

Case No. 22-1032

UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

DAN ROBERT, SSG, U.S. ARMY,
HOLLIE MULVIHILL, SSGT, U.S. MARINE CORPS
AND OTHER SIMILARLY SITUATED INDIVIDUALS,

Plaintiffs – Appellants,

v.

LLOYD AUSTIN, in his official capacity as Secretary of Defense, U.S.
Department of Defense,
XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department
of Health and Human Services, and
ROBERT CALIFF, U.S. Commissioner of Food and Drugs,

Defendants – Appellees,

On Appeal from a Final Judgment of the United States District Court
for the District of Colorado in Case No. 1:21-cv-02228-RM-STV
The Honorable Raymond P. Moore, U.S. District Judge

REPLY BRIEF OF APPELLANTS

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PRELIMINARY STATEMENT

Federal law is clear: 10 U.S.C. §1107 and 10 U.S.C. §1107a prohibit requiring use of any unlicensed vaccines on service members without their informed consent and without an express and timely presidential waiver of Plaintiffs' rights.¹ Despite representations to the contrary, the Pfizer and Moderna vaccines remain unlicensed, and are administered to service members based on a fraudulent Emergency Use Authorization issued by Defendant FDA. In Defendants' appellate brief, which includes the FDA itself as a party on the brief, they misleadingly use the phrase "then-unlicensed Pfizer vaccine" when, in fact, the Pfizer vaccine has *never* been licensed by the FDA. (Appellees Br. 5)

By imposing this unlicensed vaccine on service members (Appendix ("A") 18-19, Amended Complaint ¶¶ 23-28), Defendant Austin's mandate violates federal law, international law, Department of Defense (DoD) regulations, and as such the federal courts are the proper place for adjudicating this violation. Defendants' conduct is a bait-and-switch in violation of the foregoing legal standards: they cite a European-licensed (foreign) vaccine not eligible for US

¹ Appellants Br. at 1, 3, 10, 12, 15, 18, 29. As to terminology, Defendant FDA uses the term "unlicensed" as synonymous with "unapproved." An unlicensed vaccine may obtain limited authorization under the FDA Emergency Use Authorization procedure.

<https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained> (viewed May 29, 2022).

licensure while actually imposing a biological genetic engineering injectable that is disguised as a licensed vaccine on their very own, entirely voluntary service members and finest examples of people that form our society. The DoD, in particular, owes these people a fiduciary responsibility considering the self-sacrificing demands made of them.

On appeal concerning a motion to dismiss, Defendants over-rely on factual (and incorrect) assertions in their appellate brief that are unresolved without so much as a hearing to parse their accuracy. The issue on appeal is whether Plaintiffs state a valid cause of action, including questions of constitutionality that must be resolved, not whether the weight of the evidence supports one side or the other. Unfortunately, Defendants' appellate brief says little about the substantive issues on appeal including legitimate questions of human rights, and instead obfuscates the issues by calling unlicensed active biological agents that forever genetically modify the users, "vaccines." The so-called vaccine manufactured by Pfizer and commonly referred to as the "Pfizer vaccine" is *not* a licensed vaccine, and thus cannot be mandated by Defendant Austin. Defendants seek to further confuse that central fact by grouping a foreign-made, differently regulated and manufactured Comirnaty vaccine as collectively and singularly the "Pfizer vaccine." Defendants artfully hide behind procedure rather than address a single substantive issue of this case. It was plainly – and indisputably – unlawful for Defendant Austin to mandate

the unlicensed Pfizer vaccine, while contemporaneously refusing to count existing immunity (prior infection) as satisfactory for purposes of preventing the purportedly deadly Covid infection which carries a nearly 100% survivability rate among this class of people. Plaintiffs met their burden of stating a valid cause of action for which they should be heard.

Defendants' fact-based argument that a licensed vaccine is available to service members is doubtful, unproven and improperly asserted by Defendants on appeal from a motion to dismiss. (Appellees Br. 15 – "Plaintiffs already have access to vaccines manufactured in compliance with an approved license," Defendants argue without adequate support.) The vaccine centers to which service members are directed are incapable of acquiring the EU-licensed, foreign-manufactured and substandard version of the Covid vaccine, which would be an issue of fact to be addressed on remand. Only Emergency Use Authorization vaccines were and are available as of the date of the filing of the Amended Complaint, and regulatory prerequisites to the lawful production of this product under US standards remained unsatisfied. (A 18, Amended Complaint ¶ 22)

What matters here is whether the Department of Defense is coercing, threatening and mandating an unlicensed vaccine pursuant to an illegal order that cannot arise from anyone other than the President of the United States himself because they are experimental and inherently hazardous. Similarly, the status of the

imminent disciplinary consequences to Plaintiffs for failure to abide by Defendant Austin's unlawful order remains a factual issue for resolution by the trial court, not for the silencing of our revered military on a motion to dismiss.

Pfizer's own six-month Post-Marketing disclosure lists approximately 1,291 additional "Serious Adverse Events of Special Interest" over the known and disclosed ones, which include strokes, heart damage, blood clots and paralysis.² The Johnson & Johnson Covid vaccine mentioned favorably in Defendants' appellate brief has recently been halted (recalled) by Defendants HHS and FDA because of confirmation by the government of severe harm caused by it.³ Yet in their appellate brief the same Defendants imply that all Covid vaccines are equally "safe and effective," and that it is both lawful and appropriate for Defendant Austin to mandate participation in what amounts to the largest clinical trial of investigatory new drugs ever, not to mention gene-altering ones. This is a fully ripe issue for adjudication here and on a remand.

SUMMARY OF THE REPLY ARGUMENT

Plaintiffs have standing to challenge an order that violates federal law, puts them at risk for unnecessary injury and death and/or burdens them in any way. As

² <https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf> (viewed June 15, 2022).

³ <https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine> (viewed June 15, 2022).

alleged and thus taken as true at this preliminary stage, Defendant Austin's order (A 18-19, ¶¶ 23-28) violates applicable federal law by requiring service members to be vaccinated by an unlicensed, and therefore experimental, Covid-19 vaccine. Defendant Austin's order has burdened Plaintiffs by causing them to seek an exemption (Plaintiff Robert) or benefit from a temporary exemption (Plaintiff Mulvihill). Accordingly, Plaintiffs have legal standing to challenge the lawfulness of Defendant Austin's order, as precedent is clear that even a trifle of a burden is sufficient to establish legal standing. *See United States v. Students Challenging Regulatory Agency Procedures*, 412 U.S. 669, 689 n.14 (1973) ("identifiable trifle is enough for standing") (quotation omitted).

In their appellate brief, Defendants do not credibly dispute these fact-based arguments and they ignore the constitutional issues presented. Instead, Defendants resort to procedural arguments to avoid the central issue, which is the dangerous unlawfulness of Defendant Austin's mandate to undertake experimental genetic alteration for which the Plaintiffs complain is an unlawful burden imposed on all service members, including Plaintiffs. Defendants can hardly deny that Defendant Austin's order itself is final and fully ripe for judicial review given that more than a million service members have participated this implicit clinical trial. Defendants cannot dispute that it is a burden to seek or maintain an exemption where tens of thousands of service members have sought and been denied exemptions, and given

that even the few granted exemptions are revocable. Service members, including Plaintiffs, have a valid cause of action against an unlawful Covid-19 vaccine mandate irrespective of the short-term exemptions currently provided them; and in the case of Mulvihill a temporary exemption that will inevitably expire under its own terms. Even the burden of being subject to such expiration or revocation suffices for standing to challenge an unlawful order without any further basis required. Indeed, the temporary exemption is by itself a burden when the penalty is severe: an unfavorable separation from service with a loss of earned benefits. Where, as here, the underlying order lacks legal justification, then there is standing to challenge the order based on its burdens alone.

A temporary exemption does not negate the standing of someone challenging a final order. Defendants insist on appeal that Plaintiff Mulvihill's temporary medical exemption deprives her of standing, and therefore the federal courts of jurisdiction. (Appellees Br. 16) But Plaintiff Mulvihill is burdened by the certain expiration of her temporary exemption. As to the multitude of religious exemptions sought by service members, this court can take judicial notice of many federal court rulings which confirm that virtually no religious exemptions from vaccination in the military are granted; and oddly this is so only in respect of the Covid 19 vaccinations whereby service members' prior exemptions to other compulsory vaccinations no longer apply. *See, e.g., U.S. Navy Seals 1-26 v. Biden,*

27 F.4th 336, 341-42 (5th Cir. 2022) (“In December 2021, the Navy reported receiving 2,844 requests for religious accommodations. A more recent report suggests that more than 4,000 active duty and Navy Reserve sailors have submitted such requests. The Navy has denied them all.”).

Appellees inadequately distinguish precedents in other jurisdictions establishing standing to challenge analogous vaccine mandates, particularly concerning experimental substances inadequately tested in humans as is at issue here. As argued by Plaintiffs (Appellants Br. 29-30) and unrebutted by Defendants in their opposition brief, federal law allows only the very limited forced vaccination of service members with an IND, experimental or unlicensed (Emergency Use Authorization) vaccine after the President alone has complied with all the substantially specific and robust legal requirements of 10 U.S.C. §1107 or §1107a, none of which has been satisfied here. Conceptually, courts are for the first time faced here with the very real risk that Defendant Austin’s order at issue here is causation to transfer title of a human’s own sovereign body to global patent holders⁴ in violation of the 13th Amendment and as such his order must be enjoined and Plaintiffs respectfully ask this Court to immediately so enjoin Defendants or indicate as much with its ruling. It is noteworthy that Defendants did not deny this

⁴ See, e.g., *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013) (cited in Appellants Br. 19, 33).

argument (discussed in Appellants Br. 19, 33) in Defendants' response, which could thereby be deemed conceded and contrary to public policy.

Defendants repeatedly rely on misplaced and untested declarations in their motion to dismiss. At this stage, factual assertions by the moving party (Defendants) are irrelevant to the issue of whether Plaintiffs stated a valid cause of action. Moreover, the declarations by Defendants do not actually demonstrate the facts asserted and, as found in their Supplemental Appendix, raise issues of fact for resolution on a remand to the court below.

Defendants implicitly acknowledge in their appellate brief that Plaintiffs have already been adversely affected by this illegal order by Defendant Austin, by simply requiring the pursuit of exemptions that are temporary unless otherwise resolved by exclusion from their military careers. In fact, Plaintiffs have no obligation to seek religious or medical exemptions from an unlawful order irrespective of personal situations or beliefs, and they do not waive any such right or legal standing by seeking or temporarily benefiting from any such an exemption.

By virtue of Defendant Austin's order, Plaintiffs have already lost cognizable rights, including the right to forgo participation in a genetic engineering experiment using an unlicensed and dangerous investigative therapy that causes unknown genetic mutation of service members around them through the shedding of prions. Indeed, evidence of Defendants' own concerns about the shedding

(transmissibility) of vaccinated persons’ manufactured spike proteins exists.⁵ The resultant loss of rights due to an unlawful order imposes burden enough for standing. Otherwise defendants in this and similar other cases will simply obtain dismissals on grounds of standing by temporarily exempting plaintiffs from an illegal order. That is not the law, nor should it be allowed to become precedent.

REPLY ARGUMENT

I. The Exemptions Do Not Preclude Plaintiffs’ Right to Challenge Defendant Austin’s Mandate for Unlicensed Vaccines as Unlawful.

The existence of a burdensome process for an exemption does not negate standing to challenge an unlawful rule, as Plaintiffs do here. Defendants’ appellate brief says remarkably little in defense of Defendant Austin’s mandate, and instead stake their case on appeal by arguing to deprive Plaintiffs a forum to seek redress for a permanent life-altering and life-threatening experiment. If not these Plaintiffs, then whom should be granted standing and immediate injunctive relief? Regardless of whether Plaintiffs pursue an exemption, and regardless of whether exemptions are granted, Plaintiffs have standing to contest an unlawful mandate that burdens them by the uncertainty and effort associated with any potential exemptions. *See, e.g., Ass’n of Cmty. Orgs. for Reform Now, (“ACORN”) v. Golden*, 744 F.2d 739, 744 (10th Cir. 1984).

⁵ <https://www.fda.gov/media/144416/download> (viewed June 16, 2022).

In *ACORN v. Golden*, this Court explained:

Applying for and being denied a license or an exemption is not a condition precedent to bringing a facial challenge to an unconstitutional law. One faced with an unconstitutional law requiring him to obtain a license or exemption before engaging in First Amendment activity “may ignore it and engage with impunity in the exercise of the right of free expression for which the law purports to require a license.” See *Shuttlesworth v. City of Birmingham*, 394 U.S. 147, 151, 22 L. Ed. 2d 162, 89 S. Ct. 935 (1969) (footnote omitted). ““The Constitution can hardly be thought to deny to one subjected to the restraints of such an ordinance the right to attack its constitutionality, because he has not yielded to its demands.”” *Id.* (quoting *Jones v. Opelika*, 316 U.S. 584, 602, 86 L. Ed. 1691, 62 S. Ct. 1231 (1942) (Stone C.J., dissenting) (adopted per curiam on rehearing 319 U.S. 103, 104, 87 L. Ed. 1290, 63 S. Ct. 890 (1943))). Thus, ““*one who might have had a license for the asking may therefore call into question the whole scheme of licensing when he is prosecuted for failure to procure it.*”” *City Council of Los Angeles v. Taxpayers for Vincent*, 466 U.S. 789, n.16, 80 L. Ed. 2d 772, 104 S. Ct. 2118, 52 U.S.L.W. 4594, 4597 n.16 (1984) (emphasis added) (quoting *Thornhill v. Alabama*, 310 U.S. 88, 97-98, 84 L. Ed. 1093, 60 S. Ct. 736 (1940)); see also *Lovell v. City of Griffin*, 303 U.S. 444, 452, 82 L. Ed. 949, 58 S. Ct. 666 (1938) (“As the ordinance is void on its face, it was not necessary for appellant to seek a permit under it.”); *Schneider v. State*, 308 U.S. 147, 165, 84 L. Ed. 155, 60 S. Ct. 146 (1939) (“The ordinance in question, as applied to the petitioner’s conduct, is void, and she cannot be punished for acting without a permit.”).

744 F.2d at 744 (emphasis added).

“We decline to hold that solicitors must first apply for and be denied a license before challenging a licensing ordinance’s constitutionality.” *Pac. Frontier v. Pleasant Grove City*, 414 F.3d 1221, 1228 (10th Cir. 2005). While this and similar cases concerned First Amendment freedom of speech challenges, this case at bar also implicates constitutional issues and thus legal standing for the same reasons should be observed and granted.

Defendants rely on two sharply divided decisions by the Supreme Court which held against standing because there was not sufficient injury to the plaintiff. *See Clapper v. Amnesty Int'l USA*, 568 U.S. 398 (2013) (fear of surveillance found to be insufficient to establish standing) (cited by Appellees Br. 13, 14, 15, 20); *Lujan v. Defs. of Wildlife*, 504 U.S. 555 (1992) (standing found not to exist when there was at most an alleged tenuous environmental injury) (cited by Appellees Br. 15, 21). Those decisions of very remote possible injury are inapplicable here, when the Plaintiffs here face job termination, harassment, reduction or elimination of earned benefits and reputational disgrace due to an unlawful order by Defendant Austin.

Like the court below, Defendants wonder why HHS and FDA were included as parties in this case (Appellees Br. 11 n.3), and seek affirmance of their dismissal in particular (*id.* 24-26). But Defendants cite “FDA”, a subagency within HHS, a total of 64 times in their brief. Defendants waive any argument for specific dismissal of the FDA from this case by relying on a declaration by an FDA official (Dr. Peter Marks, discussed *infra* Point II.A) that seeks dismissal of all the claims in order to avoid undermining credibility of the FDA. Defendants’ own arguments illustrate that Defendants HHS and FDA are necessary parties whose conduct is central to the improper mandate. Defendant Austin could not impose any vaccine mandate without relying on actions by Defendant FDA, and this lawsuit is a

challenge to the insufficiency of FDA's actions to justify Defendant Austin's mandate.

II. The Declarations Emphasized by Defendants' Brief Neither Prove their Factual Assertions, Nor Are Appropriate on Defendants' Motion to Dismiss.

Defendants repeatedly rely, in their appellate brief here, on factual assertions contained in multiple declarations they submitted in their Supplemental Appendix. (citing SA 109-83) But the procedural posture here is on Defendants' motion to dismiss. "In ruling on a motion to dismiss for failure to state a claim, 'all well-pleaded facts, as distinguished from conclusory allegations, must be taken as true,' and the court must liberally construe the pleadings and make all reasonable inferences in favor of the non-moving party." *Brokers' Choice of Am., Inc. v. NBC Universal, Inc.*, 861 F.3d 1081, 1105 (10th Cir. 2017) (quoting *Ruiz v. McDonnell*, 299 F.3d 1173, 1181 (10th Cir. 2002) (cleaned up)).

Defendants' declarations should be disregarded and do not support Defendants' arguments anyway.

A. Declaration of Peter Marks, M.D., Ph.D.

Defendants repeatedly cite to a 20-page declaration by Peter Marks, M.D., Ph.D., as Defendant FDA's Director of the Center for Biologics Evaluation and

Research (“CBER”). (Appellees Br. 2, 3, 5, 6, 15; SA109)⁶ His declaration is argumentative, self-serving and omits central factual information necessary for relevancy here. For example, he declares that “[a]n injunction based on the Court’s evaluation of the vaccine would call into question the data supporting FDA’s determination that Comirnaty is safe and effective.” (SA127 ¶ 28) This is the point at issue given that Dr. Marks’ statement is misplaced for an experimental Investigational New Drug (IND),⁷ and credible evidence exists which supports the conclusion that these inoculations are more harmful than beneficial and would therefore cause the revocation of the Emergency Use Authorization for failure to meet the applicable standard.⁸ Such a central issue demands hearings on evidence submitted for determination by the lower court.

An unlawful order by Defendant Austin cannot be used by the FDA to justify its credibility. That this might undermine or call into question the FDA’s own authority? Dr. Marks’ unsupported opinion that “vaccine development process” might be undermined if “courts are willing to disregard FDA’s rigorous

⁶ As in Appellees’ brief, the abbreviation “SA__” refers to Defendants’ Supplemental Appendix.

⁷ <https://pubmed.ncbi.nlm.nih.gov/12856461/> (viewed June 16, 2022).

⁸ <https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained> (“the known and potential benefits outweigh the known and potential risks,” viewed June 16, 2022); *see also* 21 U.S.C. § 360bbb–322 (“the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product”).

review process and remove products from the market on the basis of mere allegations” is again exactly the point of courts hearing such allegations; if not this Court, then who will check these unbridled powers? If the FDA were so certain in its rigorous review process, then what would be the point of an Emergency Use Authorization in the first instance and why have other similar EUA Investigational New Drugs, such as the Anthrax vaccine, been recalled more than 20 years ago? In fact, such an assertion would invalidate the Defendant FDA’s own “pause” (recall) of Johnson and Johnson’s Covid 19 vaccine in April of this year. Further, such speculation has no rightful bearing on the issue of the lack of lawfulness in Defendant Austin’s order. (*Id.*)

Dr. Marks declares, in conclusory fashion, that the licensed foreign Comirnaty vaccine and the domestic Pfizer vaccine “are legally distinct.” (SA 112 ¶ 9) That implies, as inferences must be taken in favor of Plaintiffs at this stage, that the “legally distinct” unlicensed vaccine cannot be substituted to satisfy a legal requirement that the vaccine be licensed. At any rate, Dr. Marks does not explain what the legal distinctions are, so at this stage of the litigation no inferences are to be drawn in Defendants’ favor on this point. The “legally distinct” unlicensed Pfizer vaccine not satisfying the applicable federal law that restricts such mandates to a licensed vaccine is at issue here.

Dr. Marks opines, again in conclusory fashion, that there are certain

differences that “do not impact safety or effectiveness” between the vaccines (*id.*) yet he fails to explain how he would personally know this. Likewise, if this were so, then one would expect such a standard to allow for reciprocity in licensing requirements among the European Union and the FDA, which does not exist. Other statements in Dr. Marks’ declaration imply there are significant differences in FDA enforcement policies between regulations for licensed vaccines, such as Comirnaty, and unlicensed (experimental) vaccines including the BioNTech Covid-19 vaccine currently mandated for service members. Perhaps such enforcement policies are exactly the reason no reciprocity exists. Dr. Marks declares, “Vaccine manufactured at sites that are not listed in the [Biologics License Applications] BLA *is not subject to the lot release requirement*,” which means there is no practical way to enforce or trace quality control problems. (SA115 ¶ 13, emphasis added) The “FDA is not taking enforcement with respect to vials that bear the EUA label,” Dr. Marks states without further explanation. This is just a subjective decision by the regulator, not a regulatory standard. (*Id.* ¶ 14) Without any investigation or enforcement, what assurances does any participant in this clinical trial have that any standard of safety is applied?

Meanwhile, Dr. Marks’ declaration contains a raft of non-sequiturs, such as explaining that Comirnaty was licensed based on merely “six months of safety data,” because “requesting six-months of *follow-up* safety data is not unique to

Covid-19 vaccines” (SA119 ¶ 18 n.6), which are experimental and unlicensed. The Covid-19 vaccine was not associated with a six-month follow-up study *after* licensure, but rather was prematurely licensed based on an inadequate six-month study beforehand.

More generally, Dr. Marks fails to explain what he has personal knowledge about versus what is mere hearsay by others at the FDA. The rules of evidence in the trial court should be rigorously applied before embracing such conclusory allegations. Dr. Marks, as an administrator in Washington, D.C., is not a treating physician nor a regulatory or scientific investigator with any opportunity to develop personal knowledge about quality control over the experimental substances service members are ordered to receive. Even if Dr. Marks’ hearsay statements were correct about the ingredients of the licensed Comirnaty and Pfizer vaccines being identical, their manufacturing, preservation, standards, tolerances, potency, ratios, types of messenger RNA proteins (and their sequencing) and quality control processes are not the same. The ingredients of refrigerated and unrefrigerated pork are identical, too, and the former is healthy while the latter is toxic. Recognition of that fundamental point about quality is entirely missing from Dr. Marks’ declaration, rendering it fatally defective.

B. Declaration of Colonel Tonya Rans.

Defendants repeatedly cite a 22-page declaration by Colonel Tonya Rans,

who since June 2017 has been the U.S. Air Force Chief of Immunization, Healthcare Division, Defense Health Agency – Public Health Directorate, located in Falls Church, Virginia. (SA129) As with Dr. Marks’ declaration, it is unclear from Colonel Rans’ declaration what is actually based on her personal knowledge and what is instead based on unreliable hearsay or speculation. Much of the declaration consists of citations to general statements posted by the CDC or FDA on their websites, which are not even at issue in this litigation, particularly at this early stage.

But one statement by Colonel Rans stands out with respect to a key issue here:

As of November, 2021, the DoD has received hundreds of thousands of BLA-manufactured, EUA-labeled vaccine doses *and is using them*.

(SA141 ¶ 18, emphasis added) Defendants thereby admit that they are primarily if not universally using the *EUA-labeled* (Pfizer) vaccine rather than the quality-checked, licensed-labeled Comirnaty vaccine. It is unlawful for Defendants to be requiring service members to receive the unlicensed Pfizer vaccine, yet this declaration used by Defendants implies they are doing precisely that. Colonel Rans does say “BLA-manufactured,” while its labeling states “for emergency use.” At this stage of the litigation, Plaintiffs’ allegations must be taken as true and inferences drawn in their favor, and discovery is needed if Defendants want to insist that they are using only the licensed vaccine as required by the order itself. In

their appellate brief, Defendants do not argue that the FDA licensed Comirnaty vaccine is the one being used to implement Defendant Austin's order and evidence exists to demonstrate it is not.⁹

Colonel Rans admits prior to use of a Covid-19 vaccine, "[t]he number of active duty service members who died from COVID-19 remained very low throughout the first year of the pandemic." (SA135 ¶ 10). Accordingly, the challenged order was not motivated by any genuine need within the military, but by a civilian political motivation which must comply with federal statutes. Dismissal of this challenge below was premature.

C. Declaration of Colonel Michele Soltis.

Also employed in Falls Church, Virginia, U.S. Army Colonel Michele Soltis provided a declaration as the Director of the Public Health Directorate for the Office of The Surgeon General/U.S. Army Medical Command (OTSG/USAMEDCOM).

Her declaration contains this admission:

mandatory vaccination against COVID-19 will only use vaccines that received full licensure from the U.S. Food and Drug Administration (FDA), in accordance with FDA-approved labeling and guidance.

(SA153 ¶ 4) In addition, her declaration states:

⁹ Witness testimony on a remand is expected to reveal that the FDA admits there is no FDA-approved Comirnaty released or used in the United States.

In more than 18 years of serving as an active duty preventive medicine physician, I have not experienced, nor do I have knowledge of a Commander involuntarily immunizing a Soldier.

(SA154 ¶ 6) Far from supporting Defendants’ appeal, these admissions reinforce the validity of Plaintiffs’ claims against Defendant Austin’s unusual order.

The Pfizer vaccine has not “received full licensure from” the FDA, and thus Plaintiffs have a cause of action against requiring them. They have not been approved by the FDA, but are permitted only under the Emergency Use Authorization. “FDA-approved labeling and guidance” cannot justify imposing an unlicensed vaccine not allowed by applicable federal law, 10 U.S.C. §1107 and 10 U.S.C. §1107a, as argued in Plaintiffs’ opening brief.

D. Declaration of Brigadier General Peter D. Huntley

A declaration by United States Marine Corps Brigadier General Peter D. Huntley is often cited by Defendants in their appellate brief as to the procedure of obtaining exemptions. (Appellees Br. 8, 9, 17, 18, 20) Huntley is the Director, Operations Division, Headquarters Marine Corps, as located in Washington, D.C. (SA164 ¶ 1) But the exemption procedure, burdensome and often meaningless, does not go to the issue of standing to challenge an unlawful order, because the certainty of ultimate rejection and burden of seeking an exemption itself is enough to establish standing.

Huntley’s declaration clarifies that although vaccines are not forcibly

administered, a service member who declines mandatory vaccination faces discharge: “Although refusal to receive the vaccine may subject a member to adverse administrative or disciplinary action, the vaccine will not be forcibly administered to any member who refuses.” (SA166 ¶ 4 n.2) In other words, no one is held down today to be injected, as was originally authorized, but service members are terminated if they decline injection. Brig. Gen. Huntley fully confirms that the Covid vaccination order is mandatory, and that compliance was required by November 28 and December 28, 2021. (SA166 ¶ 4 n.2)

Like Defendants’ appellees brief itself, the Huntley Declaration is ambiguous on the issue of whether the mandated vaccine must be licensed by the FDA, and instead refers only to military rules and regulations rather than the applicable federal law, 10 U.S.C. §1107 and 10 U.S.C. §1107a.

E. Declaration of Captain Darek Wilcox

Finally, Defendants rely on a mere 4-paragraph declaration by Captain Darek Wilcox, an employee of the U.S. Army who is the Commander of Alpha Company, 2-19th Infantry Battalion, 198th Infantry Brigade, located at Fort Benning, Georgia. In his declaration Captain Wilcox admits that:

On September 28, 2021, I again counseled [Plaintiff] SSG Robert in writing and ordered him to comply with the order to become fully vaccinated no later than December 15, 2021.

(SA182 ¶ 3)

That admission confirms Plaintiff Robert’s standing for this lawsuit. While Plaintiff Robert has since pursued an exemption as recounted by the remainder of Captain Wilcox’s declaration, Plaintiff Robert is under no obligation to do so and there is no assurance that an exemption would be permanently granted to him. He has been burdened by the vaccine mandate, and his right not to be unlawfully ordered to be vaccinated has been infringed. He has legal standing to object in court in addition to pursuing an exemption.

None of Defendants’ declarations mentions Plaintiff Mulvihill. Her independent standing as someone receiving merely a temporary exemption is sufficient to establish standing by Plaintiff Robert, too. *See, e.g., Alabama v. United States EPA*, 871 F.2d 1548, 1555 (11th Cir. 1989) (“Although an injury need only be ‘trifling,’ it must nevertheless be a real or threatened injury suffered *by one* of the plaintiffs.”) (citing *Schlesinger v. Reservists Committee to Stop the War*, 418 U.S. 208, 220-21 (1974), emphasis added). Plaintiff Mulvihill was granted a temporary exemption that will cease in effect by its own terms.

III. The Lack of Transparency about the Pfizer Vaccine Reinforces the Need for a Remand to Address Unresolved Issues.

Defendants rely heavily on Dr. Marks’ declaration stating that the contents of the unlicensed vaccine by Pfizer “are not medically distinct” from the foreign-manufactured licensed vaccine named Comirnaty. (Appellees Br. 15, citing but not quoting SA112 (Dkt. No. 37-11, Marks Decl. ¶ 9)). Many automobiles have the

same ingredients (components) yet there is an enormous distinction between a pick-up truck and a high performance race car. Published reports indicate that there are differences between the unlicensed Pfizer vaccine and the foreign-licensed Comirnaty one. The very website relied on by Defendants in their brief (Appellees Br. 6, discussed *infra*) does not support the sweeping “not medically distinct” assertion. Indeed, it seems likely that Dr. Marks lacked personal knowledge about the actual ingredients, manufacturing, ratios, potency, code or genetic sequence of the mRNA nucleotides and preservation requirements of these vaccines, and was simply relying on what he had been told. The mRNA is the instruction component that causes the user to produce the referenced synthetic Spike Proteins and there are millions of potential variations in the code or sequence of these messengers, yet nowhere does Pfizer or Moderna disclose the sequence of those instruction proteins, while declarants assure themselves and the Court that general knowledge, hearsay and web page information are sufficient to be certain of the intended consequences.

Moreover, the phrase “not medically distinct” is too vague to be useful in a court of law. A LEXIS search shows use of this phrase in only three non-germane court decisions, one of which addressed the unsuccessful use of this phrase by Pfizer on an unrelated motion to dismiss. *Stube v. Pfizer Inc.*, 446 F. Supp. 3d 424, 439 (W.D. Ark. 2020) (“[T]he Court declines to consider any extrinsic documents

or weigh evidence at this time. Defendant may reassert this argument at the summary judgment stage.”).

The Pfizer vaccine is not licensed for reasons known only to Defendants, which they decline to disclose to the public or explain in their brief. In another proceeding, a public interest group had to sue Defendant FDA simply to obtain documents related to the Pfizer Covid-19 vaccine pursuant to a declined Freedom of Information Act (FOIA) request, whereby a federal judge ruled against Pfizer by ordering a staged release of required documents that will not complete until later this year. *Pub. Health & Med. Professionals v. FDA*, No. 4:21-cv-1058-P, 2022 U.S. Dist. LEXIS 5621, *1 (N.D. Tex. Jan. 6, 2022) (ordering partial releases every month of “[a]ll data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System” by the FDA). Before the federal judge ruled against it, the FDA sought to produce only “500 pages per month which, based on its calculated number of pages, would mean it would only complete its production obligation in nearly 55 years – the year 2076.”¹⁰ Initial production of previously undisclosed documents by Defendant FDA pursuant to that court order demonstrates, *inter alia*, that women suffer an eighty-two percent (82%) increase

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<https://fingfx.thomsonreuters.com/gfx/legaldocs/egvbkaeggpq/vaccine%20foia%20status%20report.pdf> (viewed June 11, 2022).

spontaneous abortions after taking a single dose of Pfizer’s Covid 19 vaccine.¹¹

The “not medically distinct” argument by Defendants on appeal is not even supported by an FDA-controlled website on which they rely in their brief.

(Appellees Br. 6) That FDA website instead states that the Comirnaty licensed vaccine “can be used interchangeably” with the Pfizer EUA-vaccine as follows:

How is Comirnaty (COVID-19 Vaccine, mRNA) related to the Pfizer-BioNTech COVID-19 Vaccine authorized for emergency use?

The FDA-approved Comirnaty (COVID-19 Vaccine, mRNA) and the FDA-emergency use authorized Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older, *when prepared according to their respective instructions for use*, can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. Therefore, providers can use doses distributed under EUA to administer the vaccination series as if the doses were the licensed vaccine. For purposes of administration, doses distributed under the EUA are interchangeable with the licensed doses. The Vaccine Information Fact Sheet for Recipients and Caregivers provides additional information about both the approved and authorized vaccines.

Can Comirnaty and the Pfizer-BioNTech COVID-19 Vaccine be used interchangeably?

The FDA-approved Comirnaty (COVID-19 Vaccine, mRNA) and the two EUA-authorized formulations of the Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older *when prepared according to their respective instructions for use*, can be used interchangeably.

The formulation of the Pfizer-BioNTech COVID-19 Vaccine authorized for use in children 5 through 11 years of age differs from the formulations authorized for older individuals. The Pfizer-BioNTech COVID-19 Vaccine

¹¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8402695/> &
<https://uncoverdc.com/2021/12/13/first-cache-of-secret-pfizer-docs-show-fda-knew-of-death-risk/> (viewed June 11, 2022).

authorized for use in children 5 through 11 years of age ***should not be used interchangeably with Comirnaty.***

Q&A for Comirnaty (COVID-19 Vaccine mRNA) (emphasis added).¹² Apparently those “respective instructions” are actually different for the two vaccines, or else the “respective” would not be used in FDA’s explanation above.

Defendant FDA’s foregoing explanation on its own website including its Purplebook interchangeability reference database states that **no drug** whatsoever is interchangeable with Comirnaty, which demands investigation as an admission.¹³ The licensed and unlicensed vaccines are differently manufactured products, and something akin to a bait-and-switch may be going on that requires development of a factual record below to flesh out and adjudicate. Defendants nonetheless claim their authority to impose the Pfizer vaccine in large quantities based on BLA licensure of a Comirnaty vaccine that is unavailable or perhaps available only in small quantities. Why? Defendants have not yet explained any reasons for a bait-and-switch, and federal law prohibits it with respect to compelling vaccination of service members. Only a licensed vaccine (Comirnaty) may be used, yet it is not.

As recently explained in a published report based on Pfizer’s own website:

¹² <https://www.fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna> (viewed June 11, 2022).

¹³ <https://purplebooksearch.fda.gov/results?query=COVID-19%20Vaccine,%20mRNA&title=Comirnaty> (viewed June 16, 2022).

Just last week, however, Pfizer admitted to the fact that Comirnaty will never actually be manufactured, let alone dispensed into any arms.

“Pfizer received initial FDA BLA license on 8/23/2021 for its COVID-19 vaccine for use in individuals 16 and older (COMIRNATY),” the company says. “At that time, the FDA published a BLA package insert that included the approved new COVID-19 vaccine tradename COMIRNATY and listed 2 new NDCs (0069-1000-03, 0069-1000-02) and images of labels with the new tradename.”

“These NDCs will not be manufactured. Only NDCs for the subsequently BLA approved tris-sucrose formulation will be produced.”

The difference between the originally approved formulation and the tris-sucrose formulation is that the latter, according to Pfizer, can be stored for a much longer period of time outside of an ultra-cold freezer. ...

In order to continue requiring American servicemen to take Pfizer’s mRNA injections, the federal government must at least order some Comirnaty vials, even if they never actually arrive.

Ethan Huff, “Pfizer quietly admits it will NEVER manufacture FDA-approved Comirnaty injection for covid” (June 9, 2022).¹⁴ According to this recently published article, the ingredients are not the same between the licensed Comirnaty vaccine and the unlicensed Pfizer vaccine that is being imposed. Dr. Marks’ declaration was dated November 22, 2021, and even if it were true then it is implausible that nothing has changed more than the six months since; manufacturers can change ingredients during a phase III clinical trial, and so on. More factual development is needed on remand.

¹⁴ <https://www.naturalnews.com/2022-06-09-pfizer-will-never-manufacture-comirnaty-covid-vaccine.html> (viewed June 11, 2022).

IV. Defendants Address VAERS, Yet Fail to Address the Irreversible, Life-Changing Impact of the Vaccine Mandated.

To their credit, Defendants address in their Supplemental Appendix the data in the Vaccine Adverse Event Reporting System (VAERS), and so should this Court. (SA 122-23, 125-26, 141) That is a government-maintained database of adverse events reported after receipt of a Covid-19 vaccine, under threat of severe punishment if reported fraudulently. Defendants do not doubt the accuracy or significance of the VAERS data, and even address VAERS in declarations made under oath. “VAERS reports provide a very important tool in monitoring vaccine safety,” the sworn declaration by Defendants’ Dr. Marks states, while also cautioning against reliance upon it alone. (SA122 ¶ 23).

Dr. Marks mentions VAERS 14 times in his declaration, on which Defendants relied below and again on appeal here. Dr. Marks explains, “Although VAERS is not designed to assess causality, FDA and CDC actively monitor VAERS reports and engage in additional studies or investigations if VAERS monitoring suggests that a vaccine might be causing a health problem.” (SA123 ¶23) Dr. Marks himself readily admits to harm caused by Covid vaccination, which is notably absent from discussion in Defendants’ brief:

Reporting rates for medical chart-confirmed myocarditis/pericarditis in VAERS have been higher among males under 40 years of age than among females and older males and have been highest in males 12-17 years of age (65 cases per million doses administered as per CDC communication on

August 20, 2021), particularly following the second dose, and onset of symptoms within 7 days following vaccination.

(SA125 ¶ 26)

Is this why the Pfizer vaccine is being used despite being unlicensed?

Defendants fail to explain and neglect to mention their internal concerns over exceedingly dangerous heart inflammation that they are reportedly tracking.¹⁵

Defendants fail to mention that VAERS currently shows a total of **1,295,329** reports of adverse events from all age groups following COVID-19 vaccines, including **28,714 deaths**, between Dec. 14, 2020, and June 3, 2022.¹⁶ Remand is necessary for factual clarification on this and similar points.

CONCLUSION

For the reasons set forth in Plaintiffs' opening brief and this reply brief, this Court should reverse the decision below, order an immediate injunction and remand for further proceedings.

¹⁵ <https://www.military.com/daily-news/2021/04/26/pentagon-tracking-14-cases-of-heart-inflammation-troops-after-covid-19-shots.html> (viewed June 16, 2022)

¹⁶ <https://vaersanalysis.info/2022/06/10/vaers-summary-for-covid-19-vaccines-through-6-3-2022/> (viewed June 16, 2022). A Harvard study reports that 1% of actual fatalities and injuries may be reported in VAERS: <https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf> (viewed June 16, 2022).

Dated: June 17, 2022

Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE

Andrew L. Schlafly, counsel for Appellants, hereby certifies that:

1. This brief complies with the type/volume limitation contained in Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure because this brief contains 6,500 words, excluding the items identified in Rule 32(f).
2. This brief complies with the typeface requirements in Fed. R. App. P. 32(a)(5) and the type-style requirements in Fed. R. App. P. 32(a)(6) because the brief has been prepared in a proportionally spaced typeface and, except for emphases, in a plain, roman style using Times New Roman in 14 point.

Dated: June 17, 2022

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