeal, Colonel Christen's appeal package sat at AFRC from 23 November 2021 until 19 January 2022. To this day, Colonel Christen has not received an answer to her appeal. COL Christen has previously had and recovered from Covid-19 in January of 2022.

30. Plaintiff Capt. Michael Doughty is a Cyber Warfare Officer in the U.S. Air Force Reserves, currently serving at Offutt Air Force Base, Nebraska. He is domiciled in Little Elm, Denton County, TX. Capt. Doughty first enlisted in the Air Force Reserves in July 2005 in response to the events of September 11, 2001, as an aircraft maintainer on the F-16 until 2012 when he was selected to go to Officer Training. Captain Doughty served as an Air Battle Manager from 2012-2020. In May 2020, he joined a new unit and cross-trained to become a Cyber Warfare Operations Officer. Capt. Doughty submitted a Religious Accommodation Request (RAR) in response to the COVID-19 vaccine mandate, which was initially denied, then rescinded as "in error." He was then informed to submit his RAR package for Covid-19 *only* and then submit a *separate* RAR for other vaccines, like influenza. Capt. Doughty did this, but shortly after was ordered to resubmit his package

for Covid-19 (again). He was informed on the phone of the RAR's denial and given the week to appeal. At the time he was informed of the denial, Captain Doughty was a non-duty status civilian, so he was ordered to comply within a time when he was not in a military status. Captain Doughty sent an official memorandum for record (MFR) to his command on March 11, 2022, requesting an extension to the appeal timeline so that he could have time to request his original packet, review it, and seek legal counsel if necessary. This request was denied the same day, and he was ordered to turn in his appeal by March 15, 2022, which he did. Captain Doughty has a documented case of COVID-19 in January 2022 and was tested positive for antibodies on February 28, 2022, and he has still not received a response to his appeal. During the pandemic, Capt. Doughty completed a 4-month temporary duty assignment at the U.S. Strategic Command (for which he received a Joint Service Commendation Medal), attended and graduated the six-month Cyber Warfare Training school, graduated a two-month Cyber Defense Analysis Initial and Mission Qualification Training, and traveled across the country for multiple trainings, all prior to the mandate and during the height of the COVID-19 pandemic.[14]

31. Plaintiff LtCol Summer Fields is a staff officer in the U.S. Air Force Reserves, originally enlisted, she eventually became a pilot in 1997-1998. As a Field Grade Officer, LtCol Fields was retrained to fly the RQ-4 Global Hawk, supporting combat missions and humanitarian and disaster relief missions. LtCol Fields became the Director of Operation for the 13th Reconnaissance Squadron at Beale AFB from 2013-2018 and then retained command in August 2018 until August 2020. During the beginning of the pandemic, LtCol Fields was the squadron commander and continued to execute worldwide

[14] Exhibit 11, Declaration of Plaintiff Capt. Michael Doughty, USAFR

missions and fly the RQ-4. In December 2020, Lt Col Fields moved to a staff position at the 10th AF and was asked to backfill as the executive officer to the 2-star Commander. Shortly after, she was asked to be the Director of Staff (DS) for 10 AF. LtCol Fields applied for the job and was given a temporary job offer in September 2021. By the time the DS position was ready to be filled, however, the COVID-19 vaccine mandate was handed down and Lt Col Fields was no longer considered for the position. The position was temporarily given to someone else, then advertised again as open, because LtCol Fields filed an RAR in response to the vaccine mandate. Her initial RA request was denied with the LtGen acknowledging her sincerely held beliefs, but denying the request based on the "compelling interest of the AFR" that neither the General, nor any of LtCol Fields superiors, could articulate to her. Since then, LtCol Fields has tested positive for COVID-19 antibodies in January 2022.[15]

32. Plaintiff MAJ Justin King, U.S. Marine Corps, is a KC-130J Aircraft Commander currently stationed at MCAS Cherry Point, NC. He is domiciled in Gilmer, Upshur County, TX. Major King was commissioned in 2009 after his graduation from the U.S. Naval Academy. Upon completion of flight training, MAJ King was initially stationed at Cherry Point, as well. After his first tour, he was competitively selected for the Naval Postgraduate School in Monterey, CA, where he graduated with distinction with an M.S. in Systems Technology. He received the Award for Academic Excellence and subsequently received orders for Marine Corps Systems Command. Upon completion of his tour at SYSCOM, Major King returned to the cockpit and flying duties at MCAS Cherry Point.

33. MAJ King submitted an RAR in response to the Covid Vaccine Mandate.

[15] Exhibit 12, Declaration of Plaintiff LtCol Summer Fields, USAFR

After he submitted his RAR, MAJ King was placed in a non-deployable status. Despite that, in March 2022, he was sent from Cherry Point to Twenty-nine Palms, CA for a Service-Level Training Exercise for seven weeks. This exercise is supposed to mimic a real deployment, including living in close-quarters with other Marines. MAJ King was told he had to go due to staff shortages at his command. In Jan 2022, he tested positive for COVID at a military medical facility with the results included in his medical records. A few weeks later, he tested positive for anti-bodies (test conducted at Harris Teeter pharmacy) and T-cells (test completed by T-detect), indicating natural immunity. MAJ King received an initial denial from the Deputy Commandant, Manpower & Reserve Affairs (DC, M&RA) on December 2, 2021 (dated November 29, 2021). The denial contained many inaccurate statements that were thoroughly addressed in his appeal. He appealed the initial denial on December 15, 2021. Major King's appeal is still pending with the Assistant Commandant of the Marine Corps.[16]

34. Plaintiff LT Thomas P. Blankenship is a Surface Warfare Officer in the U.S. Navy, currently serving in Newport, RI, at the Surface Warfare Officer School. LT Blankenship enlisted in 2000 and since then has served on nuclear deterrent sea patrols on submarines, multiple sea deployments on an Arleigh Burke class guided missile destroyer, as well as a deployment on a Ticonderoga-class guided missile cruiser. LT Blankenship is domiciled in Richardson, Collin County, TX. In 2018 he was selected to redesignate and serve as a Surface Warfare Officer (SWO) and has been a Naval Officer for 8 years. Since 2020, Lieutenant Blankenship has mentored and instructed hundreds of Naval Officers en route to their first commands after SWO School. In September 2021, Lieutenant

[16] Exhibit 13, Declaration of Plaintiff MAJ Justin King, USMC

Blankenship submitted an RA Request in response to the COVID mandate and in November 2021 it was denied. The denial contained several inaccurate statements which he corrected in his appeal. In December 2021 LT Blankenship had a documented case of COVID-19 and subsequently tested positive for antibodies, all of which was included in his appeal which he filed in January 2022 and is currently pending. Throughout the pandemic and to the current day, LT Blankenship has continued to be in contact with hundreds of students to train them for their upcoming missions, traveled for official work or personal reasons with no issue without the shot.[17]

35. Plaintiff Capt. Carley Gross is a KC-135R/T Pilot and Flight Commander in the U.S. Air Force currently serving at the 93rd Air Refueling Squadron at Fairchild Air Force Base, Spokane, WA. Capt. Gross hails from Del Rio, TX; she graduated from the Air Force Academy in May 2014. She completed Undergraduate Pilot Training in 2016 and then from 2017 until 2020 Capt. Gross flew the MQ-9 Reaper at Cannon AFB as an Aircraft Commander, with multiple tactical engagements and thousands of hours of intelligence, surveillance, and reconnaissance data. For this, Capt. Gross was selected Pilot of the Quarter once and logged 1600 combat hours. In 2020, Captain Gross changed duty stations to Air Mobility Command to fly the KC-135R/T in Washington and since has flown around the world throughout the European Command, Central, Southern, Northern, and Pacific Commands. During deployment, Captain Gross flew in combat for 4 months out of Qatar and Incirlik Airbase, Turkey, while supporting operations, including the Noncombatant Evacuation Operation (NEO) from Afghanistan. Since then, she has received multiple awards for service including the 2020 and 2021 Squadron Company

[17] Exhibit 14, Declaration of Plaintiff LT Thomas Blankenship, USN

Grade Officer (SGO) of the Quarter Award, 2021 Squadron Flight Commander of the Year Award and 2022 Squadron Flight Commander of the Quarter.

36. Additionally, Captain Gross is also a sponsored, world class athlete. She ran NCAA Division I cross country and track and field at the U.S. Air Force Academy, and competed in collegiate Olympic distance triathlons, successfully completing three USA Triathlon Collegial Club National Championships and earning All-American status twice. In 2019, Captain Gross raced at Ironman 70.3 Waco, qualifying for the 2020 Ironman 70.3 World Championships, which was delayed due to the pandemic. In May 2021, she qualified for the 2021 Ironman 70.3 World Championships but could not participate because she was deployed at the time, however, she continues to train for this year's world championships and other races. When the COVID-19 vaccination mandate was handed down in late August 2021, Captain Gross was deployed and subsequently reached out to her Base's Medical Group (MDG) during deployment for a medical exemption, while simultaneously drafting her RAR. Her medical exemption was denied, and she was informed that she did not fit the CDC criteria. Capt. Gross felt she had been unfairly evaluated because she was not physically present in the office or even in the United States at the time. Subsequently, Captain Gross filed her RAR and still has not received word on the status of the request. Captain Gross also has strong natural immunity with a documented case of COVID-19 in August of 2020 that transformed into a rare case of "long haul COVID" in which Captain Gross endured chest pains and pressures for several months. In June 2021, the morning of deployment, she tested positive for antibodies and in December 2021 tested positive for T-Cell immunity, 16 months after her initial infection. Captain Gross continues to be subject

to constant COVID testing and threatened with an LOR if her initial RAR is denied.[18]

37. Plaintiff Master Sergeant (MSG) Derrick Gibson is a career counselor in the U.S. Army Reserve on active duty in the Active Guard Reserve ("AGR") program. He is assigned to the 9TH Battalion, Army Reserve Careers Group, with duty assignment at Camp Robinson, North Little Rock, Arkansas. His domicile is Jacksonville, AR. MSG Gibson first enlisted in the Army in 1999 as a wheeled vehicle mechanic and deployed to Iraq in 2003, where he earned a Combat Action Badge. He has served honorably for over 23 years. MSG Gibson caught and recovered from Covid-19 in 2020. On July 19, 2021, MSG Gibson went to the base medical clinic and tested positive for Covid-19 with results showing "REACTIVE – Higher than Normal" more than a year after he initially had Covid-19. Because of this, he submitted a medical exemption in accordance with AR 40-562 on Aug. 23, 2021. By December, he had still heard nothing back, so he resubmitted his request with the written concurrence of his primary care manager (PCM). He still has not received a response to his medical exemption request as of this filing. Because of his 2 pending medical exemption requests, MSG Gibson is restricted to 100 miles of his base for official travel and had his Permanent Change of Station orders (PCS) to Fort Jackson, SC, for June 2022 were pulled.[19]

38. Members of the Armed Forces for Liberty ("MAFL," or "the Association") is an unincorporated association formed solely for the purpose of this litigation. It is comprised of 510 members of the Armed Forces (in addition to the 14 named plaintiffs), from all branches of the services (except the Coast Guard), active duty, Reserve,

[18] Exhibit 15, Declaration of Plaintiff Capt. Carley Gross, USAF
[19] Exhibit 16, Declaration of Plaintiff MSG Derrick Gibson, USAR

Guardsman, and from across the range of enlisted and officer ranks, up to Colonel (O-6). The common legal issue all members of the Association share is that they are all subject to the illegal enforcement of Defendant Austin's Covid-19 Mandate and the Defendant FDA's illegal regulatory actions and inactions regarding mRNA EUA products.[20]

39. The named Plaintiffs and members of MAFL represent the DOD Mandate Class or DOD Mandate Plaintiffs, which is class of members of the Armed Forces who are similarly situated to the named Plaintiffs and who are subject to the mandatory declarations and orders of the Department of Defense in relation to the compulsory use of Covid-19 vaccines. Certain Plaintiffs also represent the following two sub-classes: (1) the Vaccine Injury Sub-Class or Vaccine Injury Plaintiffs, which include servicemembers who are similarly situated to Plaintiffs, who have taken either the Pfizer/BioNTech or Moderna COVID-19 vaccines and suffered a vaccine-related injury, and who may be required to take "booster" shots in the future; and (2) the Natural Immunity Sub-Class or Natural Immunity Plaintiffs, which includes members of the Armed Forces who are similarly situated to the named Plaintiffs and who have had a documented case of Covid-19 and recovered from it.

JURISDICTION AND VENUE

40. There is a legitimate controversy because the plaintiffs in this case have been ordered to take an experimental EUA "vaccine" without their informed consent for a virus and from which some members of the class already have immunity. Those class members should be exempt from the shots by DoD regulation regardless of the vaccine's

[20] Because of the voluminous documents, all of the MAFL members' individual declarations and information will be submitted separately by Plaintiffs in accordance with instructions from the Clerk of Court.

legal status. The case is neither speculative nor hypothetical as Defendant DoD has notified this group of plaintiffs that they must submit to the mandate now, their various requests for exemption or accommodation have been denied, and – in many cases – so have their final appeals.

41. This case arises under federal law, namely the Fifth and Fourteenth Amendments of the United States Constitution, U.S. Const. Amends. V & XIV; the APA, 5 U.S.C. § 551, *et. seq*.; 10 U.S.C. § 1107a; 21 U.SC. § 360bbb-3; and 42 U.S.C. § 262.

42. Jurisdiction is proper in this Court under the Administrative Procedure Act review (5 U.S.C. §704 and §706), the Declaratory Judgment Act (28 U.S.C. §2201), and under 28 U.S.C. §§1331, 1346, and 1361.

43. Venue is proper in this Court pursuant to 28 U.S.C. §1391(e)(1) and §1402(a)(1) because a number of members of the DOD Mandate Class, as well as of the Vaccine Injury Sub-Class and the Natural Immunity Sub-Class, are domiciled or stationed in the Eastern District of Texas. Other members of the plaintiff class are aboard Defendant DoD military reservations in the court's district subject to the DOD COVID-19 Vaccine Mandate Order, and all members are directly affected by and subject to its mandate to take an experimental, EUA shot.

44. N.B. Some of the named plaintiffs and members of the Association have filed for religious accommodations or medical exemptions; in all cases, those requests have been denied. The plaintiffs do not press any RFRA-related claims here and only note their place in the process – whether they have received a denial, have appealed, are pending an appeal, only insofar as it becomes necessary to motion the court for relief so that plaintiffs are not discharged by the Defendants.

FACTUAL & REGULATORY BACKGROUND

I. LEGAL HISTORY

"…when experience is not retained, as among savages, infancy is perpetual. Those who cannot remember the past are condemned to repeat it."[21]

45. An Institute of Medicine report in 1993 estimated that some 60,000 members of the ***United States*** military were used as human subjects in the 1940s, and that just for two chemical agents – mustard and lewisite, both poisonous gases – and the majority of these people were not informed about the nature of the experiments, nor were they given proper medical care or follow-up after the research.[22]

46. In the 1940s, the U.S. government repeatedly exposed military members to nuclear test blasts, producing a class of men who would come to be known as "Atomic Veterans." Estimates place the number of Atomic Veterans at approximately 400,000. It took until May 20, 1988, for the U.S. government "[t]o amend title 38, United States Code, to provide a presumption of service connection to veterans (and survivors of such veterans) who participated in atmospheric or underwater nuclear tests as part of the United States nuclear weapons testing program or in the American occupation of Hiroshima or Nagasaki, Japan, and who suffer from certain diseases that may be attributable to exposure to ionizing radiation, and other purposes."[23]

47. During the 1950s and 60s, the CIA and the Army engaged in

---

[21] George Santayana, "Reason in Common Sense," Chptr. XII, 1905

[22] Institute of Medicine, Committee to Survey the Health Effects of Mustard Gas and Lewisite, David P. Rall, and Constance M. Pechura. *Veterans at Risk: The Health Effects of Mustard Gas and Lewisite*. Washington, D.C.: National Academy Press, 1993, pp. 3-4, 6-8, 50-52, 224-226.

[23] *See, e.g.*, Pub. L. 100-321, "Radiation Exposed Veterans Compensation Act of 1988." *See also* S. Prt. 103-97, "Is Military Research Hazardous to Veterans' Health? Lessons Spanning Half a Century," Staff Report for the Comm. on Veterans Affairs.

experimentation on U.S. service members, both with and without their knowledge. In several different experiments, the DoD caused service members to unknowingly ingest hallucinogens. Most of the experiments centered around "mind control" and interrogation of persons under the effects of hallucinogens. This was prompted by the perception in U.S. intelligence that China and the Soviet Union had used, and were using, hallucinogens for "brainwashing" and interrogation of prisoners of war. This program was known by the code name MKULTRA. It involved giving LSD and another substance known as quinuclidinyl benzilate, a hallucinogen code-named BZ, to unsuspecting members of both the Armed Forces and even civilians.[24]

48. In 1958, Master Sergeant James Stanley responded to a posting on Fort Knox, Kentucky, that solicited volunteers to help the Army develop methods for testing and defending against chemical weapons. The volunteers were told they would be testing protective clothing. MSgt Stanley was transferred to Aberdeen, Maryland, for the testing. He did not learn until 17 years later that he had been given LSD during the program without his knowledge. He found this out accidentally in 1975 when contacted by Walter Reed Army Medical Center, which was conducting follow-up on those who had participated in the 1958 test. Walter Reed wanted to know of any long-term health consequences to MSgt Stanley from his ingestion of the hallucinogen. MSgt Stanley in the intervening years had suffered health problems and hallucinations that he had no explanation for, and which he claimed had destroyed his marriage. MSgt Stanley sued and his case went all the way to the Supreme Court, which found that MSgt – and all military members – had no cause of

[24] *Human Drug Testing by the CIA, 1977*: *Hearings Before the Subcommittee on Health and Scientific Research of the Committee on Human Resources*, U.S. Senate, 95th Cong., 1st Session, 20-21 September 1977. Washington: U.S. Govt. Print. Off., 1977.

action if the harms they suffered were "incident to miliary service." *See United States. v. Stanley*, 483 U.S. 669 (1987).

49. Just two years after the *Stanley* decision, prior to the first Gulf War, the DOD sought to pretreat service members with several unlicensed (i.e. "investigational") new drugs, including pyridostigmine bromine ("PD") and a botulinum toxoid ("BT") vaccine, which could not be administered without informed consent. The DOD successfully petitioned the FDA to establish a new rule waiving U.S. servicemembers right to informed consent.[25] The administration of these experimental drugs has been correlated with "Gulf War illnesses" that "debilitated over 174,000 service members." *Id*. at 724 (citations omitted).

50. After extensive hearings in Congress across multiple committees documenting systemic, repeated failures by the DOD involving the health of America's volunteer force, including the ill-fated and disastrous anthrax vaccine – the first EUA product in U.S. history – the U.S. Congress passed Title 10 U.S.C. §1107 in 1997, requiring that in any instance in which the DOD sought to use ANY unlicensed product on the Armed Forces, NO ONE short of the Commander-in-Chief himself or herself could waive a servicemember's right to informed consent.

51. In the following years, as the anthrax vaccine program kicked off yet remained mired in failed FDA inspections and controversy, Congress continued to hold hearings on the subject and strengthened 10 U.S.C. §1107's protections and requirements

[25] *See generally* Ex. 9, Efthimios Parasidis, *Justice and Beneficence in Military Medicine and Research*, 73 Ohio St. L.J. 723, 732-39 & 759-60 (2012).

for both the Secretary of Defense and Commander-in-Chief.[26]

52. In 2003, the district court for the District of D.C. issued an injunction against both the Defendant DoD and Defendant FDA for their violations of that statute. *See Doe v. Rumsfeld*, 297 F. Supp. 2d 119 (D.D.C. 2003)("*Rumsfeld I*"). In the middle of that litigation in 2004, and in part as a result of the Anthrax Letter Attacks that occurred the week after 9/11, Congress passed the Project BioShield Act, the first version of the current EUA statute, 21 U.S.C. §360bbb-3.

II. FDA APPROVAL/LICENSURE AND AUTHORIZATION OF VACCINES

A. FDA Regulatory Schema

53. The Food, Drug and Cosmetic Act ("FDCA") prohibits anyone from introducing or delivering for introduction into interstate commerce any "new drug" or "biological product" (i.e. vaccines) unless and until the FDA has approved a drug as "safe and effective." 21. U.S.C. §331(a). The PHSA similarly prohibits the introduction of biological products, including vaccines, unless and until the FDA has approved the Biologics License Application ("BLA") demonstrating that the biological product is "safe, pure and potent," 42 U.S.C. § 262(a)(1)(C)(i)(II), where "potent" is interpreted by the FDA as equivalent "effective" under the FDCA.[27]

54. PHSA Section 351(j), 42 U.S.C. § 262(j), directs the FDA to apply the requirements of FDCA Section 505, 21 U.S.C. § 355, for approval of drugs to vaccines and other biologics. A vaccine – or any drug or biologic product – must demonstrate

[26] Compare 10 U.S.C. §1107 (1997) with 10 U.S.C. §1107 (2000). *See also* 144 Cong. Rec. H. 4616, 16 June 1998.

[27] *See* 21 C.F.R. § 600.3(s); FDA Guidance, "Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products" at 4 (May 1998), available at https://www.fda.gov/media/71655/download (last visited May 4, 2022).

"substantial evidence" of both "safety" and "efficacy" (or "potency" for biologics) through "well-controlled, clinical investigations."[28] Accordingly, the FDA largely applies the same requirements for licensure of a biologic under the PHSA as it does for approval of new drugs under the FDCA, except for the additional requirement "purity" under the PHSA, which pertains to biologic manufacturing facilities and processes, and the specific application requirements and contents set forth in the PHSA Section 351(a). 42 U.S.C. § 262(a).

55. The PHSA expressly prohibits the sale of any biologic product in interstate commerce unless the package is "plainly marked with" "the proper name of the biological product," (e.g., Comirnaty or Spikevax) and "the name, address and applicable license number of the manufacturer." 42 U.S.C. § 262(a)(1)(B)(i)-(ii). These requirements are mandatory, not discretionary. See 21 C.F.R. § 610.60(a)(1)(2) (directing that the "proper name" and "license number" "shall appear on the label" of biological product); see also 21 C.F.R. § 207.37(a)(2) (a product is "deemed … misbranded" if labeling codes used to "denote or imply FDA approval of [an unapproved] drug").

56. The FDA's entire *raison d'être* is in ***prohibition*** – that is, placing the burden of proof upon those who want to "introduce" regulated products into the stream of commerce and denying them entry until and unless they meet the standards set forth in the Act.

57. All FDA-licensed or approved products – biologic, drug, or device – are

[28] *See, e.g.*, 21 U.S.C. §355(b)(1)(A)(i)("…shall submit…full reports of investigations which have been made to show whether such drug is *safe* for use and whether such drug is *effective* in use.") *See also* 21 C.F.R. §314.50 *et seq*. *Accord* "FDA Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biologic Products," DHHS/FDA/CBER/CDER, pp. 2-4, May 1998 (last accessed May 4, 2022).

tracked by various elements within Defendant H&HS by statute and regulation. The Defendant FDA manages the National Drug Code ("NDC") under 21 C.F.R. §207. Every "product," which includes "drugs" and "biologics" such as COMIRNATY or SPIKEVAX, is given a unique NDC, but the regulations are explicit that "[r]egistration of an establishment or listing of a drug does not denote approval of the establishment, the drug, or other drugs of the establishment, nor does it mean that a product may be legally marketed. *Any representation that creates an impression of official approval or that a drug is approved or is legally marketable because of registration or listing is misleading and constitutes misbranding*." 21 C.F.R. §207.77 (emphasis added).

B. FDA Emergency Use Authorization of Unlicensed Products

58. Section 564 of the FDCA, 21 U.S.C. § 360bbb-3, authorizes the FDA to issue an EUA for a medical drug, device, or biologic, **only** where certain pre-conditions have been met. As relevant here, these conditions are: first, 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 second that the Defendant 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).

59. The FDA has a specific and affirmative statutory duty to "prohibit **(d)** the introduction or delivery for introduction into interstate commerce of any article in violation of section… 360bbb-3 of this title." 21 U.S.C. §331(d).

60. There are significant differences between "FDA-approved" products and those products that are merely granted an EUA; those differences are why the two classes

are necessarily "legally distinct."[29] First, the requirements for efficacy are much lower for EUA products than for licensed products. In particular, rather than requiring an applicant to prove that a vaccine is "*safe*" and "*effective*" (or *potent*, in the case of biologics) based on well-controlled clinical trials, mere speculation unsupported by evidence regarding safety and efficacy is sufficient to grant an EUA. EUAs require only a showing that, based on scientific evidence "if available" (*i.e.*, evidence is optional), "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 not subject to the PHSA's stringent manufacturing and labeling requirements, enjoy broader product liability protections, and therefore cannot be mandated due to informed consent laws and regulations. 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) which is titled "Conditions of Authorization/Unapproved Product/Required Conditions" explicitly notes that it is designed "…to ensure that individuals to whom the product is administered are informed…of the option to accept or refuse administration of the product." *Id.*

61. The FDA's approval of a biologics license application ("BLA") means not only that the FDA has found that the meets the PHSA's statutory requirements (*safety, purity, potency*), but also that the BLA addresses specific labeling and manufacturing requirements (including location, process, and storage requirements, etc.), none of which

[29] Exhibit 17, August 23, 2021 FDA Pfizer-BioNTech EUA Re-Issuance Letter, at 2 n.8, available at: https://www.fda.gov/media/150386/download (last visited Apr. 29, 2022)("Aug 23, 2021 Pfizer/BioNTech EUA Re-Issuance")

are addressed in an Emergency Use Authorization.

C. FDA Interchangeability Determinations for Biological Products

62. A biologic product's *interchangeability* with another biologic product is governed by federal statute. 21 U.S.C. § 262(i)(3)("The term 'interchangeable' or 'interchangeability', in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.")

63. This piece of Title 21 was enacted as part of the Biologics and Price Competition and Innovation Act of 2009. The FDA guidance regarding bioequivalents makes clear that there is a higher standard than normal for making a bioequivalence determination.

> *In order to meet the higher standard of interchangeability*, a sponsor must demonstrate that the biosimilar product can be expected to produce the same clinical result as the reference product in any given patient and, for a biological product that is administered more than once, that the risk of alternating or switching between use of the biosimilar product and the reference product is not greater than the risk of maintaining the patient on the reference product.[30] (Emphasis added).

64. Subsection (k)(4) is just one among a long list of requirements under Section 262(k) that must be met before any "biologic product," which BNT162b2 unquestionably is, could possibly be deemed "bioequivalent" to, and thus "interchangeable with," an already licensed "reference product," including terms of years of exclusivity for

[30] FDA, "Implementation of the Biologics Price Competition and Innovation Act of 2009, *available at*: https://www.fda.gov/drugs/guidance-compliance-regulatory-information/implementation-biologics-price-competition-and-innovation-act-2009 (last visited May 4, 2022).

the reference product itself. *See* 42 U.S.C. §§ 262(k)(6) and (k)(7).

III. CHALLENGED REGULATORY ACTIONS

A. FDA Comirnaty Approval & EUA Re-Issuances

65. On 23 August 2021, Defendant FDA issued a BLA ("Biologic License Application") Approval letter to BioNTech Manufacturing Gmbh ("BioNTech"), of Mainz, Germany. The letter reflects the Defendant FDA's issuance of

> A Dept. of Health and Human Services U.S. License (No. 2229) to BioNTech Manufacturing GmbH, Mainz, Germany, under the provisions of section 351(a) of the PHS Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.
>
> Under this license, you are authorized to manufacture the product, COVID-19 Vaccine, mRNA, which is indicated *for active immunization to prevent coronavirus* disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.
>
> The review of this product was associated with the following National Clinical Trial (NCT) numbers: NCT04368728 and NCT04380701.
>
> The shot has the name "COMIRNATY."[31]

66. On August 23, 2021, the FDA and Pfizer/BioNTech issued several related documents. First, Defendant FDA put out a press release announcing that "FDA Approves First Covid Vaccine." The sub-heading was "Approval Signifies Key Achievement for Public Health."[32]

67. Second, Pfizer/BioNTech made a filing to the FDA indicating that

---

[31] Exhibit 18, BioNTech FDA BLA Approval Letter at 1-2 (Aug. 23, 2021) (emphasis added)

[32] FDA Press Release, "FDA Approves First Covid Vaccine" (Aug. 23, 2021), available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (lasts visited May 4, 2022).

COMIRNATY was **unavailable** in the U.S. market. COMIRNATY'S approved BLA (No. 125742) label packaging and insert list its "Marketing Start Date" and "Marketing End Date" both as "23 Aug 2021."[33]

68. Third, the Defendant FDA's Chief Scientist, RADM Denise Hinton, sent a letter to Pfizer, Inc. advising it that the Emergency Use Authorization ("EUA") previously issued by the FDA for a different, "legally distinct" mRNA injectable with the name BNT162b2 ("Pfizer BNT") would *remain in place* because the licensed product COMIRNATY was "not available..." in sufficient quantities.[34] To be clear – an EUA can**not** issue unless "the Secretary concludes… that there is no *adequate*, *approved*, and *available* alternative to the product for diagnosing, preventing, or treating such disease or condition." 21 U.S.C. §360bbb-3(c)(3).

69. The FDA's August 23, 2021 EUA Re-Issuance Letter also included a footnote erroneously claiming that:

> The licensed vaccine [COMIRNATY] has the same formulation as the EUA-authorized vaccine [BNT162b2] and the products can be used *interchangeably* to provide the vaccination series without presenting *any safety or effectiveness concerns*. The products are legally distinct with certain differences that do not impact *safety* or *effectiveness*.[35]

But the FDA's offhand statement in a footnote has no legal force, because neither the FDA nor Pfizer/BioNTech complied with the requirements for an interchangeability determination under the PHSA.

---

[33] *See*, *e.g.*, Archived FDA Approved Labeling and Package Insert for COMIRNATY, available at: https://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=595377#section-13 (last visited May 4, 2022).
[34] *See* Exhibit 17, at 5, n.9
[35] *Id.*, at 2, n.8 (emphasis added)

70. COMIRNATY cannot be a "reference product," as defined in the PHSA (42 U.S.C. § 262(k)), for the prior, unlicensed EUA Pfizer/BioNTech mRNA treatment. Neither Pfizer nor BioNtech have taken the steps necessary to make this mRNA injectable – COMIRNATY – into a bioequivalent product. Moreover, COMIRNATY's listing in the Defendant FDA's "Purple Book" Database, which contains all biologics and any bioequivalent or interchangeable products, shows that COMIRNATY has no interchangeable or bioequivalent products, including BNT162b2.[36]

71. Fourth, Pfizer, Inc.'s Senior VP for Global Regulatory Affairs, Donna Boyce, issued a "Notice to Health Care Professionals" erroneously asserting that, while most of the Pfizer-BNT vaccine was only usable under its current EUA, the Comirnaty approval had the effect of *retroactively* licensing seven *already manufactured* lots of this EUA product (that had been manufactured, labeled and distributed under the EUA) were claimed to be in compliance with the August 23, 2021, BLA Approval Letter from Defendant FDA (hereinafter referred to as "BLA-compliant" lots) for COMIRNATY.[37]

---

[36] *See* Exhibit 19, FDA Purple Book database listing for COMIRNATY. Defendant FDA also maintains a searchable online Purple Book database, available here: https://purplebooksearch.fda.gov/.

[37] The assertion that so-called "BLA-compliant" lots manufactured prior to FDA approval on August 23, 2021 were retroactively licensed is incorrect as a matter of law. In *Doe #1-#14 v. Austin*, --- F.Supp.3d ---, 2021 WL 5816632, at *6 (N.D. Fla. Nov. 12, 2021) ("*Austin*"), the court explained that:

> FDA licensure does not retroactively apply to vials shipped before BLA approval. *See* 21 U.S.C. § 355(a) ("No person shall introduce ... into interstate commerce any new drug, unless an approval of an application [for FDA licensure] *is effective* with respect to such drug." (emphasis added)). Thus, as a legal matter, vaccines sent before August 23—and vaccines produced after August 23 in unapproved facilities—remain "product[s] authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act." § 1107a(a)(1).

The memo noted that all other lots of the Pfizer-BNT vaccine remained EUA and **were not** subject to the BLA license for COMIRNATY issued by the FDA.[38]

72. Fifth, Pfizer and BioNTech issued a COVID-19 "Vaccine EUA Fact Sheet for Recipients and Caregivers." The fact sheet states in pertinent part:

> "**This EUA** for the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed."[39]

B. DOD Mandate of Unlicensed EUA COVID-19 Vaccines

73. On or about July 29, 2021, President Biden directed the Defendant DoD to "look into how and when… [to] add COVID-19 to the list of required vaccinations for members of the military."[40]

74. On Aug. 9, 2021, Defendant Lloyd Austin sent a "Message to the Force" concerning the possibility of a vaccine mandate for members of the Armed Forces.

> Based on these consultations and on additional discussions with leaders of the White House COVID Task Force, I want you to know that I will seek the President's approval to make the vaccines mandatory no later than mid-September, or immediately upon the U.S. Food and Drug Administration (FDA) licensure, whichever comes first.
>
> By way of expectation, public reporting suggests the Pfizer-BioNTech vaccine could achieve full FDA licensure early next month.[41]

Plaintiffs do not accept Defendants' assertion that so-called "BLA-compliant," EUA-labeled vaccines are equivalent legally or medically with Comirnaty, whether manufactured before or after August 23, 2021.

[38] *See* Exhibit 20, Aug. 23, 2021 Pfizer VP Boyce "Notice to Healthcare Professionals."

[39] Exhibit 21, Aug. 23, 2021 Pfizer-BioNTech Vaccine EUA Fact Sheet at 8 (emphasis added).

[40] White House FACT SHEET, (July 29, 2021;), available at: https://tinyurl.com/4zm78sey (last visited May 4, 2022)

[41] Secretary of Defense Message to the Force, (Aug. 9, 2021)(emphasis added), available at: https://tinyurl.com/2a2t5b4e (last visited May 4, 2022).

75. On August 24, 2021, the day after COMIRNATY had been given the first and only BLA approval for a COVID-19 "vaccine" and then removed from the market by its manufacturer, Defendant Austin issued a DoD-wide Memorandum directing "the Secretaries of the Military Departments to immediately begin full vaccination of all members of the Armed Forces under DoD authority on active duty or in the Ready Reserve, including the National Guard who are not fully vaccinated against COVID-19."[42] Defendant Austin's memo states that, "Those with previous COVID-19 infections are not considered 'fully vaccinated.'" *Id.* at 1.[43]

76. Defendant Austin's Memorandum further states that, "Mandatory vaccination against COVID-19 will *only* use COVID-19 vaccines that receive *full licensure* from the Food and Drug Administration (FDA), in accordance with FDA-approved labeling …" (emphasis added). *Id*.

77. On the date the order was issued, Aug. 24, 2021, there was no available "COVID-19 vaccine" with "full-licensure" from the FDA. Nor has any FDA-licensed COMIRNATY or SPIKEVAX labeled in accordance with FDA requirements been available in the United States from that date to the present.[44]

---

[42] *See* Exhibit 22, Aug. 24, 2021 SECDEF Memo (The "Vaccine Mandate")

[43] Defendant Austin's memo is also of questionable validity with regard to his assertion of the right to compel National Guardsman to be compelled to take these shots, though that argument is not pressed here. *See Abbott and Dunleavy v. Biden*, No. 6:22-cv-00003, filed in this court. *See also Perpich v. Dept. of Defense*, 496 U.S. 334 (1990).

[44] 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* Exhibit 23, Sep. 13, 2021 NIH-Pfizer Announcement of Comirnaty Unavailability. The FDA has subsequently confirmed that Comirnaty remains unavailable in the United States. Exhibit 24, FDA Nov. 8, 2021 Summary Basis of Regulatory Action – Comirnaty, at 5 ("Nov. 8 Comirnaty

78. Notwithstanding that there was no "fully licensed" "COVID-19 vaccine" available, Commanders within Defendant DoD moved quickly to begin vaccination of their units of following Defendant Austin's Aug. 24, 2021 Memorandum. Because there was no COMINARTY available, all DoD units began using – and used – the EUA Pfizer-BNT vaccine that is *not* licensed by FDA, based on the DoD's determination that the EUA vaccine and the licensed vaccine were "interchangeable" and could each be mandated.[45]

79. In fact, this was ultimately justified as a service-wide practice by a Memorandum from the Assistant Secretary of Defense for Health Affairs – the direct subordinate of Defendant Lloyd J. Austin – Ms. Terry Adirim.

> *Per FDA guidance*, these two vaccines are "interchangeable" and DoD health care providers ***should*** "use doses distributed under the EUA to administer the vaccination series *as if the doses were the licensed vaccine*."[1]
>
> *Consistent with FDA guidance*, DoD health care providers will use both the Pfizer-BioNTech COVID-19 vaccine and the Comirnaty COVID-19 vaccine ***interchangeably*** for the purpose of vaccinating Service members in accordance with Secretary of Defense Memorandum, "Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members," August 24, 2021.[46]

SBRA"); Numerous members of the Plaintiff class have confirmed (repeatedly) that neither Comirnaty nor Spikevax have been available since the inception of the mandate through the present. *See, e.g.*, Declaration of TSgt Tyler Whitney in *Robert, Mulvihill v. Austin*, 1:21-cv-02228-RM-STV, ECF No. 43, p. 8, ¶14. TSgt Whitney is a Plaintiff member of MAFL.

[45] *See, e.g.*, Exhibit 25, Dept. of the Navy, Bureau of Medicine and Surgery Memorandum, Subject: Interchangeability of the FDA-Approved Pfizer-BioNTech Vaccine COMIRNATY and FDA-Authorized Pfizer-BioNTech Vaccine Under EUA (Sep. 3, 2021); *see also* Exhibit 26, Office of The Judge Advocate General, "SJA Update" at 2 (Sept. 10, 2021)

[46] Exhibit 27, Asst. Secretary of Defense Memorandum "Mandatory Vaccination of Service Members Using the Pfizer-BioNTech COVID-19 and COMIRNATY COVID-19 Vaccines," Sept. 14, 2021 (emphasis added). Footnote 1 in the memorandum contains a link to Defendant FDA's website "Q&A for Comirnaty (COVID-19 Vaccine mRNA)," where the FDA states that the two vaccines "can be used interchangeably," rather than "should" as used in the DoD guidance.

80. The DoD and FDA Defendants have both incorrectly asserted that the EUA BioNTech Vaccine and the conditionally approved Comirnaty Vaccine have the "same formulation" and can or should be used "interchangeably." Exhibit 17, Aug. 23, 2021 EUA Re-Issuance Letter, at 2 n.8. There is, however, no basis in law or in the publicly available record materials that the two admittedly "legally distinct" products are "interchangeable" and ample evidence for finding that they are not.

81. The FDA has never asserted that the EUA and licensed versions are legally interchangeable. The FDA's EUA reissuance letters have consistently acknowledged that the two vaccines are "legally distinct." *Id*. The FDA has confirmed that the FDA has not made any "statutory interchangeability determination" and instead described the products as only "medically interchangeable," another new status that does not exist under the PHSA or any FDA statutory authority.[47]

82. The EUA is a "distinct regulatory pathway" under 21 U.S.C. § 360bbb-3 from FDA licensing under the PHSA.[48] For FDA licensure under the PHSA, the applicant must satisfy the distinct and higher statutory requirements regarding safety, purity, and potency (or effectiveness), as well as distinct requirements for FDA approval of biologics manufacturing and labeling that are not required for EUA products. Accordingly, even if the EUA and licensed product had the "same formulation" – and as discussed *infra* there is evidence in the record that they do not – the EUA version "is legally distinct and can be

[47] *See* Exhibit 28, Declaration of Peter Marks, ¶ 11 (submitted January 14, 2022 as ECF 15-14 in *Crosby v. Austin*, No. 8:21-cv-2730-TPB-HTC (M.D. Fla.)); *see also* Exhibit 29, FDA Mar. 29, 2022 Pfizer/BioNTech EUA Re-Issuance letter at 10; Exhibit 30, FDA Mar. 29, 2022 Moderna EUA Re-Issuance letter at 11.

[48] *See* Exhibit 31, Congressional Research Service, *FDA Approval of the Pfizer-BioNTech COVID-19 Vaccine: Frequently Asked Questions* at 1 (Updated Sept. 29, 2021) ("CRS Report")

manufactured, marketed, distributed and ***administered only pursuant to the EUA***." CRS Report at 5 (emphasis added). One of these key "legal distinctions" is that an FDA-approved vaccine may be mandated, while an EUA vaccine may not be without Presidential authorization, which Defendant Austin has neither requested nor received.

83. The publicly available information indicates that there are differences in the composition of the EUA and licensed products.[49] There is also no dispute that the FDA EUA did not address manufacturing processes or locations, which are solely addressed in the Comirnaty licensure. In any case, the FDA documents severely understate the complexities of the novel mRNA vaccines and nano-lipid delivery systems, which Pfizer has stated include "more than 280 materials," rather than 10 or 11 disclosed in FDA filings, "made by suppliers in 19 countries."[50]

C. HHS Re-Defined "Vaccine" and "Vaccination" to Cover mRNA Treatments

84. On September 1, 2021, the CDC, an agency within Defendant HHS control, defined "immunity", "vaccination", and "vaccine" as –

> **Immunity**: Protection from an infectious disease. If you are immune to a disease, you can be exposed to it without becoming infected.
>
> **Vaccine**: A product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease. Vaccines are usually administered through needle injections, but can also

[49] *See, e.g., Austin*, 2021 WL 5816632, at *3 n.5. *Compare* Exhibit 32, Aug. 23, 2021 FDA Comirnaty SBRA at 9 (listing 11 components, including .450 ml per vial of a redacted excipient), *with* Exhibit 17, Aug. 23, 2021 EUA Re-Issuance Letter, at 7 (listing 10 components, all of which also appear on the Comirnaty SBRA) *and* Exhibit 24, Nov. 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).

[50] Stephanie Baker & Vernon Silver, *Pfizer Fights to Control Secret of $36 Billion Covid Vaccine Recipe*, Bloomberg (Nov. 14, 2021), available at: https://www.bloomberg.com/graphics/2021-pfizer-secret-to-whats-in-the-covid- vaccine/ (last visited May 2, 2022).

be administered by mouth or sprayed into the nose.

Vaccination: The act of introducing a vaccine into the body to produce immunity to a specific disease.[51]

85. On September 2, 2021, after the "vaccine" mandate had already been announced – and begun – the CDC changed the definitions of "vaccine" and "vaccination" (changes italicized).

Vaccine: A *preparation that is used to stimulate the body's immune response against diseases*. Vaccines are usually administered through needle injections, but some can be administered by mouth or sprayed into the nose.

Vaccination: The act of introducing a vaccine into the body to produce *protection from* a specific disease.[52]

86. Thus, just as plaintiffs were being ordered to take a "vaccine" from the Department of Defense's mandatory "vaccine" list, the CDC eliminated the word "immunity" from its definitions of "Vaccine" and "Vaccination." The CDC did so because senior members knew then that the mRNA injections do not produce immunity to the disease known as COVID-19 and therefore did not qualify as "vaccines."[53]

87. The mRNA shots currently being forced upon members of the military are

---

[51] CDC, *Immunization: The Basics* (archived version from Sept. 1, 2021), available at: https://web.archive.org/web/20210901163633/https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm (last visited May 4, 2022).

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

[53] 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* Exhibit 33, CDC FOIA Response Emails from Aug. 13, 2021 - Sept. 1, 2021) at 2 ("The definition of vaccine we have posted is problematic and people are using it to claim that the COVID-19 vaccine is not a vaccine based on our own definition."); *id.* at 3 ("these definitions are outdated and being used by some to say COVID-19 vaccines are not vaccines per CDC's own definition.")

not "vaccines" in any sense of the word. First, the mRNA shots do not confer *immunity* by the CDC's own definition. That is, these products fail the first and foremost test of being a "vaccine" – they do not provide "protection from an infectious disease." Second, these products also *do not prevent transmission* of the very virus for which they're being given.[54] For the absence of confusion, it bears repeating: these mRNA shots do NOT stop someone from getting COVID-19, NOR from transmitting it to someone else. Third, these injections do not have a scintilla of the virus itself within them. Instead, these shots have messenger RNA (mRNA) contained within lipid nanoparticles that pass unimpeded through the cell wall, avoiding *all* of the body's normal and natural immune system layers. *See, e.g.*, Hou, X., Zaks, T., Langer, R. *et al.* "Lipid nanoparticles for mRNA delivery." *Nat Rev Mater* **6,** 1078–1094 (2021). https://doi.org/10.1038/s41578-021-00358-0

88. These mRNA clusters then instruct the body's own nuclei to encode and produce ONLY the "spike protein" contained within the original (unmutated) nucleocapsid of the virus on the *hypothesis* that this will induce the body's immune system to respond and therefore be prepared for a subsequent encounter of the "spike protein." *Id.* The spike protein is the harm-causing portion of the SARS-CoV-2 virus, but comprises only a small percentage of the overall virus. Missing from these shots is anything – any introduction of the body's immune system to the virus itself – that would allow the myriad aspects of the human immune system to prevent the production of the "spike protein" in the first place. The sole commonality these shots have with a real vaccine is in their method of

[54] None of the COVID-19 vaccines has "demonstrated in a conclusive, randomized, placebo-controlled trial" that they "reduce the risk of Omicron infection or any of its complications." Exhibit 2, McCullough Decl., ¶ 8. Further, "COVID-19 vaccinations do not impede the changes that a person will transmit the [Omicron variant] to another person." *Id.*, ¶ 9.

introduction: the fact that they are in the form of a shot given in the way that most other traditional, real vaccines have typically been given.

89. The Defendant FDA and Department Heads within H&HS in control of the relevant agencies (such as the CDC and NIH) have all publicly acknowledged that the mRNA shots currently in an EUA status do not stop the transmission of SARS-CoV-2.

a. NIAID Director Dr. Anthony Fauci to NPR: "We know now as a fact that [vaccinated people with Covid-19] are capable of transmitting the infection to someone else."[55]

b. CDC Website: "The Omicron variant spreads more easily than the original virus that causes COVID-19 and the Delta variant. *CDC expects that anyone with Omicron infection can spread the virus to others, even if they are vaccinated or don't have symptoms.*" (Emphasis added)[56]

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

> Although we expect to submit BLAs [biologics license applications] for our mRNA-based product candidates in the United States, and in the European Union, mRNA therapies have been classified as gene therapy medicinal products, and other jurisdictions may consider our mRNA-based product candidates to be *new drugs*, *not biologics* or gene therapy medicinal products, and require different marketing applications.[57] (Emphasis added).

91. Similarly, in its June 30, 2020 Quarterly Report to the SEC, Moderna noted

---

[55] Stieg, C (July 28, 2021). *Dr. Fauci on CDC mask guidelines: 'We are dealing with a different virus now',* CNBC, available at: https://www.cnbc.com/2021/07/28/dr-fauci-on-why-cdc-changed-guidelines-delta-is-a-different-virus.html (last visited May 4, 2022)

[56] *See* CDC, *Omicron Variant: What You Need to Know*, available at: https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html (last visited May 4, 2022).

[57] *BioNTech SE Form 20-F,* U.S. Securities and Exchange Commission (2020), at page 26 (last visited March 1, 2022).

with regard to the mRNA technology underpinning its injection: "Currently, mRNA is considered a gene therapy product by the FDA."[58] These products can only be defined as "therapeutics" or "treatments."

D. FDA Spikevax Approval and EUA Re-Issuance for Moderna Vaccine

92. Defendant FDA has engaged in this same "switch" – again – of an unlicensed mRNA product for a licensed one. After "SpikeVax" was given a BLA approval by the Defendant FDA on Jan. 31, 2022, that "vaccine" was declared insufficiently "available" by Defendant FDA (in another footnote) and then an EUA was reissued for "Moderna COVID-19 Vaccine" on the same exact day.[59] Both the Jan. 31, 2022 and Mar. 15, 2022 letters allow Moderna to substitute a separate mRNA injectable called "Moderna COVID-19 Vaccine" in placed of the licensed "Spikevax."

> Although SPIKEVAX (COVID-19 Vaccine, mRNA) and Comirnaty (COVID-19 Vaccine, mRNA) are approved to prevent COVID-19 in certain individuals within the scope of the Moderna COVID-19 Vaccine authorization, there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA.
>
> The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.[60]

E. DoD Implementation of Vaccine Mandate

93. Defendant DoD and each branch of the armed services have and continue

---

[58] *Moderna SE Form 10-q,* U.S. Securities and Exchange Commission, (2020) https://www.sec.gov/Archives/edgar/data/1682852/000168285220000017/mrna-20200630.htm at page 70 (last visited March 1, 2022).

[59] That Jan. 31, 2022, EUA letter is no longer available on Defendant FDA's website, but it is referenced (and its absence somewhat explained) in Defendant FDA's Mar. 29, 2022 EUA extension letter to Moderna included as Exhibit 30.

[60] https://www.fda.gov/media/144636/download, FN 11, and FN 13.

to compel Plaintiffs to take the EUA only Pfizer-BNT and Moderna vaccines. They are making no distinction between what they acknowledge are "legally distinct" licensed and unlicensed products. Upon information and belief, there is no COMINARTY or SPIKEVAX available for ordering within the Defendant DoD's medical supply system, and the licensed biologics remain unavailable in the United States. *See supra,* FN 43.

94. Unlicensed, experimental, EUA (non)-vaccines have been, and are being used, in hundreds of thousands of involuntary inoculations administered by Defendant DoD.

95. 10 U.S.C. §1107a states in pertinent part:

> (a) Waiver by the President —
>
> (1) In the case of the administration of a product authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act to members of the armed forces, the condition described in section 564(e)(1)(A)(ii)(III) of such Act and required under paragraph (1)(A) or (2)(A) of such section 564(e), designed to ensure that individuals are informed of an option to accept or refuse administration of a product, **may be waived only by the President only** if the President determines, **in writing**, that complying with such requirement is not in the interests of national security (emphasis added).

As of the date of this filing, there has been no such waiver of servicemembers' right to informed consent issued by the President of the United States. *See Austin*, 2021 WL 5816632, *7.

96. DoD Instruction 6200.02 ("DoDI") states (in part) that –

> The Heads of DoD Components…**Shall**, *when requesting approval to use a medical product under an EUA* or IND application, develop, in coordination with the Secretary of the Army, medical protocols, compliant with this Instruction, for use of the product and, if the request is approved, execute such protocols *in strict compliance* with their requirements[;]
>
> …**Shall**, *when using medical products under a force health protection program pursuant to an EUA*, comply with Enclosure 3, Federal Food Drug and Cosmetic Act section 564 (Reference (d)), section 1107a of Reference

(e) and applicable FDA requirements[;]

DODI 6200.02, ¶¶ 5.2.2, 5.2.3 (emphasis added).

97. The Defendant DoD has not complied with any of the above requirements for vitiating the informed consent rights of servicemembers regarding unapproved biologics. Instead, the DoD is relying upon a memorandum from the Asst Secretary of Defense for Health Affairs that purports to authorize the "interchangeability" of an unlicensed, experimental gene-therapy BNT162b2 – not a "vaccine" by the CDC definition prior to Sep. 2, 2021 – in the place of a "legally distinct" FDA-approved product (which was immediately removed from the U.S. market on the same day it was approved.)

F. DoD Elimination of Natural Immunity Exemption

98. Army Regulation 40-562 "Immunization and Chemoprophylaxis for the Prevention of Infectious Diseases"[61] presumptively exempts from any vaccination a service member that the military knows has had a documented previous infection for the same disease.

99. AR 40-562 was signed on Oct. 7, 2013, went into effect on Nov. 7, 2013, and remains in effect today. It applies to all branches of the military. The Regulation also applies whether the proposed COVID-19 vaccines Defendant DoD seeks to administer to Plaintiffs and the class are "Investigational New Drugs" as defined in 21 CFR 56.104(c) ("IND"), an EUA issued under 21 USC § 360bbb-3, or a fully approved FDA vaccine for other illnesses such as chicken pox, measles, or mumps, for example.

100. The SECDEF Memo effectively repeals the AR 40-562 for those with

[61] This document is an all-service publication and has an equivalent name for each of the applicable services. We have chosen to use the Army designation throughout for ease, but these arguments apply equally under AFI 48-110, BUMEDINST 6230.15B, COMDETINST M6230.4G. *See*, AR 40-562, ¶2-6a.(1)(b).

previous documented infections, without any discussion or even acknowledging that it had done so. The Armed Services implementation order similarly eliminated the exemption and categorically prohibited granting medical exemptions for those with documented previous infections.

101. The Air Force, Navy and Marine Corps categorically deny the AR 40-562 exemption for those with documented previous infections.[62] The Army Guidance states that "service members with previous infections or positive serology are not automatically exempt," and the Army has indicated that it will not grant, or even consider, requests for exemptions based on previous documented infection.[63]

G. DoD Policy of Uniformly Denying Religious Accommodations

102. Defendants have also systematically denied religious accommodation requests. The tables below, which include information taken from Defendants' compliance notice in the *Navy SEAL 1* Proceeding, (*see* Exhibit 16 of that case – Defendants February 4, 2022 Compliance Notice), demonstrate that the Armed Services have granted zero or nearly zero religious accommodation requests, while denying thousands. (Plaintiff includes statistics for all Armed Services to demonstrate that there is a DoD-wide policy of uniformly denying religious accommodations that, upon information and belief, was

[62] *See* Exhibit 34, 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"), ¶ 4.5.1.2 ("Previous infection or positive serology do not exempt Service members from full vaccination requirements."); Exhibit 35, 2021-2022 Navy Mandatory COVID-19 Vaccination and Reporting Policy," NAVADMIN 190/21 (Sept. 1, 2021) ("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."); Exhibit 36, "Mandatory COVID-19 Vaccination of Marine Corps Active and Reserve Components," MARADMIN No. 462/21 (Sept. 1, 2021) ("MARADMIN 462/21"), ¶ 3.a (same).

[63] Exhibit 37, Dept. of the Army, Fragmentary Order 5 to Headquarters Dept. of the Army Executive Order 225-21 (Sept. 14, 2021) ("Army FRAGO 5"), ¶ 3.D.8.B.6

ordered by Secretary Austin.)

Table 1: Religious Accommodation Requests & Appeals

Armed Service	Initial RA Requests			RA Appeals		
	Filed	Denied	Approved	Appeals	Denied	Approved
Air Force	12,623	3,180	5	2,221	443	1
Army	3,523	391	0	55	0	0
Coast Guard	1,308	578	0	224	0	0
Marine Corps	3,539	3,458	0	1,150	119	3
Navy	4,095	3,728	0	1,222	81	0
Total	**25,008**	**11,335**	**5**	**4,872**	**643**	**4**

103. Defendant DOD and the Armed Services have been consistently found to have violated the Religious Freedom Restoration Act ("RFRA") and the First Amendment.[64] While Plaintiffs are not making a RFRA or First Amendment claim, they highlight these damning statistics as evidence of both Defendant DoD's disregard for the law and servicemembers' rights, but also the animus behind its policies and actions.

104. In sum, the Defendants have decided on a "zero tolerance" policy, or a "vaccination *uber alles*," regardless of what the Constitution, the law, their own regulations, or sound medical practice requires in individual cases.

105. Plaintiffs note that the Air Force and Marine Corps purport to have granted

[64] *See generally Navy SEAL 1 v. Austin,* --- F.Supp.3d ---, 2022 WL 534459 (M.D. Fla. Feb. 18, 2022) ("*Navy SEAL 1* PI Order") (Navy and Marine Corps), *stay denied* --- F.Supp.3d ---, 2022 WL 710321 (M.D. Fla. Mar. 2, 2022) (denying emergency stay) ("*Navy SEAL 1* Stay Order"), *stay denied pending appeal* No. 22-10645 (11th Cir. Mar. 30, 2022); *Navy SEAL 1 v. Austin*,; *U.S. Navy SEALs 1-26 v. Biden*, --- F.Supp.3d. ---, 2022 WL 34443 (N.D. Tex. Jan. 3, 2022) ("*Navy SEALs 1-26* PI Order") (Navy), *stay denied*, --- F.4th ---, 2022 WL 594375 (5th Cir. Feb. 28, 2022) ("*Navy SEALs 1-26* Stay Order"); *Air Force Officer v. Austin*, --- F.Supp.3d ---, 2022 WL 468799 (M.D. Ga. Feb. 15, 2022) ("*Air Force Officer*") (Air Force); *Poffenbarger v. Kendall*, No. 3:22-cv-1, 2022 WL 594810 (S.D. Oh. Feb. 28, 2022) ("*Poffenbarger*"); *Doster v. Kendall*, --- F.Supp.3d ---, 2022 WL 982299 (S.D. Ohio Mar. 31, 2022) (*"Doster*") (Air Force).

a handful of requests and appeals, however, these RARs appear to have been granted to those on terminal leave or conditioned upon their separation from the military. *See Navy SEAL 1*, 2022 WL 534459, at *19 (Marine Corps approvals); *Poffenbarger*, 2021 WL 594810, at *13 n.6 (Air Force approvals). Thus, even the exceptions to the general policy of denying them all demonstrate that the process is a sham because the result is that no service member will be granted any accommodation and allowed to continue their service.

H. Disciplinary Actions for Vaccine Refusal

106. 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.[65] 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.*

IV. SCIENTIFIC EVIDENCE & STUDIES

A. Efficacy Data for COVID-19 Vaccines

107. None of the COVID-19 vaccines has "demonstrated in a conclusive, randomized, placebo-controlled trial" that they "reduce the risk of Omicron infection or any of its complications." Exhibit 3, McCullough Supp. Decl., ¶ 8. Further, "COVID-19 vaccinations do not impede the changes that a person will transmit the [Omicron variant] to another person." *Id.,* ¶ 9. This is because the spike protein produced by the vaccines, which was developed using the original Alpha variant, has long since become "obsolete"

[65] *See* Exhibit 34, Air Force Guidance, ¶ 5.3; Exhibit 37, Army FRAGO 5, ¶ 3.D.8.B & Annex 20; Exhibit 36, MARADMIN 462/21, ¶ 3.1; Exhibit 35, NAVADMIN 190/21, ¶ 5

with the emergence of the Delta variant and Omicron variants. *Id.*, ¶ 10.

108. According to Pfizer's CEO, "we know that the two doses of the vaccine" mandated by the DOD" offer very limited protection, if any,"[66] against the Omicron variant that accounts for nearly 100.0% of cases. Pfizer's own Factsheet admits that Comirnaty's "duration of protection against COVID-19 is currently unknown."[67] 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.

109. Even before the FDA approved Comirnaty, studies from Israel found that the Pfizer-BioNTech vaccine's relative effectiveness decreased from over 90% to 39% after six months for infections and 40.5% for symptomatic cases.[68] A November 4, 2021 study published in *Science*, which examined the Veterans Health Administration ("VHA") records 780,000 U.S. veterans,[69] found that from February 2021 to October 2021, the shots' relative effectiveness against infection (VE-I) declined from 87.9% to 48.1% overall and

---

[66] *New COVID-19 Vaccine That Covers Omicron 'Will Be Ready in March,' Pfizer CEO Says* Yahoo!Finance (Jan. 10, 2022) (transcript of video interview with Pfizer CEO Albert Bourla), available at: https://finance.yahoo.com/video/covid-19-vaccine-covers-omicron-144553437.html (last visited May 4, 2022).

[67] Exhibit 21, Pfizer-BioNTech EUA Vaccine Fact Sheet, at 4

[68] *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 Feb. 28, 2022); 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 May 4, 2022).

[69] *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 Feb. 28, 2022).

43.3% for the Pfizer-BioNTech vaccine.

110. The above numbers by both manufacturers and the FDA are also misleading because they report *only* Relative Risk Reduction (RRR), rather than both the RRR *and* the Absolute Risk Reduction (ARR), the only way to understand these products' claimed efficacy. "The absence of reported absolute risk reduction in COVID-19 vaccine clinical trials can lead to outcome reporting bias that affects the interpretation of vaccine efficacy."[70] It has (previously) been the Defendant FDA's stated position about communication of risks and rewards for products such as vaccines to publish ARR figures.[71] It requires no special training, nor credential, nor expertise, to understand and calculate these numbers.[72]

111. The pharmaceutical companies, and Defendant FDA, publicly claim that the various experimental gene therapies have wildly successful "Relative Risk Reduction[s]" (RRR) for these products. These RRR numbers are 95.1% for Pfizer, 94.1% for Moderna, and 67% for the Johnson & Johnson shots.[73] RRR is simply the Relative Risk (RR), as a percentage, subtracted from 100%, or 1. The RR is the amount of adverse outcomes, as a

---

[70] *See, e.g.*, Brown, R.B. "Outcome Reporting Bias in COVID-19 mRNA Vaccine Clinical Trials." Medicina 2021, 57, 199. https://doi.org/10.3390/ medicina57030199. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7996517/

[71] *See* Fischhoff, B.; Brewer, N.; Downs, J. "Communicating Risks and Benefits: An Evidence-Based User's Guide," Food and Drug Administration (FDA), US Department of Health and Human Services: Silver Spring, MA, USA, 2011.

[72] For a quick lesson on how to calculate RR, RRR, and ARR, see the discussion page at the government's National Institute of Health website at: https://www.ncbi.nlm.nih.gov/books/NBK63647/

[73] *See* Brown, R.B. "Outcome Reporting Bias in COVID-19 mRNA Vaccine Clinical Trials." Medicina 2021, 57, 199, *infra* n. 42. *See also* Doshi, P. "Pfizer and Moderna's "95% effective" Vaccines—Let's Be Cautious and First See the Full Data." Available online: https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-andfirst-see-the-full-data/ (accessed on 23 December 2020)

percentage of the test group divided by the percentage of adverse outcomes, as a percentage of the control group.

> However, RRR should be seen against the background risk of being infected and becoming ill with COVID-19, which varies between populations and over time. Although the RRR considers only participants who could benefit from the vaccine, the absolute risk reduction (ARR), which is the difference between attack rates with and without a vaccine, considers the whole population. ARRs tend to be ignored because they give a much less impressive effect size than RRRs: 1.3% for the AstraZeneca–Oxford, 1.2% for the Moderna–NIH, 1.2% for the J&J, 0.93% for the Gamaleya, and 0.84% for the Pfizer–BioNTech vaccines.[74]

112. From the National Institute of Health website, Pfizer's experimental gene therapy has an ARR of 0.7% (95% confidence interval), 0.59% to 0.83%; p<0.000; Moderna's experimental gene therapy has a similar ARR of 1.1% (95% CI), 0.97% to 1.32%; $p < 0.000$; Johnson & Johnson had an ARR of 1.2%.[75]

113. Put into understandable terms, this means that the ARR of the Pfizer experimental gene therapy confers a benefit to less than one person in every one hundred that receive the injection – and this is from the manufacturer's own data. For every one person that receives a benefit, 142 would not. The "CI" or "confidence interval is 95% for a range of 0.59% to 0.83%, and the odds these results could be achieved randomly (the assumption is wrong) is 0.000%. The data for the Moderna experimental gene therapy is roughly the same, as noted above, with roughly 1 in 100 people receiving a benefit from the shots (which is to say, 99 would not receive any benefit). This is also known as the Number Needed to Vaccinate (NNV), which is to say, the number of people needed to be

[74] *See*, *e.g.*, Olliaro, P., Torreele, E., Vaillant, M., "COVID-19 vaccine efficacy and effectiveness – the elephant (not) in the room," www.thelancet.com/microbe, Vol 2 July 2021.
[75] *Id.*

vaccinated before one person would obtain a benefit from the treatment. This, of course, doesn't sound nearly as good for marketing and public relations as "95% relative effectiveness(!)."

114. These experimental gene therapies also come with their own concomitant risk. For the adult recipients (age 16 and older), the Pfizer COVID-19 clinical trial found the overall incidence of severe adverse events during the two-month observation period to be 1.1%, or 1 in 91, which is *larger* than the ARR for the Pfizer experimental gene therapy.[76] When this phenomenon was further studied after the EUA was granted and injections were performed on the general public, it was found the rate of severe adverse events[77] went from 1:91 to 1:43, over double the trial rate.[78] This means that as a matter of relatively straightforward mathematics, the Pfizer "vaccine" is more than three times as likely to result in a harm to a recipient as it is to result in a benefit, which (as noted *infra*) requires 142 people to be vaccinated, before the 143rd person will obtain that benefit. According to the numbers, we should expect at least *three* people out of that same 143 to have had a serious adverse event by from being injected with the Pfizer shot.

115. Defendants may claim that they have relied on CDC recommendations in

---

[76] Pfizer-BioNTech COVID-19 vaccine (BNT162, PF-07302048): Vaccines and Related Biological Products Advisory Committee briefing document. Meeting date: 10 December 2020. 2020 Nov 30: 38, 46. https://www.fda.gov/media/144246/download.

[77] Severe adverse events were defined to include fever greater than 102.1° F; vomiting that requires IV hydration; diarrhea of six or more loose stools in 24 hours; and severe fatigue, severe headache, severe muscle pain, or severe joint pain that prevents daily activity.

[78] Clark, T. "Anaphylaxis following mRNA COVID-19 vaccine receipt." COVID-19 Vaccines Work Group of the Advisory Committee on Immunization Practices (ACIP). Centers for Disease Control and Prevention. 2020 Dec 19; [cited 2021 Mar 16]. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-19/05-COVID- Clark-508.pdf.

imposing the mandate, yet the DOD and Armed Services have ignored the November 19, 2021 CDC/ACIP unanimous recommendation that all eligible adults receive the third shot of the booster,[79] due to the rapidly declining effectiveness of the vaccine. Neither the DOD nor the Armed Services have provided any explanation for why they followed the CDC recommendation for a two-dose regimen, but ignored it for the third booster shot.

B. Safety Data for COVID-19 Vaccines

116. 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." Exhibit 2, McCullough Decl., ¶ 27. Through April 2022, COVID-19 vaccination "has led to more than 12,000 deaths and more than 13,000 permanently disabled Americans." Exhibit 3, McCullough Supp. Decl., ¶ 17.

117. The COVID-19 vaccines pose a particular risk of myocarditis (heart inflammation) to those who are in the prime ages for military service. Exhibit 2, McCullough Decl., ¶ 30. Due to these risks, in Dr. McCullough's expert medical opinion, "no individual under age 30 under any set of circumstances should feel obliged to take this risk with the current genetic vaccines particularly the Pfizer and Moderna products." Id., ¶ 32. *See also* Exhibit 3, McCullough Supp. Decl., ¶ 12 (discussing FDA myocarditis warnings).

118. Three different military doctors have also testified to the Senate Homeland

[79] *See* CDC, *CDC Expands Eligibility for COVID-19 Booster Shots to All Adults,* CDC Media Statement (Nov. 19, 2021), available at: https://www.cdc.gov/media/releases/2021/s1119-booster-shots.html (last visited May 4, 2022).

Security and Governmental Affairs Committee that the Department of Defense's own Defense Medical Epidemiological Database (DMED) shows alarming trends of medical injuries coinciding with the rollout of the DoD Mandate. This is separate from the VAERS data query that one of the doctors made to the CDC, which reported 300 disabled servicemembers and 119 active-duty deaths as of Feb. 11, 2022, from the vaccines, while the number of deaths from Covid-19 itself for active duty servicemembers since the beginning of the pandemic is a fraction of that number.[80]

C. Evidence of Natural Immunity from Previous COVID-19 Infection

119. Plaintiffs, individually, and as class members have previously suffered and recovered from COVID-19 infections with the development of natural immunity as demonstrated to or documented by the military.

120. At the time of Defendant Austin's memorandum, there was more than sufficient evidence to establish that previous infection with COVID-19 provided greater immunity to an individual that the Pfizer-BNT or COMIRNATY vaccine.[81]

121. Service members that have natural immunity from surviving the virus should be granted a medical exception from compulsory vaccination because the DoD Instruction reflects the well-established understanding that prior infection provides the immune system's best possible response to the virus, as opposed to simulated infection with something other than the virus itself. "COVID-19 did not occur in anyone over the

[80] *See, e.g.*, Exhibit 38, Declaration of LTC Theresa Long, U.S. Army, MD, MPH, FS, for Sen. Homeland Sec. and Governmental Affairs Comm., p. 6, 13-14.

[81] *See* Exhibit 2, McCullough Decl., ¶ 12. *See also* "Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections," Gazit, Shlezinger, et al., (preprint study examining ~26% of the Israeli population from Mar. 1, 2020 – Aug. 14, 2021), *available at*: https://doi.org/10.1101/2021.08.24.21262415 (last visited May 4, 2022).

five months of the study among 2579 individuals previously infected with COVID-19, including 1359 who did not take the vaccine."[82] "Following the science" as it relates to COVID-19 validates and reaffirms the wisdom of maintaining long-established virology protocol, codified by Defendant DOD's own experts in AR 40-562 in 2013.

122. Numerous studies demonstrate the superiority of natural immunity over vaccine-induced immunity. *See generally* Exhibit 2, McCullough Decl., ¶¶ 52-57 & studies cited therein. 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. Further, "there are no randomized placebo-controlled … trials of COVID-19 vaccination … demonstrating any clinical benefit" for those who have recovered from a previous infection. Exhibit 3, McCullough Supp. Decl., ¶ 12. There is, however, significant evidence that those with previous infections face 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.,* ¶ 12 & studies cited therein. Thus, in his expert opinion, "COVID-19 vaccination is contraindicated in COVID-19 survivors." *Id*.

123. The combined Phase 1/2/3 clinical trial for Pfizer BNT162b2 is listed on

[82] *See* Nabin K Shrestha, Patrick C Burke, Amy S Nowacki, Paul Terpeluk, Steven M Gordon, "Necessity of Coronavirus Disease 2019 (COVID-19) Vaccination in Persons Who Have Already Had COVID-19," *Clinical Infectious Diseases*, 2022; ciac022, https://doi.org/10.1093/cid/ciac022; *see also* Zhongfang Wang, Xiaoyun Yang, Jiaying Zhong, et al, "Exposure to SARS-CoV-2 generates T-cell memory in the absence of a detectable viral infection," NATURE COMMUNICATIONS, https://doi.org/10.1038/s41467-021-22036-z; O Murchu E, Byrne P, Carty PG, et al. "Quantifying the risk of SARSCoV2 reinfection over time." *Rev Med Virol*. 2021; e2260. https://doi.org/10.1002/rmv.2260; Turner, J. S. et al. "SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans." *Nature* https://doi.org/10.1038/s41586-021- 03647-4 (2021).

the National Clinical Trials database as Clinical Trial (NCT) 04368728. This study began just after the start of the pandemic – in April 2020 – and it will not be completed until May 2023. It is still ongoing right now.[83]

V. PLAINTIFFS HAVE SUFFERED CONCRETE AND PARTICULARZED INJURIES DUE TO DEFENDANTS' UNLAWFUL ACTIONS

124. 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 clearly, medically entitled under regulations currently in force regarding natural immunity and other conditions. *See, e.g.*, ¶¶20-22, 38 *supra*. *See also* Exhibits 5, 6, and 16, Declarations of Major Joshua Wilson, LCDR Michael Groothousen, and MSG Derrick Gibson. In LCDR Groothousen's case, he is a cancer survivor **and** a participant in a clinical trial, which is a specific, listed exemption from the DoD Mandate, yet he is being ordered to take the shots and his exemption for participation in a separate military clinical trial has been rescinded because of how compromised military medical treatment has become over the politicization of these shots.

125. All Plaintiffs will face adverse employment or disciplinary actions, up to and including termination, separation, dishonorable discharge, court martial, loss of post-separation veterans' benefits, requirement to pay back any transferred education benefits to their children, and permanent damage to their reputation and employment prospects resulting from less than a full "honorable" discharge. *See, e.g.*, MARADMIN 462/21,

[83] *See* Pfizer/BioNTech, Trial NCT04368728, *Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals* available at: https://www.clinicaltrials.gov/ct2/show/NCT04368728?term=NCT04368728&draw=2&rank=1 (last visited May 4, 2022).

533/21, 612/21. Several already face promotion or duty restrictions as a result of vaccine refusal. *See, supra*, ¶¶17-40. Moreover, they will face significant obstacles to future employment due to their unvaccinated status and unfairly blemished service records (for failure to comply with an unlawful order), and will be completely barred from employment by the federal government or federal contractors (which are by far the largest employers of veterans) due to the federal employee and federal contractor mandates.[84] This also includes the potential loss of their security clearance for the "misconduct" of refusing to be injected with an mRNA gene therapy that doesn't prevent, nor stop the transmission of, Covid-19.

126. 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 mRNA treatment. *See e.g.*, ¶¶17-18 *supra*, and Exhibit 4, Declaration of SSG Steven Brown, U.S. Army.

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

VI. MALINCENTIVES TO APPROVE

> "…*You tell me whar a man gits his corn-pone, en I'll tell you what his 'pinions is*."
>
> - Mark Twain, "Corn-pone Opinions" 1901

[84] *See* Exec. Order 14,043, 86 Fed. Reg. 50,989, "Requiring Coronavirus Disease 2019 Vaccination for Federal Employees" (Sept. 9, 2021) ("Federal Employee Mandate"); Exec. Order 14,402, 86 Fed. Reg. 50,985, "Ensuring Adequate COVID Safety Protocols for Federal Contractors" (Sept. 9, 2021) ("Federal Contractor Mandate").

128. The Defendant FDA is responsible for oversight of more than $2.7 trillion in consumptives, which includes food, medical products, and tobacco.[85] "About 54 percent, or $3.3 billion, of FDA's budget is provided by federal budget authorization. The remaining 46 percent, or $2.8 billion, is paid for by industry user fees."[86] *Id.*, p. 2.

129. The regulation of Biologics merits only 7.2% of the FDA's budget – a total of slightly over $254 million. User fees – i.e. payments from the industry being regulated – add an additional $182 million – or roughly 42% of the total for regulation of pharmaceutical companies who submit biologics license applications. *Id*.

130. This funding from industry is completely separate from two other sources that flow to regulators: research grants and royalties on patents that U.S. government officials are allowed to own and license to industry because of two separate laws: the Bayh-Dole Act (35 U.S.C. §§200-212), previously known as the Patent and Trademark Act Amendments of 1980, and the Stevenson-Wydler Technology Innovation Act, which was later amended by the Federal Technology Transfer Act of 1986 (15 U.S.C. §§3701-3714). These acts together provide "US federal government laboratories such as the NIH with the legal authority to patent and license inventions made by government scientists to companies for commercial development." *See* Chatterjee, S., Rohrbaugh, M. "NIH inventions translate into drugs and biologics with high public health impact," *Nat Biotechnol* **32,** 52–58 (2014). https://doi.org/10.1038/nbt.2785

131. This is neither speculative nor hypothetical, but instead directly relates to

[85] *See* "FDA at a Glance," Office of the Commissioner, US FDA, Nov. 2021. Available for download here: https://tinyurl.com/2ke79ypz

[86] *See, generally*, The Nat'l L.Rev., "FDA User Fees: How Do They Work?" Jan. 28, 2020. Available here: natlawreview.com/article/fda-user-fees-how-do-they-work

the "vaccines" that are the subject of this action. To wit:

> The National Institutes of Health (NIH) is at legal odds with Moderna, claiming that Moderna neglected to add three NIH scientists to Moderna's patent application on a principal COVID-19 vaccine. If a court ends up siding with NIH, it would co-own any issued patents on the technology, which could prove to be quite valuable; in 2021, Moderna's vaccine sales were forecasted to be in the range of $15 billion and $18 billion. With an equal undivided interest in the patent, NIH could do whatever it wishes with it, such as licensing it to others and collecting royalties.[87]

132. Prior to the pandemic, Moderna, Inc. had revenue of only $60 million in 2019. That shot up to $803 million in 2020, and was $18.471 billion in 2021.[88]

133. In what can only be called a "Washington, D.C." coincidence, the last Commissioner of the FDA, Stephen Hahn (2019-21), is now the Chief Medical Officer for the company that is funding Moderna, Flagship Pioneering.[89] Scott Gottlieb, his immediate predecessor as Commissioner of the FDA (2017-19), now sits on the Board of Directors for Pfizer, Inc.[90] SecDef Austin swore under oath during his confirmation hearings – and in writing, as is required by government ethics rules – to divest himself of his millions of dollars of various stock and ownership interests in Tenet Healthcare and Pine Island Capital Partners.[91] To date, Plaintiffs are unable to find any proof Defendant Austin has done so

---

[87] *See, e.g.*, William Honaker, "NIH's Fight for Ownership of Moderna's COVID-19 Patent Highlights Hazards of Business Collaborations," IPWatchdog, Mar. 31, 2022. Available here: https://tinyurl.com/yckny95s

[88] *See* Sovereign Wealth Fund Institute (SWFI), "Scientists Discover DNA Chunk in COVID That Matches Moderna Patented Sequence from Before Pandemic," Feb. 28, 2022. Available here: https://tinyurl.com/mrxh52va

[89] *See, e.g.*, "He Authorized Moderna's vaccine 6 months ago. Now ex-FDA chief joins biotech's backer," Available here: https://tinyurl.com/2bdf2hbv

[90] *See, e.g.*, "Cue the revolving door criticism: Former FDA commissioner Gottlieb joins Pfizer's board," Available here: https://tinyurl.com/yjnr5c6f

[91] *See* Office of Government Ethics (OGE) form 278 for Lloyd Austin, available here: https://tinyurl.com/4ze3x8ck; *see also* David Sirota, "Potential Biden Officials' Firm is Promising Big Profits Off Administration Access," *Jacobin Magazine*, Nov. 8, 2020. Available here: https://tinyurl.com/2p87u6yy

while Tenet Healthcare, a massive healthcare conglomerate, has a contract providing health insurance to military members via its contract with TriWest, and reaps a fortune in reimbursement for providing Covid-19 shots though its hospitals located near military bases.

FIRST CAUSE OF ACTION
Violation of Fifth and Fourteenth Amendment Procedural Due Process Rights
U.S. CONST. AMENDS. V & XIV
(All Plaintiffs Against Defendants DOD and HHS)

134. Plaintiffs reallege all facts in Paragraphs 1-10, 17-40, 54-65, 66-93, 94-106, 107, and 108-128, as if fully set forth in this cause of action.

135. 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.

136. 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.

137. The DOD Mandate "threatens to substantially burden the liberty interests" of Plaintiffs "put to a choice between their job(s) and their jab(s)." *BST Holdings, LLC v. OSHA*, 17 F.4th 604, 2021 WL 5279381, at *8 (5th Cir. 2021) ("*OSHA*"). Plaintiffs face not only the loss of the current employment, but also will be barred from employment by the federal government or federal contractors due to the Federal Employee and Federal Contractor Mandates, and they will also face significantly difficulties with private employers due to their vaccination, loss of security clearances for "misconduct", and discharge status.

138. Vaccine refusal may also result in deprivation of protected property

interests. Disciplinary action or discharge status may cause Plaintiffs to lose retirement, veterans, and other governmental benefits to which they are entitled. Loss of pay and benefits amount to hundreds of thousands or even millions of dollars in many cases for pilots and other highly-trained specialists.

139. 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, while Pfizer has acknowledged that the two-dose regimen required by the DOD Mandate does not protect against the Omicron variant. *See supra* ¶ 108. "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 v. Trustees of Ind. Univ.,* --- F.Supp.3d. ---, 2021 WL 3073926, at *12 (N.D. Ind. July 18, 2021).

140. The injections are not vaccines, but are, as a factual, legal, and scientific matter, medical treatments. The CDC intentionally changed its own definitions of "Vaccine" and "Vaccination" overnight on Sep. 1, 2021, to eliminate the word "immunity" from the definition. Immunity is the *sine qua non* of all vaccines; it is the entire point of vaccination as a public health measure. *See supra* ¶¶ 85-92.

141. This definitional change without public comment or input was an intentional act, taken by Defendant FDA's agents after it was clear that the mRNA shots

did not produce sterilizing immunity. This was also done despite the fact that the manufacturer had already specifically applied for, and received a BLA license from Defendant FDA "to manufacture the product, COVID-19 Vaccine, mRNA, which is indicated for *active immunization to* ***prevent*** coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older." Exhibit 18, BioNTech FDA BLA Approval Letter at 1-2.

142. This action as designed to obviate plaintiffs' rights to refuse unwanted medical treatment by recategorizing a "treatment" as a "vaccine" and thereby relying upon legal precedent around mandatory vaccination in order to compel plaintiffs to take a medical treatment without their informed consent and to deprive them of their rights to life, liberty and property without procedural due process.

143. Accordingly, Plaintiffs are entitled to temporary, preliminary, and permanent injunctive relief restraining Defendants from enforcing the Defendant DoD's Vaccine Mandate.

144. Pursuant to 28 U.S. Code §§ 2201-02 and other applicable law, Plaintiffs are entitled to a declaration that the Defendant DoD's Vaccine Mandate is unlawful and any further relief which may be appropriate

SECOND CAUSE OF ACTION
Violation of Fifth and Fourteenth Amendment Substantive Due Process Rights
U.S. CONST. AMENDS. V & XIV
(All Plaintiffs Against Defendant DOD)

145. Plaintiffs reallege all facts in Paragraphs 1-10, 17-40, 54-65, 66-93, 94-106, 107, and 108-128 as if fully set forth in this cause of action.

146. The military "vaccine" mandate violates the liberty protected by the Fifth and Fourteenth Amendments to the Constitution, which includes rights of personal

autonomy, self-determination, bodily integrity and the right to reject medical treatment.

147. The ability to decide whether to accept or refuse medical treatment is a fundamental right. Accordingly, Defendant Austin's "Vaccine" Mandate violates Plaintiffs' constitutional rights with regard to medical treatment.

148. Because the injections are treatments, and not vaccines, strict scrutiny applies. The US Supreme Court has recognized a "general liberty interest in refusing medical treatment." *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 278, 110 S. Ct. 2841, 2851, 111 L.Ed.2d 224, 242 (1990). It has also recognized that the forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty. *Washington v. Harper*, 494 U.S. 210, 229, 110 S. Ct. 1028, 1041, 108 L.Ed.2d 178, 203 (1990), see also *id*. at 223 (further acknowledging in dicta that, outside of the prison context, the right to refuse treatment would be a "fundamental right" subject to strict scrutiny).[92]

149. Because mandated medical treatments are a substantial burden, Defendants

[92] Although *Cruzan* was decided under the due process clause of the Fourteenth Amendment, the Supreme Court has long held that the same substantive due process analysis applied to the states under the due process clause of the Fourteenth Amendment also applies to the federal government under the due process clause of the Fifth Amendment. *See, e.g., Bolling v. Sharpe,* 347 U.S. 497, 500 (1954) ("In view of our decision that the Constitution prohibits the states from maintaining racially segregated public schools, it would be unthinkable that the same Constitution would impose a lesser duty on the Federal Government.") *See also, Adarand Constructors v. Pena*, 515 U.S. 200 (1995)(same); *Frontiero v. Richardson*, 411 U.S. 677 (1973) (holding federal law discriminating on basis of sex unconstitutional under the Fifth Amendment due process clause based on Fourteenth Amendment analysis); *Califano v. Goldfarb*, 430 U.S. 199 (1977)(striking down federal racial classification on basis of Fifth Amendment due process clause stating that strict scrutiny is the proper standard for analysis of all racial classifications, whether imposed by a federal, state, or local actor. *Id*. at 231, superseded by statute); *Jimenez v. Weinberger*, 417 U.S. 628 (1974) (striking down provision of the Social Security Act based upon illegitimacy applying substantive due process analysis through the due process of clause of the Fifth Amendment).

must prove that the Vaccine Mandate is narrowly tailored to meet a compelling interest.

150. No such compelling interest exists because, as alleged above, the injections are not effective against the now dominant Omicron variant of SARS-CoV-2 in that they do not prevent the recipient from becoming infected, getting reinfected, or transmitting SARS-CoV-2 to others. Indeed, evidence shows that vaccinated individuals have more SARS-CoV-2 in their nasal passages than unvaccinated people do. *See supra* ¶¶ 108-119.

151. By Defendant FDA's own standards, the current EUA shots only demonstrate that they *may* have been effective against the original SARS-CoV-2 Alpha variant, but that strain has come and gone, and the injections—designed to fight yesterday's threat—are simply "obsolete" against the current variant. *See* Exhibit 3, McCullough Supp. Decl., ¶ 12.

152. Since the injections are ineffective against the Delta and Omicron viral variants, and the original variant has been supplanted, there can be no compelling interest to mandate their use.

153. Even if there were a compelling interest in mandating the injections, the Defendant DoD's mandate is not narrowly tailored to achieve such an interest.

154. The blanket mandate ignores individual factors increasing or decreasing the risks that the plaintiffs pose to themselves or to others. For example, many of the plaintiffs are fighter pilots or crew in aircraft that use individual oxygen, such that some of these plaintiffs do not even share the same air with anyone else while performing their duties.

155. Defendants also entirely disregard whether Plaintiffs have already obtained natural immunity despite the fact that natural immunity does actually provide immunity whereas the injections do not. All members of the Natural Immunity Sub-Class have a

documented previous infection from which they have fully recovered, in most cases a quite recent infection by the Omicron variant, thus have stronger and more durable immunity from reinfection than they would acquire from vaccination.

156. Treating all servicemembers the same, regardless of their individual medical status, risk factors, and natural immunity status is not narrowly tailored.

157. Moreover, the Vaccine Mandate fails entirely to consider other existing treatment options beyond the injections as part of a more narrowly tailored approach.

158. Given these facts, the Vaccine Mandate has no real or substantial relation to Force Protection and is, instead, a public health policy backed by force, turning the entire program into a plain, palpable invasion of rights secured by the fundamental law.

159. Accordingly, Plaintiffs are entitled to temporary, preliminary, and permanent injunctive relief restraining Defendants from enforcing the Defendant DoD's Vaccine Mandate.

160. Pursuant to 28 U.S. Code §§ 2201-02 and other applicable law, Plaintiffs are entitled to a declaration that the Defendant DoD's Vaccine Mandate is unlawful and any further relief which may be appropriate.

THIRD CAUSE OF ACTION
Unconstitutional Conditions
(All Plaintiffs Against Defendant DOD)

161. Plaintiffs reallege the facts in Paragraphs 1-10, 17-40, 74-84, and 94-98 as if fully set forth in this Count.

162. The Vaccine Mandate violates the unconstitutional-conditions doctrine, under which the government may not condition employment "on a basis that infringes [an employee's] constitutionally protected interests." *Perry v. Sindermann*, 408 U.S. 593, 597 (1972); see also *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 606 (2013)

("[T]he unconstitutional conditions doctrine forbids burdening the Constitution's enumerated rights by coercively withholding benefits from those who exercise them.").

163. Unconstitutional conditions case law focuses on the existence of coercion by the government to induce a citizen – or class of citizens – to give up a right or benefit. According to this doctrine, the Defendants cannot impair Plaintiff's right to refuse medical care through forms of coercion and through this mandate. *See, e.g.*, *Memorial Hosp. v. Maricopa Cty.*, 415 U.S. 250 (1974) ("[An] overarching principle, known as the unconstitutional conditions doctrine ... vindicates the Constitution's enumerated rights by preventing the government from coercing the people into giving them up.")

164. The decision whether or not to take a medical treatment is a fundamental human right which all Plaintiffs have. The Plaintiffs cannot be forced to choose between their right to refuse medical treatment, on the one hand, and on the other hand, the loss of their livelihoods, benefits, and fundamental rights, as well as further punishment under Article 92 of the UCMJ for refusal to obey what is in actuality an unlawful order.

165. Accordingly, Plaintiffs are entitled to temporary, preliminary, and permanent injunctive relief restraining Defendants from enforcing the Defendant DoD's Vaccine Mandate.

166. Pursuant to 28 U.S. Code §§ 2201-02 and other applicable law, Plaintiffs are entitled to a declaration that the Defendant DoD's Vaccine Mandate is unlawful and any further relief which may be appropriate.

FOURTH CAUSE OF ACTION
Violation of Fifth and Fourteenth Amendment Equal Protection
U.S. CONST. AMENDS. V & XIV
(All Plaintiffs Against Defendants DOD and HHS)

167. Plaintiffs reallege all facts in Paragraphs 1-10, 17-40, 46-53, 74-84, 85-92,

93, 94-98, 99-102, 103-107, 120-124, and 125-128 as if fully set forth in this cause of action.

168. The Equal Protection Clause prohibits legal classifications that affect equally situated groups of citizens differently than others. (*Engquist v. Or. Dept. of Agric.* (2008) 553 U.S. 591, 601.) The touchstone of this analysis is whether a state creates disparity between classes of individuals whose situations are arguably indistinguishable. (*Ross v. Moffitt* (1974) 417 U.S. 600, 609.)

169. The Defendant DoD's Mandate creates two new classes of soldier that is recorded in no doctrine – and exists completely at the whim of the Defendant Lloyd Austin: (1) the "fully vaccinated, an undefined medical term also creates its own opposing sub-class (2) known as those "*not* fully vaccinated." The members of the second class get removed from their jobs even if they request religious or medical accommodation – in flagrant violation of the Religious Freedom Restoration Act and the DoD's own orders that claims that no adverse action will be taken against them during the "accommodation process."[93]

170. The "not fully vaccinated" also includes Plaintiffs who have had a severe adverse reaction or injury to the shot(s), but whose adverse reactions are being ignored in pursuit of the "mission" to inoculate every member of the Armed Services, individual medical conditions or needs be damned.

---

[93] *See, e.g.*, *Navy SEAL 1 v. Biden,* No. 8:21-cv-2429, 2021 WL 5448970 (M.D. Fla. Nov. 22, 2021). The Air Force and Marine Corps purport to have recently granted a handful of RARs (*i.e.*, roughly a dozen out of nearly 25,000). However, these RARs appear to have been granted to those on terminal leave or conditioned upon their separation from the military. *See Navy SEAL 1 v. Austin*, --- F.Supp.3d ---, 2022 WL 534459, at *19 (M.D. Fla. Feb. 18, 2022); *Poffenbarger v. Kendall*, No. 3:22-cv-1, 2022 WL 594810, at *13 n.6 (S.D. Oh. Feb. 28, 2022).

171. The "not fully vaccinated" are threatened with discharge and punishment for speaking out or refusing to take unlicensed, EUA products under the aegis of "failure to obey a lawful order" under Article 92, UCMJ. At best, they cannot advance their careers because they are refused assignments, shifted out of their career field, and told they will be separated for "misconduct" for refusing a medical treatment. Further, they may receive less than a full honorable discharge from the Armed Forces, severely damaging their future employment prospects (if they can find employment at all due to federal and private vaccine mandates).

172. Those who apparently comply with whatever number of injections and boosters the Secretary eventually decides is sufficient to be considered "fully vaccinated," in stark contrast, are applauded, get to advance in their profession and careers, provide for their families, and they will be given an "honorable" characterization for their voluntary military service. The number of shots required for full vaccination with mRNA COVID-19 vaccines is currently two, but if the DOD follows the CDC/ACIP recommendations, this will likely increase and may even become an annual requirement.

173. But the situations of these two classes of service member are *indistinguishable* with regard to the entire justification for forcing them to take the injections: fully vaccinated soldiers can and frequently do become infected or re-infected with SARS-CoV-2 and can transmit SARS-CoV-2 to fellow soldiers, *just like those who are not fully vaccinated*. The injections make *no difference* in this critical respect between the injected and un-injected. (In fact, the evidence continues to point toward the conclusion that the injected catch and transmit Covid-19 more than the un-injected. *See supra* ¶¶ 120-124.) In any case, the CDC openly admits that the injections' only function is to make

symptoms of the virus *less severe*.

174. Discriminating against the un-injected controverts the Equal Protection Clause's goal of equality before the law. The Equal Protections Clause's requirement is for the laws of the Nation to treat similarly situated individuals *equally*.

175. The Defendant DoD's arbitrary choices and Defendant HHS's new definitions that exclude those who have already had the virus as being "not fully vaccinated" are incoherent, illogical, and violate the Equal Protection rights of those who are un-injected, particularly where DoD considers those who have *already had* SARS-CoV-2 as "not fully vaccinated." Such an arbitrary and irrational policy cannot survive even rational basis review.

176. This is inexplicable given that the DoD's own regulation (AR 40-562) on service wide vaccination, written and published in 2013, specifically exempts those whom have already had infection with a virus from vaccination for it.

177. The Natural Immunity Plaintiffs' Equal Protection rights under the Fourteenth Amendment are violated by the Defendant DoD and HHS/CDC's arbitrary, unscientific, unsupportable distinctions between Natural Immunity Plaintiffs, who have naturally acquired immunity, and other similarly situated military members who have only artificially induced immunity through mRNA injectables. The scientific evidence shows that vaccines (a) do not stop reinfection among the vaccinated, and (b) do not stop spread of the virus by the vaccinated. *See supra* ¶¶ 120-124. Thus, there is no impact on good order and discipline or the health of the Total Force by Plaintiffs who have already had COVID-19 remaining unvaccinated; and no logical reason why the class of Plaintiffs should be treated any differently than their peers. Accordingly, the policy cannot satisfy

either rational basis review, much less the strict or intermediate scrutiny that should be applied here.

178. The DOD's asserted justifications—military health and military readiness—are belied by the facts, and should be considered pretextual justifications that are not due deference by this Court. The health and safety rationale is belied by the DOD's own numbers. *See* Exhibit 1, Rans Decl. (31 total active-duty servicemember deaths over two years) & *supra* ¶ (survival rate of 99.98%). DOD claims that the DOD Mandate is needed for military readiness are not plausible, because the vaccine mandate itself will create a crisis in readiness, as it may ultimately result in loss of 25,000 to 50,000 servicemembers based on the number of servicemembers seeking religious accommodations and the uniform denials of these requests. *See supra* ¶103 & Table.

179. Moreover, the fact that Defendants target those with natural immunity and disregard their medical exemptions proves Defendants' policy is driven by improper animus against the small minority (1-2% for active-duty personnel) of servicemembers who are unvaccinated nearly all of whom also have sought religious accommodations. *See Trump v. Hawaii*, 138 S.Ct. 2392, 2420 (2018) (quoting *Dep't of Agriculture v. Moreno*, 413 U.S. 528, 534 (1973)(noting that the Court has struck down policies as illegitimate under rational basis where "a common thread has been that the laws at issue lack any purpose other than a 'bare. . . desire to harm a politically unpopular group'").

180. Defendant DOD and the Armed Service are thus discriminating against Plaintiffs both based on their medical condition or perceived disability and their religious beliefs, with a near perfect overlap, triggering strict scrutiny.

181. As a result of the Defendants' unlawful actions, the Plaintiffs have suffered

damages, including being required to take an unlicensed drug of unknown long-term safety profile; being subject to or threatened with disciplinary action under the Uniform Code of Military Justice (UCMJ), and including adverse administrative action that would characterize Plaintiffs' voluntary service as less than a full honorable discharge.

182. Pursuant to the Fifth and Fourteenth Amendments, Plaintiffs are entitled to temporary, preliminary, and permanent injunctive relief restraining Defendants from enforcing the DoD's Vaccine Mandate.

FIFTH CAUSE OF ACTION
Violation of Informed Consent Laws and the PHSA
10 U.S.C. §1107a, 21 U.S.C. 360bbb-3, 42 U.S.C. §262, & 5 USC § 706(2)(C)
(All Plaintiffs Against Defendants DOD and FDA)

183. Plaintiffs reallege, as if fully set forth in this count, the facts in Paragraphs 1-10, 17-40, 46-53, 54-65, 66-73, 74-84, 85-92, 93, 94-98, 99-102, 103-106, and 107.

184. Defendants have violated the Informed Consent Laws, the PHSA, and the FDA's mandatory labeling regulations. These laws do not provide a private right of action. Accordingly, Plaintiffs' claims for Defendants' *ultra vires* actions in excess of their statutory authority, and in violation of Plaintiffs' rights under applicable statutes and regulations, are brought under the APA. *See, e.g., Austin*, at *2 & *7 n.12 (informed consent violations are "APA claims"). It is well-settled that, where a statute does not provide a cause of action, plaintiffs "are nevertheless entitled to enforce [the statute's] substantive requirements through the judicial review provisions of the APA." *Int'l Brominated Solvents Ass'n v. Am. Conf. of Governmental Indus. Hygienists, Inc.,* 393 F.Supp.2d 1362, 1378 (M.D. Ga. 2005).

185. It is undisputed that the FDA-licensed COVID-19 vaccines (Comirnaty and Spikevax) are not available and have not been available since the announcement of the

mandate. *See, e.g., supra* ¶¶ 68-69. Defendants are instead mandating EUA vaccines that prominently bear EUA labels. *See Austin*, 2021 WL 5816632, at *7. The Informed Consent Laws prohibit the mandatory administration of an EUA product. *See* 10 U.S.C. § 1107a and 21 U.S.C. § 360bbb-3. Plaintiffs' statutory rights are reflected in the fact sheet that the FDA requires to be included as part of product labeling, which expressly states that recipients have the "option to accept or refuse" the EUA product (*i.e.*, it cannot be mandated). *See* Exhibit 21, Pfizer-BioNTech EUA Vaccine Fact Sheet at 13.

186. Defendants seek to circumvent this express statutory prohibition on mandating an EUA product, stated clearly in the FDA's required product labeling, through guidance documents asserting that ***any EUA vaccine*** may be used interchangeably with, or "as if" it were, an FDA-licensed vaccine. *See, e.g.,* Exhibit 34, Air Force Guidance, § 3.1.1.

187. Defendants' guidance relies on FDA statements regarding interchangeability in the EUA Re-issuance Letters. *See, e.g.,* Exhibit 17, Aug. 23, 2021 EUA Re-Issuance Letter, at 2 n.8. But the FDA—the agency expressly delegated the authority to make EUA determinations under 21 U.S.C. § 360bbb-3 and to make statutory interchangeability determinations under 42 U.S.C. § 262—has never made any finding that an EUA product may be mandated, nor any statutory interchangeability determination. Nor has the FDA waived the labeling required by the Informed Consent Laws, the PHSA and the FDA's labeling regulations thereunder, if it even could legally. *See supra* ¶¶ 54-58 (discussing PHSA labeling requirements in 42 U.S.C. § 262(a)(1)(B)(i)-(ii) & 21 C.F.R. § 610.60(a)). This is consistent with the fact that all EUA products available and offered to Plaintiffs identify such products as EUA products on every vial, and the fact that every

packaging insert continues to advise patients and caregivers that they have the "option to accept or refuse" administration of the product; conversely, no COVID-19 vaccines are available that are labeled as FDA-licensed products (*i.e.*, Comirnaty or Spikevax).

188. The FDA documents relied on by Defendants expressly state that the EUA and the licensed product are "legally distinct" and acknowledge that there are "certain differences" between these products. These legal distinctions include the fact that the EUA BioNTech Vaccine is subject to the laws governing EUA products, including the statutory right of informed consent (*i.e.*, the "option to accept or refuse"). *See supra* ¶¶ 80-81. The FDA-licensed Comirnaty, by contrast, is subject to the heightened statutory requirements under the PHSA for FDA-licensed products, namely, that it meets the PHSA's requirements for safety, potency (or efficacy), and purity, and must use FDA-approved labeling and manufacturing facilities and processes.

189. While the FDA initially asserted that EUA products and the FDA- licensed products are interchangeable because they have the "same formulation," while admitting that there are "certain differences" between them, the FDA subsequently expanded the scope of interchangeable products to encompass products with different formulations that are chemically distinct but "analytically comparable." *Cf.* Exhibit 17, Aug. 23, 2021 Pfizer/BioNTech EUA Re-Issuance Letter & Exhibit 29, March 29, 2022 Pfizer/BioNTech EUA Re-Issuance Letter.

190. In short, the FDA has abandoned enforcement of a huge swath of the Act it has been chartered by Congress to enforce, 42 U.S.C. §262, and the marketing and labeling requirements in its own regulations.

191. The DOD Mandate and the Armed Services Guidance are *ultra vires* actions

taken in excess of their statutory authority, and in violation of the substantive requirements of the Informed Consent Laws, the PHSA, and the FDA's labeling regulations, insofar as they: (1) mandate an EUA product and seek to override service members' statutory informed consent and rights to refuse a non-FDA-licensed product; (2) direct the Armed Services, health care providers, and military treatment facilities to administer unlicensed EUA products as if they were legally interchangeable with (or legally equivalent to) FDA-licensed products; and (3) seek to deceive service members' into forfeiting their informed consent rights by misrepresenting non-FDA-licensed EUA products as if they were FDA-licensed products, and/or (4) by directing service members to ignore (or refusing to provide altogether) the clear statements in the FDA-required labeling that they have the right to refuse the EUA product. The FDA statements on which Defendants rely do not purport to override or waive informed consent rights, to establish any legal equivalency between EUA and FDA-licensed products, or to waive the mandatory requirements of the FDA's labeling regulations.

192. The DOD Mandate and Armed Services Guidance must therefore be declared unlawful and enjoined insofar as they seek to mandate an EUA product, consistent with applicable precedent. *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)(enjoining mandatory administration of EUA anthrax vaccine).[94]

[94] It is worth noting that the final chapter to the *Doe v. Rumsfeld* saga was an Equal Access to Justice Act (EAJA) suit by the *Doe* plaintiffs for payment of their legal fees. The court there found that the FDA and DoD's arguments for the mandatory immunization of an unlicensed biologic – the same exact issue present here using the exact same arguments – were "not substantially justified" and the government was eventually ordered to pay plaintiffs' reasonable attorneys' fees. *Doe v. Rumsfeld*, 501 F. Supp. 2d 186, 190 (D. D.C. 2007).

193. Plaintiffs' note that, in other legal challenges to the DOD Mandate, Defendants have asserted the affirmative defense that the DOD Mandate is limited to EUA-labeled, (but) "BLA-compliant" vaccines (*i.e.*, vaccines manufactured in accordance with the Comirnaty BLA). *See generally Austin*. The DOD Mandate and the Armed Services Guidance, however, never use the terms "BLA-compliant," or suggest any such limitation, and the publicly available documents refer only to "EUA" vaccines, without any limitation to "BLA-compliant" lots. The purported limitation of the mandate to "BLA-compliant" lots was announced in the first instance by agency defense counsel in court filings and is entirely unsupported in the record. Courts may not accept "post hoc rationalization by counsel as prime authority for agency decision[s]." *Harrison v. Ocean Bank*, 2011 WL 2607086, at *4 (S.D. Fla. June 30, 2011).

194. Moreover, the DoD and Army administrative records submitted in the *Coker* proceeding, and filed separately in this proceeding confirm that: (1) all references to interchangeability in the record indicate that ***all*** unlicensed EUA-labeled COVID-19 vaccines (*i.e.*, without limitation to EUA-labeled, BLA-compliant lots) are deemed to be interchangeable with the licensed version; and (2) that there is no discussion of interchangeability with respect to "BLA-compliant" lots, nor is there any policy, directive, or guidance limiting the DoD Mandate to EUA-labeled, "BLA-compliant" lots. *See also Austin*, 2021 WL 5616632, at *6 ("the DoD concedes that … its current [EUA-labeled] vials are not BLA-compliant, and that there is no policy to ensure that servicemembers get only BLA-compliant vaccines."). Accordingly, Defendants are barred by the "record rule" from asserting any defense for which there is no support in the record and that was asserted only by agency defense counsel.

195. Nor should this Court impose any requirement for Plaintiffs to plead that he specifically requested or was denied a "BLA-compliant" vaccine. Nevertheless, several Plaintiffs have inquired regarding the availability of Comirnaty and/or a BLA-compliant version of the Pfizer/BioNTech vaccines, and were informed neither Comirnaty nor any EUA-labeled, BLA-compliant vaccines. *See, e.g.,* Exhibit 4, Declaration of Plaintiff SSG Steven Brown.

196. As a result of Defendants' unlawful actions, Plaintiffs will be required either to take a non-FDA-licensed EUA vaccine, or else face the serious disciplinary consequences outlined above that will result in the loss of their livelihoods, careers, benefits, and fundamental rights.

197. As a result of the defendants' unlawful actions, the Plaintiffs have suffered damages, including being required to take an unlicensed drug of unknown long-term safety profile; being subject to or threatened with disciplinary action under the Uniform Code of Military Justice (UCMJ), or adverse administrative action that would characterize Plaintiffs' voluntary service as "other than honorable."

SIXTH CAUSE OF ACTION
Violation of Administrative Procedures Act,
5 U.S.C. §§ 706(2)(A) & 706(2)(E)
(All Plaintiffs Against Defendant DOD)

198. Plaintiffs reallege, as if fully set forth in this count, the facts in Paragraphs 1-10, 13-40, 46-53, 54-65, 66-107, 108-124, and 125-128.

199. The DOD Mandate and Armed Services' guidance are *ultra vires* actions "in excess of statutory jurisdiction [and] authority," 5 U.S.C. § 706(2)(C), for the reasons set forth under the Fourth Cause of Action above. 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."). While Congress and the President have delegated the Secretary of Defense broad authority, they have expressly withheld the authority to mandate an EUA vaccine without Presidential waiver, which Secretary Austin has neither received nor requested.

200. The DOD Mandate and the Armed Services' guidance must be set aside as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(A), and because it is not supported by "substantial evidence." 5 U.S.C. § 706(E). The entirety of the DOD Mandate is a two-page memorandum from the Secretary of Defense that cites no statute, regulation, executive order or other legal authority, and indeed in many places appears to patently exceed his authority, insofar as it seeks to regulate State Guardsman. The DOD Mandate is also arbitrary and capricious insofar as it imposes an entirely new mandate on over two million active duty and reserve service members without any explanation, justification, legal basis or authority; any findings of facts or analysis (cost-benefit or otherwise) supporting the directive; seeks to exercise *ultra vires* action in excess of DOD or Secretary Austin's authority and/or that is expressly delegated to another agency; and is based on patent misrepresentations of the law.

201. The DOD Mandate is arbitrary and capricious insofar as its 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." Exhibit 22, SECDEF Memo at 1. Given that the DOD Mandate was issued on the very next day after FDA Comirnaty Approval, it is apparent the DoD either blindly relied on the FDA approval and out-of-context FDA statements regarding interchangeability or was fully involved in a scheme to commit fraud upon members of the Armed Forces by denying them their Constitutional and statutory rights and obviate the Congressional requirements of 10 U.S.C §1107a.

202. Defendants also purport to rely on the CDC's recommendations in adopting the two-dose regimen, but have ignored the CDC's unanimous recommendation that all eligible adults should receive a third booster shot. *See* CDC, *CDC Expands Eligibility for COVID-19 Booster Shots to All Adults,* CDC Media Statement (Nov. 19, 2021), available at: https://www.cdc.gov/media/releases/2021/s1119-booster-shots.html. Such selective picking and choosing of which recommendations to follow, without any explanation, is the essence of arbitrary and capricious decision-making.

203. The DOD Mandate is also arbitrary and capricious because it constitutes an unannounced and unexplained departure from a prior policy. As the Fifth Circuit recently noted in issuing a Preliminary Injunction against the OSHA vaccine mandate:

> Because it is generally "arbitrary or capricious" to "depart from a prior policy *sub silentio*," agencies must typically provide a "detailed explanation" for contradicting a prior policy, particularly when the "prior policy has engendered serious reliance interests." OSHA's reversal here strains credulity, as does its pretextual basis. Such shortcomings are all hallmarks of unlawful agency actions.[95]

---

[95] *BST Holdings, LLC v. OSHA*, No. 21-60845, p. 12 (5th Cir. 2021)(citations omitted)(emphasis added).

204. The first vaccine that Defendant FDA ever granted EUA status to was the anthrax vaccine in 2005 – and it is directly relevant because in that prior case, both the Defendants DoD and FDA took the exact *opposite* legal position on the record than that which they are taking right now.

205. After the D.C. District Court enjoined the Defendant DoD's anthrax vaccine program in 2003, *see Doe v. Rumsfeld*, 297 F. Supp. 2d 119 (D.D.C. 2003) ("*Rumsfeld I*"), the defendant DoD and FDA both took various actions to continue Secretary Cohen's 1998 anthrax vaccine mandate. *See Doe v. Rumsfeld*, 341 F.Supp.2d 1 (D.D.C. 2004) ("*Rumsfeld II*"). After being enjoined again, and facing a permanent injunction, the Defendant DoD filed an emergency motion with that court to Modify the Injunction because Defendant FDA had reclassified the anthrax vaccine as an EUA product – the first time any vaccine had ever been granted that status:

> Defendants have now filed an Emergency Motion to Modify the Injunction, seeking clarification that there exists a third option - an alternative to informed consent or a Presidential waiver - by which defendants can administer AVA to service members even in the absence of FDA approval of the drug: that is, pursuant to an Emergency Use Authorization ("EUA") under the Project BioShield Act of 2004, 21 U.S.C.A. § 360bbb-3.

John Doe #1 v Rumsfeld, 2005 WL 774857 (D.D.C. 2005) (enjoining mandatory administration of EUA anthrax vaccine).

206. The FDA placed several conditions on granting the EUA, but only one is important to this litigation. Noting that 21 USC 360bbb-3(e)(1)(A)(ii)(III) contains not only an informed consent requirement, but also a requirement that individuals to whom the product is administered be informed of the option to accept or refuse administration of the product, the FDA determined that an option to refuse vaccination meant that DOD's AVIP

could not be mandatory, and that there could be no disciplinary or other punitive measures taken against service members, civilian employees, or civilian contractors who refused the shot.

> With respect to condition (3), above, relating to the option to accept or refuse administration of AVA, the AVIP will be revised to give personnel the option to refuse vaccination. Individuals who refuse anthrax vaccination will not be punished. Refusal may not be grounds for any disciplinary action under the Uniform Code of Military Justice. Refusal may not be grounds for any adverse personnel action. Nor would either military or civilian personnel be considered non-deployable or processed for separation based on refusal of anthrax vaccination. *There may be no penalty or loss of entitlement for refusing anthrax vaccination*.

70 Fed Reg. 5452, 5455 (Feb.2, 2005)(emphasis added).

207. In other words, in circumstances virtually identical to those presented here, the FDA determined that the statutory requirement of an option to refuse a mandatory EUA vaccination meant that there can be no punitive action against someone who does not want the shot. This requirement applied to both military members and civilian employees and contractors, all of whom were subject to the anthrax vaccination program in its original form.

208. Additionally, 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.[96] 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,

[96] *See* Exhibit 39, Office of Legal Counsel, Vaccine Mandate Opinion, at 16.

at *5 (*quoting FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515, 129 S. Ct. 1800, 173 L.Ed.2d 738 (2009)).

209. The DoD and Army administrative records provide further confirmation that Defendants acted arbitrarily and capriciously in enacting the mandate because Defendants failed altogether to consider any alternatives to 100% vaccination, including measures that had been effectively employed over the previous 18 months prior to the mandate (*e.g.,* masking, social distancing, testing, quarantine, etc.). Nor did Defendants provide any explanation in the record as to why these alternatives were inadequate or consider the relative costs and benefits of alternative measures. This is confirmed by the findings of the five U.S. district courts in the RFRA context that the DOD and other Armed Services failed to consider any alternative less restrictive measures. *See, e.g., Navy SEAL 1*, 2022 WL 534459, at *18; *Air Force Officer v. Austin*, 2022 WL 468799, *10 (M.D. Ga. Feb. 15, 2022) ("*Air Force Officer*"). Where an agency like DOD "provide[d] little or no explanation for the [its] choices," "omit[s] explanation for rejecting alternatives," and did "not address alternative (or supplementary) requirements," its order is arbitrary and capricious and must be vacated. *Health Freedom Def. Fund v. Biden*, 2022 WL 1134138, at *18-19 (M.D. Fla. Apr. 18, 2022).

210. Finally, the DOD Mandate and Armed Services Guidance are arbitrary and capricious, and unsupported by substantial evidence, insofar as they categorically eliminated existing exemptions for previous documented infections under AR 40-562, or to consider natural immunity in its religious exemption decisions. *See, e.g., Navy SEAL 1*, at *16 & n.10; *Navy SEALs 1-26*, at *10; *Air Force Officer*, at *10. In doing so, Defendants have "entirely failed to consider an important aspect of the problem." *Motor Vehicle Mfrs.*

Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).

211. As a result of Defendants' unlawful actions, Plaintiffs will be required either to take an unlicensed vaccine, pursuant to an unlawful directive, or else face the serious disciplinary consequences outlined above that will result in the loss of their livelihoods, careers, benefits, and fundamental rights.

212. As a result of the Defendants' unlawful actions, the Plaintiffs have suffered damages, including being required to take an unlicensed drug of unknown long-term safety profile; being subject to or threatened with disciplinary action under the Uniform Code of Military Justice (UCMJ), and including adverse administrative action that would discharge the Plaintiffs for "misconduct" and characterize their voluntary service as "other than honorable."

WHEREFORE, Plaintiffs respectfully ask this Court to:

A. Find that the use of Pfizer-BNT COVID-19 vaccine for forcible inoculation of U.S. military members to be illegal until and unless the Secretary of Defense complies with his statutory requirements in requesting a waiver of informed consent and until the President makes the requisite finding under 10 U.S.C. §1107a; and

B. Find that all members of the Plaintiffs' class that have survived infection with COVID-19 are still entitled to a medical exemption from vaccination even after the Defendants have complied with their legal obligations under the implementing DoDI 6200.02;

If applicable,

C. Find that the use of vaccines under an EUA is illegal until and unless all of the Defendants comply with their statutory obligations in requesting a waiver of informed consent under 10 U.S.C. §1107a and the implementing regulations and laws;

D. Find that all members of the Plaintiffs' class that have survived infection with COVID-19 are entitled to individual assessment to determine their

eligibility for a medical exemption from vaccination even after the Defendants have complied with their legal obligations under DoDI 6200.02;

Plaintiffs also ask this Honorable Court to:

E. Find and declare that any order issued by DoD requiring the Plaintiffs to receive inoculation with COVID-19 EUA vaccines are *per se* unlawful;

F. Enjoin the DoD from vaccinating any service members until this action has completed and the status of any vaccine has been determined and the requirements for taking away Plaintiffs' rights of informed consent have been met;

G. Find that there is no longer any Emergency with respect to the Members of the Plaintiff class that justifies vitiating their rights, as Plaintiffs are all young, healthy, and at less risk from the Covid-19 virus than they are from the treatments currently being mandated by the government; and

H. Award Plaintiffs their costs and attorneys' fees and any other relief this Court may find appropriate.

Date: May 23rd, 2022

Respectfully submitted,

/s/ Jerri Lynn Ward
Jerri Lynn Ward, Esq.
Texas Bar #20844200
Garlo Ward, P.C.
1017 Rose Circle
College Station, Texas 77840
(512) 302-1103 ext. 115
jward@garloward.com
Attorney for the Plaintiffs

/s/ Dale Saran
Dale Saran, Esq.
MA Bar #654781
19744 W 116th Terrace
Olathe, KS 66061
Telephone: 480-466-0369
Email: dalesaran@gmail.com
Attorney for the Plaintiffs/Lead Counsel
(PHV Motion Pending)

/s/ Brandon Johnson

Brandon Johnson, Esq.
DC Bar No. 491370
Defending the Republic
2911 Turtle Creek Blvd.,
Suite 300 Dallas, TX 75219
Tel. 214-707-1775
Email: bcj@defendingtherepublic.org
Attorney for the Plaintiffs
(PHV Motion Pending)