UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

NAVY SEAL 1, *et al.*, for themselves and all others similarly situated,	)	
Plaintiffs,	)	
v.	)	No. 8:21-cv-2429-SDM-TGW
JOSEPH R. BIDEN, in his official capacity as President of the United States, *et al.*,	)	
Defendants.	)	

PLAINTIFFS' REPLY IN SUPPORT OF MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

LEGAL ARGUMENT

I. PLAINTIFFS FACE IMMEDIATE, IRREPARABLE HARM ABSENT INJUNCTIVE RELIEF.

Defendants contend that Plaintiffs face no irreparable harm because post-disciplinary measures can correct any injuries they suffer. (Dkt. 23, Opposition, at 30–31.) But, while generally true in the employment context, Defendants' contention ignores the seminal First Amendment questions before the Court. And there can be no dispute that Defendants' substantial burden on Plaintiffs' religious exercise constitutes irreparable harm as a matter of law. As the Supreme Court has held time and again, Plaintiffs "are irreparably harmed by the loss of free exercise rights for even minimal periods of time." *Tandon v. Newsom*, 141 S. Ct. 1294, 1297 (2021). "There can be no question that the challenged [mandate], if enforced, will cause irreparable harm." *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 67 (2020). Contrary to

Defendants' assertions, Plaintiffs' constitutional injuries in the instant matter are presumed to be irreparable harm. *See, e.g.*, *Ne. Fla. Chap. of Ass'n of Gen. Contractors v. City of Jacksonville*, 896 F.2d 1283, 1285 (11th Cir. 1990). Indeed, suffering consequences for failure to violate their sincerely held religious belief represents "direct penalization" of First Amendment rights, which "constitutes irreparable injury." *Cate v. Oldham*, 707 F.2d 1176, 1188 (11th Cir. 1983).

Defendants' false reduction, that Plaintiffs face only the loss of a job and the potential discharge of their commissions rather than the loss of First Amendment rights, must be rejected. "The harm [Plaintiffs] would suffer is not only, as [Defendants] argue[], the loss of [their] job[s] *per se,* but also the penalty for exercising [their First Amendment] rights. The chilling effect of that penalty cannot be adequately redressed after the fact." *Romero Feliciano v. Torres Gaztambide*, 836 F.2d 1, 4 (1st Cir. 1987). As the "chief function" of a preliminary injunction is "to preserve the status quo until the merits of the controversy can be fully and fairly adjudicated," *Robinson v. Attorney General*, 957 F.3d 1171, 1178 (11th Cir. 2020), Defendants' contentions that lost First Amendment freedoms can be made whole after the status quo has been altered is incorrect as a matter of law.

The testimony before this Court demonstrates the immediate and irreparable harm that Plaintiffs and other members of the Class are facing right now. As the sworn testimony of Lieutenant Colonel, United States Marine Corp, demonstrates, **Defendants are already taking action against military servicemembers for failure to**

violate their sincerely held religious convictions. (**EXHIBIT A**, Declaration of Lieutenant Colonel, USMC, ¶¶8-9 (testifying that Lieutenant Colonel's request for religious accommodation was denied and that "**based upon the command's presumption that my appeal would be denied, I was preemptively removed from my Executive Office leadership position on 1 November 2021** (emphasis original)).) In order to comply with his sincerely held religious convictions, Lieutenant Colonel requested that the USMC permit him to accept early retirement, but his request for even that consideration – a benefit to which his nearly 19 years of service entitles him – has been stalled and denied. (Ex. A, Lieutenant Colonel Decl. ¶11.) Lieutenant Colonel faces termination and disciplinary measures, even though he has sought other alternative mechanisms "as a means of avoiding the conflict between the COVID shot order and [his] faith." (*Id.*, ¶13) And, even that imminently reasonable request has not been approved.

Federal contractors subject to Defendants mandates are likewise suffering irreparable harm that cannot wait for final resolution of Defendants' purported administrative process. As Federal Contractor Employee witness puts it, **the process for even obtaining a religious exemption is a sham because every one of the requests has been denied by his employer**. (**EXHIBIT B**, Declaration of Federal Contractor Employee, ¶36.) Federal Employee Contractor was denied a religious exemption **explicitly because of Defendant Biden's executive order mandating that contractors ensure their employees are vaccinated**. (Ex. B, Federal Contractor Employee Decl.

¶25.) Thus, Defendants' contentions that Plaintiffs need only let the process play out is belied by the facts before this Court. There is no process to play out, Plaintiffs and the members of the Class are merely waiting for the consequence of termination to occur. The testimony of federal contractor Field Test Technician similarly bears this out. (**EXHIBIT C**, Declaration of Federal Contractor Employee Field Test Technician, ¶20.) Indeed, the blanket denial of religious exemptions mirrored the exact language denying other federal contractors' denials. (*Compare id. with* Ex. B at 25.) As is readily apparent, federal contractors subject to Defendant Biden's mandate are plainly denying all requested religious exemptions and failing to provide any process for religious accommodations.

Moreover, Defendants' contentions that Plaintiffs and other members of the Class should just allow the process to play out is completely undermined by the situations faced by numerous federal contractors. (*See* **EXHIBIT D**, Declaration of Network Services Level 3 Federal Contractor Employee.) Not only has Network Services Level 3 witness been denied his requested religious accommodation, **he has been informed that – absent intervention by this Court – his employment will terminate as of Monday, November 15 at 2:00 p.m**. (Ex. D ¶9.)

Plaintiffs and other members of the Class are also being subjected to unconscionable actions and pressure to violate their sincerely held religious beliefs by accepting a COVID-19 vaccine. (*See* **EXHIBIT E**, Declaration of Air Force Civilian Registered Nurse). On October 21, Air Force Civilian Registered Nurse was subjected,

along with her colleagues, to an active shooter drill wherein the scenario was based upon an active shooter being an individual "forced to take a Covid injection against their will," who "became violent," and "enter[ed] the clinic shooting and killing many staff." (Ex. E ¶23.) Subjecting individuals to exercises portraying them as unhinged and dangerous unquestionably represents substantial pressure on the sincerely held religious beliefs of those holding religious objections to COVID-19 vaccines. And, the Free Exercise Clause was intended to prevent this precise type of coercion. *See, e.g.*, *Sch. Dist. of Abington Tp. v. Schempp*, 374 U.S. 203, 222 (1963) (noting that the Free Exercise Clause was intended to protect "the right of every person to freely choose his or her own course . . . **free from compulsion from the state**." (emphasis added)). Indeed, "the Free Exercise Clause protects against **indirect coercion** or penalties on the free exercise of religion." *Trinity Lutheran Church of Columbia, Inc. v. Comer*, 137 S. Ct. 2012, 2022 (2017) (emphasis added).

II. DEFENDANTS' JURISDICTIONAL ARGUMENTS ARE ERRONEOUS ATTEMPTS TO EVADE SCRUTINY OF THEIR UNCONSTITUTIONAL MANDATES.

A. Defendants' Jurisdictional Contentions Fail to Recognize That Facial Challenges to Military Regulations Are Permissible and Justiciable Under the First Amendment.

Defendants attempt to escape this Court's review by claiming that Plaintiffs are not permitted to bring as-applied challenges under *Speigner v. Alexander*, 248 F.3d 1292 (11th Cir. 2001). (Opp'n 13–16.) *Speigner*, however, recognized its "holding in no way bars facial challenges to military regulations." 248 F.3d at 1298. The reason is simple:

Plaintiffs and other military members did not forego their constitutional rights upon enlistment or commission. *See, e.g.*, *Chappell v. Wallace*, 462 U.S. 296, 304 (1983) ("This Court has never held, nor do we now hold, that military personnel are barred from all redress in civilian courts for constitutional wrongs suffered in the course of military service."). *Speigner* specifically recognized a host of Supreme Court precedents permitting constitutional challenges to military regulations, such as the COVID-19 vaccine mandates at issue in the instant litigation. *See* 248 F.3d at 1297–98 (collecting cases); *see also Goldman v. Weinberger*, 475 U.S. 503, 507 1986) (considering a First Amendment challenge to dress code violations and holding the distinctives of military service "do not, of course, render entirely nugatory in the military context the guarantees of the First Amendment"); *Brown v. Glines*, 444 U.S. 348 (1980) (considering First Amendment facial challenge to speech restrictions on members United States Air Force). Defendants' efforts to evade this Court's review of their unconstitutional mandates fails.

1. Plaintiffs' First Amendment challenges need not wait for the Government's unlawful application.

Finding no refuge in their assertion of nonjusticiability, Defendants retreat to the equally unavailing position that Plaintiffs' facial challenges are not ripe because they have not exhausted administrative remedies. (Opp'n 14.) Defendants fail to recognize, however, that Plaintiffs have brought a First Amendment challenge to their unconstitutional mandates. (V. Compl. ¶¶ 194–211.) As the Supreme Court has held, "we have not required that all of those subject to overbroad regulations risk

prosecution to test their rights." *Dombrowski v. Pfister* 380 U.S. 479, 486 (1965). As the Eleventh Circuit, too, has held: "We will not force a plaintiff to choose between intentionally violating a law to gain access to judicial review and foregoing what he or she believes to be constitutionally protected activity in order to avoid criminal prosecution." *White's Place, Inc. v. Glover*, 222 F.3d 1327, 1329 (11th Cir. 2000). Put simply, "one does not have to await the consummation of threatened injury to obtain preventive relief. If the injury is certainly impending, that is enough." *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979) (cleaned up); *see also Steffel v. Thompson*, 415 U.S. 452, 459 (1974) ("[I]t is not necessary that petitioner first expose himself to actual arrest or prosecution to be entitled to challenge a statute that he claims deters the exercise of his constitutional rights."); *ACLU v. The Florida Bar*, 999 F.2d 1486, 1492 (11th Cir. 1993) ("When a plaintiff has stated that he intends to engage in a specific course of conduct 'arguably affected with a constitutional interest,' however, he does not have to expose himself to enforcement to be able to challenge the law." (quoting *Babbitt*, 442 U.S. at 298)).

"If the rule were otherwise, the contours of regulation would have to be hammered out case by case—and tested only by those hardy enough to risk criminal prosecution to determine the proper scope of the regulation." *Drombrowski*, 380 U.S. at 486. Under that scenario, the First Amendment—"of transcendent value to all society, and not merely those exercising their rights—might be the loser." *Id.*

The Government has no answer to the above. Ignoring First Amendment precedent, Defendants claim that Plaintiffs have not been subjected to any

consequences of the COVID-19 vaccine mandates, so there is no claim *yet*. (Opp'n 14.) But pre-enforcement challenges are permissible in the First Amendment context.

> We are not troubled by the pre-enforcement nature of this suit. The State has not suggested that the newly enacted law will not be enforced, and we see no reason to assume otherwise. We conclude that plaintiffs have alleged an actual and well-founded fear that the law will be enforced against them. Further, the alleged danger of this statute is, in large measure, one of self-censorship; a harm that can be realized even without an actual prosecution.

Virginia v. Am. Booksellers Ass'n, Inc., 484 U.S. 383, 393 (1988); *see also Hallandale Prof'l Fire Fighters Local 2238 v. City of Hallandale*, 922 F.2d 756, 760 (11th Cir. 1993) (recognizing the availability of pre-enforcement challenges to government restrictions on First Amendment activity); *Int'l Soc'y for Krishna Consciousness of Atlanta v. Eaves*, 601 F.2d 809, 817 (5th Cir. 1979) (same).[1]

Defendants' contention that Plaintiffs must await actual enforcement, which for Plaintiffs includes the threat of dishonorable discharge (V. Compl. ¶ 134), is incorrect. The threat of Defendants' enforcement of the COVID-19 Vaccine Mandate is "latent in the existence of the [order]," *Majors v. Abell*, 317 F.3d 719, 721 (7th Cir. 2003), and thus confers standing on Plaintiffs to challenge it before it is enforced against them.

2. Plaintiffs' RFRA claims need not wait for the Government's unlawful application.

Plaintiffs may also seek injunctive relief on their RFRA claims. Numerous courts have found that RFRA challenges are ripe for review prior to the government's

[1] Fifth Circuit cases prior to October 1, 1981 are binding in the Eleventh Circuit. *Bonner v. City of Prichard*, 661 F.2d 1206, 1207 (11th Cir. 1981).

enforcement. *See, e.g.*, *Hobby Lobby Stores, Inc. v. Sebelius*, 723 F.3d 1114, 1126 (10th Cir. 2013) (en banc) (holding plaintiffs had standing to bring RFRA challenge to government restrictions before deadline for compliance); *Adam v. Barr*, No. 18-cv-2106(AJN), 2019 WL 1426991, at *3 (S.D.N.Y. Mar. 29, 2019) (pre-enforcement challenges to government regulations are permissible under RFRA); *Oklevueha Native American Church of Hawaii, Inc. v. Holder*, No. 09–00336 SOM/BMK, 2012 WL 6738532, at *4 (D. Hi. Dec. 31, 2012) (allowing pre-enforcement challenge under RFRA).

Plaintiffs have alleged that the various COVID-19 Vaccine Mandates against the United States Military Servicemembers, Federal Employees, and Federal Contractors violate RFRA by substantially burdening the exercise of their religious beliefs and that the mandates fail strict scrutiny. (V. Compl. ¶¶ 212–234.) As the en banc Tenth Circuit stated, Plaintiffs "face an imminent [injury], traceable to the requirement." *Hobby Lobby*, 723 F.3d at 1126. Imminent threat of injury is enough for a pre-enforcement challenge to the mandates.

3. Even in the military context, Plaintiffs are not required to exhaust administrative remedies to assert First Amendment and RFRA claims in this Court.

In addition to being settled law outside of the military context, Defendants' contention (Opp'n 28) that Military Servicemembers must exhaust administrative remedies before bringing their RFRA and First Amendment claims in this Court is incorrect. A military plaintiff need not exhaust administrative remedies in order to bring a First Amendment or RFRA challenge to a military policy. *See, e.g.*, *Adair v.*

England, 183 F. Supp. 2d 31, 55 (D.D.C. 2002) (military plaintiff need not exhaust administrative remedies to bring First Amendment Free Exercise challenge to military regulations); *Singh v. Carter*, 168 F. Supp. 3d 216, 226 (D.D.C. 2016) (military plaintiff not required to exhaust administrative remedies to bring RFRA challenge to military policies substantially burdening his religious exercise). As *Singh* noted, "RFRA certainly provides no textual support for the defendants' position that the plaintiff is required to exhaust administrative remedies in a court-martial proceeding before bringing his constitutional and RFRA claims before this Court." 168 F. Supp. 3d at 226; *see also Oklevueha Native Am. Church of Hawaii, Inc. v. Holder*, 676 F.3d 829, 838 (9th Cir. 2012) ("We decline, however, to read an exhaustion requirement into RFRA where the statute contains no such condition and the Supreme Court has not imposed one.").

"Resolving a claim founded solely upon a constitutional right is singularly suited to a judicial forum and clearly inappropriate to an administrative board." *Downey v. Warner*, 481 F.2d 642, 643 (9th Cir. 1973). In *Downey*, the Ninth Circuit held that a military servicemember need not exhaust administrative remedies to bring a constitutional challenge. *Id.* There, as here (V. Compl. ¶¶ 194–234), Plaintiffs' "complaint rests solely upon the resolution of her constitutional claim." 481 F.2d at 643. Accordingly, the plaintiff "was not barred from the district court through her failure to exhaust administrative remedies." *Id.*

In *Dilley v. Alexander*, the court explained why military plaintiffs may bring their claims directly in federal court. 603 F.2d 914, 920 (D.C. Cir. 1979). The court reasoned that deference to the military is

> wholly inappropriate, however, when a case presents an issue that is amenable to judicial resolution. Specifically, courts have shown no hesitation to review cases in which a violation of the Constitution, statutes, or regulations is alleged. It is a basic tenet of our legal system that a government agency is not at liberty to ignore its own laws and that agency action in contravention of applicable statutes and regulations is unlawful. The military departments enjoy no immunity from this proscription.

Id. (citations omitted).

As the district court said in *Adair*, Defendants' contention that Plaintiffs must exhaust all administrative remedies before bringing a First Amendment or RFRA challenge in federal court "falls flat." 183 F. Supp. 2d at 55.

B. Defendants' Contentions That No Plaintiff Has Standing to Challenge the Executive Order Mandating COVID-19 Vaccines for Federal Employees Is Incorrect.

Defendants' claim (Opp'n 17) that no Plaintiff has standing to challenge the Executive Order mandate that federal employees receive a COVID-19 vaccine is incorrect. Plaintiffs have made class allegations concerning the unconstitutionality and unlawfulness of Defendants' Executive Orders as pertaining to "military servicemembers, civilian federal employees, and civilian federal contractors." (V. Compl. ¶ 157.) Plaintiffs allege that the other members of the requested class "are all members of the United States Armed Forces, civilian federal employees, or civilian federal contractors." (V. Compl. ¶ 158.) Thus, Plaintiffs, on behalf of themselves and the

other federal employees in the Class, have standing to challenge Defendants' COVID-19 vaccine mandates as to federal employees.

C. This Court Has Jurisdiction Under the First Amendment and RFRA to Review the Constitutionality and Enjoin Enforcement of Defendant Biden's Orders.

The Government contends that this Court cannot issue an injunction against the President in his official capacity. (Opp'n 17.) But Defendants' argument proves too little. As the Supreme Court noted in *Franklin v. Massachusetts*, although ordinary injunctive relief is inappropriate against the President, "the President's actions may still be reviewed for constitutionality." 505 U.S. 788, 801 (1992). And the Supreme Court has upheld an injunction against enforcement, by a subordinate official, of an executive order deemed an unconstitutional abuse of executive power. *See Youngstown Sheet Tube Co. v. Sawyer*, 343 U.S. 579 (1952).

Moreover, even if the Supreme Court had not recognized that presidential actions may be reviewed for constitutional infirmity, which it has, RFRA explicitly provides that Plaintiffs may seek injunctive relief against Defendant Biden. *See* 42 U.S.C. §2000bb-2(1) ("the term 'government' includes a *branch*, department, agency, instrumentality, and *official* (or other persons acting under color of law) of the United States" (emphasis added)). *See also Tanzin v. Tanvir*, 141 S. Ct. 486 (2020) (holding that RFRA's definition of "government" includes "all government officials"); *id.* ("A 'government,' under RFRA, extends beyond the term's plain meaning to include officials. And the term 'official' does not refer solely to an office, but rather to the actual person 'who is invested with an office.'"). And, as Congress's explicit findings

make clear, the "purpose" of RFRA was "to guarantee its application in all cases where free exercise of religion is substantially burdened." 42 U.S.C. §2000bb(b)(1).

III. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS OF THEIR FIRST AMENDMENT AND RFRA CLAIMS BECAUSE DEFENDANTS' UNLAWFUL REQUIREMENT THAT PLAINTIFFS ACCEPT OR RECEIVE A COVID-19 VACCINE SUBSTANTIALLY BURDENS THEIR RELIGIOUS EXERCISE AND FAILS STRICT SCRUTINY.

A. Plaintiffs Have Raised a Facial Challenge to Defendants' Mandate.

Defendants wrongfully assert that Plaintiffs have not raised a facial challenge to Defendants' COVID-19 vaccine mandates. (Opp'n 27.) On the contrary, Plaintiffs allege that they are bringing a facial challenge to Defendants' mandates at least 20 times in Plaintiffs' Verified Complaint. (V. Compl. ¶¶ 198–207, 222–228, 230, 233.) Plaintiffs allege, "The Federal COVID-19 Vaccine Mandate, on its face and as applied, targets Plaintiffs' sincerely held religious beliefs by prohibiting Plaintiffs from seeking and receiving exemption and accommodation for their sincerely held religious beliefs." (V. Compl. ¶ 222.) Moreover, Plaintiffs allege, "The Federal COVID-19 Vaccine Mandate, on its face and as applied, constitutes a substantial burden on Plaintiffs' exercise of their sincerely held religious beliefs." (V. Compl. ¶ 228.)

B. Plaintiffs' Facial Challenges to Defendants' COVID-19 Vaccine Mandate on Military Plaintiffs Are Likely to Succeed Under RFRA.

Defendants erroneously contend that Military Plaintiffs are not likely to succeed on the merits of their RFRA claims because this Court should wait until adverse action has been taken against them. (Opp'n 27–28.) But Plaintiffs are not required to exhaust administrative remedies before bringing their RFRA claims for relief in this Court.

Forcing Plaintiffs to live under the daily threat of court martial and/or termination is itself a substantial burden on religious exercise. The DOD mandate was issued August 24, and the mandate for civilian federal employees and contractors was announced on September 9—more than two months ago. Yet not one religious accommodation has been granted. Military Servicemembers have instead been threatened with discipline and told there will be no religious exemptions. And civilian contractors have received no guidance as to the procedures for submitting a religious exemption/accommodation request.

1. RFRA plainly protects Military Plaintiffs' religious exercise.

RFRA applies to the United States Armed Forces. RFRA defines "government" to include "a branch, department, agency, instrumentality, and official (or other person acting under color of law) of the United States." 42 U.S.C. §2000bb-2(1). As all Defendants represent branches, departments, agencies, or officials of the United States, Plaintiffs claims against them are justiciable under RFRA.

The explicit text of the statute is recognized by numerous federal courts that have considered RFRA challenges from military members. *See, e.g.*, *Singh v. McHugh*, 185 F. Supp. 3d 201, 218 (D.D.C. 2016) ("on its face, the statute plainly applies to the U.S. Army. Defendants acknowledge that Congress specifically intended RFRA to apply to the military."); *Singh v. Carter*, 168 F. Supp. 3d 216, 226 (2016) ("Congress nowhere inserted any exception for the U.S. Armed Forces from RFRA's application or any exhaustion requirement"); *Rigdon v. Perry*, 962 F. Supp. 150 (D.D.C. 1997)

(applying RFRA against a military regulation restricting the speech of certain military chaplains).

2. Plaintiffs need not await administrative exhaustion or rejection of their requested exemptions to bring claims in this Court.

Plaintiffs need not await administrative adjudication before bringing claims in this Court. (*See supra* Section II.A.)

3. Forcing Plaintiffs to choose between their sincere religious beliefs and compliance with Defendants' Mandates is a substantial burden on religious exercise.

a. Defendants' attempts to probe the truth of Plaintiffs' religious beliefs is impermissible as a matter of law.

Defendants contend that Plaintiffs cannot show a substantial burden on their religious exercise because they have proceeded in this case under pseudonyms, and thus Defendants cannot prod the sincerity of Plaintiffs' religious beliefs. (Opp'n 28.) This is wrong. First, Defendants' knowledge of Plaintiffs' identities is irrelevant to the inquiry of whether these Plaintiffs have alleged violation of their sincerely held religious beliefs.[2] Defendants' contention "dodges the question that RFRA presents,"

[2] Plaintiffs' identity is not critical to the determinations of whether they have alleged in the Verified Complaint and asserted to Defendants their sincerely held religious beliefs. In fact, as many courts have recognized, plaintiffs are often permitted to proceed using a pseudonym when the underlying claims involve religious beliefs. "[R]eligion is perhaps the quintessentially private matter." *Doe v. Stegall*, 653 F.2d 180, 186 (5th Cir. 1981); *see also, e.g.*, *Doe v. Porter*, 370 F.3d 558, 560 (6th Cir. 2004) (affirming district court's order allowing pseudonymous plaintiffs where the "suit—challenging a government activity—forces Plaintiffs to reveal their beliefs about a particularly sensitive topic that could subject them to considerable harassment"); *Doe v. Franklin Bank, SSB*, No. A-08-CA-293 LY, 2008 WL 11334179, * (W.D. Tex. Sept. 3, 2008) (same); *Doe v. Barrow Cnty.*, 219 F.R.D. 189, 193 (N.D. Ga. 2003) (same); *id.* (noting involvement of "religious beliefs" and "the proper interaction

namely, "whether the [government's] mandate imposes a substantial burden on the ability of the objecting parties to conduct business in accordance with *their religious beliefs*." *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 724 (2014). Contrary to Defendants' contentions, "it is not for us to say that their religious beliefs are mistaken or insubstantial." *Id.* at 725. Defendants' understanding of RFRA claims would turn the courts into roving seminary professors and adjudicators of religious doctrine. Plaintiffs have plainly alleged sincerely held religious beliefs against Defendants' COVID-19 vaccine mandates. (V. Compl. ¶¶ 58-–88.) Plaintiffs have plainly alleged that they requested exemptions and accommodations from the COVID-19 vaccine mandates because of their sincerely held religious beliefs. (V. Compl. ¶¶ 17–41, 98–115.) Those allegations, which have been verified by each of Plaintiffs in this action, are sufficient to demonstrate Plaintiffs' sincerely held religious beliefs.

The resolution of the question of whether Plaintiffs' have sincerely held religious beliefs "is not to turn upon a judicial perception of the particular belief or practice in question; religious beliefs need not be acceptable, logical, consistent, or comprehensible in order to merit First Amendment protection." *Thomas v. Rev. Bd. of Ind. Empl. Sec. Div.*, 450 U.S. 707, (1981). As the Supreme Court has held numerous times, "[i]t is not within the judicial ken to question the centrality of particular beliefs or practices to a faith, or the validity of particular litigant interpretations of those creeds." *Hernandez v. Comm'r*, 490 U.S. 680, 699 (1989).

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between government and religion" are sufficiently private to warrant a plaintiff's proceeding anonymously). And, Plaintiffs will demonstrate this to the Court in their forthcoming Motion.

Contrary to this established precedent, however, Defendants raise the novel contention that this Court cannot make a decision before Plaintiffs identify themselves and provide proof of their religious beliefs that have already been asserted. (Opp'n 28.) But, this would turn the Court into the arbiter of religious doctrine. That is plainly forbidden. Since time immemorial,

> Men may believe what they cannot prove. They may not be put to the proof of their religious doctrines or beliefs. Religious experiences which are as real as life to some may be incomprehensible to others. Yet, the fact that they may be beyond the ken of mortals does not mean they can be made suspect before the law.

United States v. Ballard, 322 U.S. 78, 87 (1944). Defendants' attempts to suggest relief cannot be had without a deep dive into the veracity of Plaintiffs' religious beliefs is plainly incorrect. What matters, for purposes of RFRA, is that Plaintiffs "sincerely believe that [compliance with the mandate] lies on the forbidden side of the line," *Hobby Lobby*, 573 U.S. at 725, and this Court's "narrow function" is to determine whether Plaintiffs' line represents "an honest conviction [and] there is no dispute that it does." *Id.*

b. Defendants' mandates impose a substantial burden on Plaintiffs' religious beliefs.

Defendants' only response to Plaintiffs' assertion of a substantial burden is that Plaintiffs' anonymity precludes an ability to find a substantial burden. (Opp'n 27.) This is also incorrect. Defendants' mandates put Plaintiffs to the choice: receive a COVID-19 vaccine or face disciplinary consequences. (V. Compl. ¶¶ 50–56.) Defendants, for their part, concede that a failure to receive a COVID-19 vaccine under

the mandates will result in "adverse action" and "discipline." (Opp'n 6, 8.) Moreover, Plaintiffs have alleged that they face dishonorable discharge, court martial, other life-altering disciplinary procedures, and termination for failure to comply with a mandate that violates their sincerely held religious beliefs. (V. Compl. ¶¶ 1, 134.)

As the Court said in *Singh v. Carter*, making out a case for a substantial burden under RFRA is "easily satisfied since, absent an accommodation, the plaintiff would face serious disciplinary action" for conforming his behavior to his sincere religious beliefs. 168 F. Supp. 3d 216, 228 (D.D.C. 2016). As in *Holt v. Hobbs*,

> The Department's grooming policy requires petitioner to shave his beard and thus to "engage in conduct that seriously violates [his] religious beliefs." . . . If petitioner contravenes that policy and grows his beard, he will face serious disciplinary action. Because the grooming policy puts petitioner to this choice, it substantially burdens his religious exercise.

574 U.S. 352, 361 (2015) (quoting *Hobby Lobby*, 573 U.S. at 720).

Here, Defendants' mandates put Plaintiffs to the choice: comply with the mandates or face serious disciplinary action. In fact, Defendants' COVID-19 vaccine mandates impose a substantial burden as a matter of binding law because they require Plaintiffs to engage in activity contrary to their sincerely held religious beliefs. *See, e.g.*, *Midrash Sephardi, Inc. v. Town of Surfside*, 366 F.3d 1214, 1227 (11th Cir. 2004) ("We have held that an individual's exercise of religion is 'substantially burdened' if a regulation completely prevents the individual from engaging in religiously mandated activity, or if the regulation requires participation in an activity prohibited by religion."); *see also Adkins v. Kaspar*, 393 F.3d 559, 570 (5th Cir. 2004) ("[A] government action or regulation creates a 'substantial burden' on a religious exercise

if it truly pressures the adherent to significantly modify his religious behavior and significantly violates his religious beliefs.").

C. Plaintiffs' Facial Challenges to the Mandates' Singling Out Religious Exercise for Especially Harsh Treatment Are Likely to Succeed Under the First Amendment.

Aside from their contention that Plaintiffs have not brought a facial challenge to the mandates (Opp'n 27), which is belied by the Verified Complaint (*see supra* Section III.A), Defendants ignore Plaintiffs' First Amendment claims. Defendants fail to contest, and therefore concede, that Defendants have virtually unfettered discretion to deny religious exemption requests yet readily grant medical exemption requests. And that failure is fatal to Defendants' COVID-19 vaccine mandates. Indeed, "government regulations are not neutral and generally applicable, and therefore trigger strict scrutiny under the Free Exercise Clause, whenever they treat *any* comparable secular activity more favorably than religious exercise." *Tandon v. Newsom*, 141 S. Ct. 1294, 1296 (2021). By failing to even grapple with the disparate treatment of religious exemption requests, which are being universally denied (V. Compl. ¶¶ 17–41), and the permanently available, nonreligious medical exemptions (V. Compl. ¶ 96), which are being granted (V. Compl. ¶ 30), Defendants have failed to demonstrate that the mandates are neutral and generally applicable.

D. Defendants Cannot Satisfy Strict Scrutiny Under RFRA or the First Amendment.

Because Defendants' COVID-19 Vaccine Mandates substantially burden Plaintiffs' religious exercise, and are neither neutral nor generally applicable, they are

subject to strict scrutiny under RFRA and the First Amendment. And, under strict scrutiny, it is Defendants' burden to demonstrate that the mandates are supported by a compelling interest and are the least restrictive means. *Tandon*, 141 S. Ct. at 1296 ("the government bears the burden to establish that the challenged law satisfies strict scrutiny"). Defendants' fail that test.

1. Defendants have not satisfied their burden to demonstrate that the refusal to grant religious exemptions is supported by a compelling interest where other exemptions are available.

Defendants just assert that stemming the spread of COVID-19 is a compelling government interest. (Opp'n 28.) No one, including Plaintiffs, doubts that the government has an interest in protecting health and preventing disease. But, as Defendants admit, the Nation has been dealing with COVID-19 since January 31, 2020 and had its first declaration of emergency on March 13, 2020. (Opp'n 2.) The Nation has thus been dealing with emergency proclamations *for 23 months*. As Justice Gorsuch noted recently, while stemming the spread of COVID-19 may be a compelling interest, it "cannot qualify as such forever. . . . If human nature and history teach anything, it is that civil liberties face grave risks when governments proclaim indefinite states of emergency." *Does 1-3 v. Mills*, No. 21A90, 2021 WL 5027177, at *4 (Oct. 29, 2021) (Gorsuch, J., dissenting).

Under strict scrutiny, this Court must "look beyond broadly formulated interests and . . . scrutinize the asserted harm of granting specific exemptions to particular religious claimants." *Hobby Lobby*, 573 U.S. at 726–27 (cleaned up). And, as in *Gonzales*, the government's "mere invocation" of a compelling interest "cannot carry

the day." 546 U.S. at 432. Where the government permits exceptions to the policy that it claims a compelling interest in advancing, those exceptions undermine any claims of a compelling interest. *Id.* at 433. Here, Defendants permit a host of nonreligious, medical exemptions (V. Compl. ¶ 96.) To permit a broad swath of medical exemptions without demonstrating that "the denied exemptions could not be accommodated" fails the compelling interest test. *Gonzalez*, 546 U.S. at 435. "Slice it how you will, medical exemptions and religious exemptions are on comparable footing when it comes to the State's asserted interest," *Does*, 2021 WL 5027177, at *4 (Gorsuch, J., dissenting), and yet Defendants permit medical exemptions while precluding religious exemptions. (*See, e.g.*, V. Compl. ¶ 32.) That double standard, "leav[ing] appreciable damage to that supposedly vital interest unprohibited," *Republican Party of Minn. v. White*, 536 U.S. 765, 780 (2002), undermines Defendants' ostensibly compelling interest.

2. Defendants have not satisfied their burden to demonstrate that denying all religious exemptions is the least restrictive means.

Defendants' final and probably most egregious error is their failure to even attempt to justify their mandates as the least restrictive means. Defendants merely state that "preventing infectious disease through vaccines [is] the least restrictive means." (Opp'n 29.) But this fails to understand the requirements of narrow tailoring. As the Supreme Court said in *Tandon*,

> narrow tailoring requires the government to show that measures less restrictive of the First Amendment activity could not address its interest in reducing the spread of COVID. Where the government permits other activities to proceed with precautions, it must show that the religious exercise at issue is more dangerous than those activities even when the

> same precautions are applied. Otherwise, precautions that suffice for other activities suffice for religious exercise too.

141 S. Ct. at 1296–97 (emphasis added).

Here, Defendants make only one assertion: "that the military is best situated to assess whether . . . less restrictive alternatives are available." (Opp'n 30.) But this simply begs the question. Under strict scrutiny, the government must show it "seriously undertook to address the problem with less intrusive tools readily available to it," meaning that it "considered different methods that other jurisdictions have found effective." *McCullen v. Coakley*, 573 U.S. 464, 494 (2014); *see also Agudath Israel of Am. v. Cuomo*, 983 F.3d 620, 633 (2d Cir. 2020) (same). And Defendants must "show either that substantially less-restrictive alternatives were *tried and failed*, or that the alternatives were *closely examined and ruled out for good reason*," *Bruni v. City of Pittsburgh*, 824 F.3d 353, 370 (3d Cir. 2016) (emphasis added), and that "imposing lesser burdens on religious liberty 'would fail to achieve the government's interest, not simply that the chosen route was easier.'" *Agudath Israel*, 983 F.3d at 633 (quoting *McCullen*, 573 U.S. at 495). Put simply, "[g]iven the vital First Amendment interests at stake it is not enough for [Defendants] to simply say" that they are best suited to make the least restrictive means determination. *McCullen*, 573 U.S. at 496. Defendants' failure to even attempt to demonstrate that other methods would not achieve its interest is fatal, and the mandates are not the least restrictive means.

IV. PLAINTIFFS' CLAIMS UNDER THE EUA ARE LIKELY TO SUCCEED ON THE MERITS BECAUSE DEFENDANTS CANNOT OVERCOME THE RECORD EVIDENCE THAT THERE ARE NO FULLY APPROVED COVID-19 VACCINES AVAILABLE.

Defendants contend that the interchangeability of Comirnaty and the EUA vaccines renders Plaintiffs' EUA claims unlikely to succeed. (Opp'n 22–26.) The sworn testimony before this Court, the allegations of the Verified Complaint, and statements from the FDA, CDC, and others confirm that Defendants' contentions are meritless. Although the FDA has stated that the two vaccines have the "same formulation . . . and can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns," that does not mean they are the same vaccine. (**EXHIBIT F**, Declaration of Robert Malone, ¶21.) In fact, the FDA has explained that the two "products are legally distinct" but "with certain differences that do not impact safety or effectiveness." (*Id.*) Indeed, the Pfizer-BioNTech vaccine and BioNTech COMIRNATY vaccine are legally distinct products, as described by the FDA documents available at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-COVID-19/comirnaty-and-pfizer-biontech-COVID-19-vaccine. (*Id.* ¶ 22) These vaccines and any other FDA regulated medicinal products consists of the entirety of the data supporting the safe and effective use of the product, as well as the quality systems, production methods and processes, laboratory assays (including in-process and release assays), materials, facilities & equipment, and packaging & labeling of the product. (*Id.*) Packaging and labeling specifically includes a package insert summarizing the data supporting the intended safe and effective use,

and also describing the risks associated with the medical product. (*Id.*) Indeed, "[t]hese packaging and labeling aspects for the Pfizer-BioNTech vaccine and BioNTech's COMIRNATY, which are intrinsic aspects of the regulated product, are explicitly not identical between these two legally distinct products." (*Id.* ¶ 23.) For example, BioNTech's COMIRNATY includes FDA approved labeling and a package insert designed to inform the recipient of the (incomplete, as recognized by the FDA) list of risks and benefits of the product, whereas the Pfizer-BioNTech vaccine does not. (*Id.*) Therefore, the Pfizer-BioNTech vaccine and BioNTech's COMIRNATY are neither identical legally nor functionally. (*Id.*)

Defendants claim that, despite the unequivocal statements of the FDA, they do indeed have a supply of "BLA-compliant vaccine." (Opp'n 24.) But that cannot be true. As Dr. Malone testifies, based on the statements from the National Institutes of Health, the Centers for Disease Control, and the FDA letters concerning the vaccines, the "FDA regulated product labeled COMIRNATY is the only FDA licensed SARS-CoV-2 vaccine . . . but it is not yet available for use in the United States." (Malone Decl. ¶ 26.) As stated in the CDC COVID-19 Vaccine Related Codes document (Malone Decl., Ex. E), COMINARTY products are not orderable at this time. NDCs are listed per FDA Structured Product Label (SPL) document for the BLA licensed product. (*Id.* ¶ 27.) These codes are not included in CDC Vaccine Code Set files at this time. (*Id.*)

Pfizer has provided the following statement regarding the COMINARTY branded NDCs and labels: 'Pfizer received FDA BLA license on

8/23/2021 for its COVID-19 vaccine for use in individuals 16 and older (COMIRNATY). 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. (*Id.*) At present, Pfizer does not plan to produce any product with these new NDCs and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution. (*Id.*) As such, the CDC, AMA, and drug compendia may not publish these new codes until Pfizer has determined when the product will be produced with the BLA labels.'" (*Id.* and Ex. E.)

On September 13, 2021, the NIH published the identical Pfizer statement: "At present, Pfizer does not plan to produce any product with these new NDCs and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution. As such, the CDC, AMA, and drug compendia may not publish these new codes until Pfizer has determined when the product will be produced with the BLA labels." (*See* Malone Decl. ¶ 28 and Ex. 28.)

As Dr. Malone's declaration, the statements of the FDA, CDC, and NIH, and Pfizer itself establish, Defendants' assertion that they have the FDA-approved COVID-19 vaccines available for Plaintiffs to accept is false.

CONCLUSION

For the foregoing reasons, Plaintiffs' Motion for Preliminary Injunction should be granted.

Respectfully submitted,

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Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of November, 2021, I caused a true and correct copy of the foregoing to be electronically filed with this Court. Service will be effectuated on all counsel of record via this Court's ECF/electronic notification system.

/s/ Roger K. Gannam
Roger K. Gannam

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

NAVY SEAL 1, et al., Plaintiffs, v. JOSEPH R. BIDEN, et al., Defendants.	)	No. 8:21-cv-2429-SDM-TGW

DECLARATION OF LIEUTENANT COLONEL, UNITED STATES MARINE CORPS

I, Lieutenant Colonel, United States Marine Corps do hereby declare as follows:

1. I am over 18 years old, these matters set forth in this Declaration are my personal experiences and observations, and if called upon to testify to them, I would and could do so competently.

2. I am a Lieutenant Colonel in the United States Marine Corps with 18 years and 10 months of honorable service. I am a Weapons and Tactics Instructor pilot having accumulated over 4,400 flight hours with 797 of those being combat flight hours flown in Iraq and Afghanistan.

3. On 8 September 2021, I submitted a request for religious accommodation to be exempt from the COVID shot mandates based upon my sincerely-held, non-negotiable Protestant Christian beliefs.

4. Two (2) days later, on 10 September 2021, my Commanding General issued an order stating that the aircraft under his purview would only be operated by "*fully vaccinated"* aircrew. This order pertains to only 6 total aircraft and approximately 35 total active duty pilots. Other than myself, I am aware of only 1 other pilot in this group that is grounded as a result of this order.

5. By September 2021, I had been flying frequently and safely amidst the pandemic for 18 months, instructing pilots and carrying passengers throughout the region. There was no appreciable acceleration in local infection metrics in the preceding days to otherwise explain the General's order. Many unvaccinated Marine aviators outside of my chain of command continue to fly today. My impression is that the order was *not* simply coincidental with my submission of a Religious Accommodation request only 2 days prior.

6. Although I have not flown since 10 September, I was and currently remain, on paper, the lead instructor and standardization pilot for the squadron. My perishable skill set that American citizens have paid dearly for is eroding by the day.

7. My employability in the civilian aviation industry is also dwindling rapidly which is of key personal concern given that we are told to expect involuntary separation from the Marine Corps very soon. Whereas my plan for nearly the last 19 years has included departure from the service with a pension and healthcare for my family of 6, now I must recalculate to leave involuntarily and with nothing other

than having my honor questioned. Like many military aviators nearing transition out of service, aviation is the primary marketable skill I have chosen to pursue. This punitive grounding directly detriments my ability to smoothly enter the civilian marketplace and support my family. My wife and I remain Faithful that the Lord takes care of his people, but these stressors are real and are taking a toll on our household.

8. I received a denial of my religious accommodation on 22 October 2021. This denial was a form letter, identical to dozens of others I have seen from Marines I am acquainted with. I submitted my appeal on 5 November 2021 within the statutory timeline I was afforded by the applicable order.

9. My chain of command was aware that I would appeal and pursue the full administrative process afforded for Religious Accommodation. **However, based upon the command's presumption that my appeal would be denied, I was preemptively removed from my Executive Officer leadership position on 1 November 2021.**

10. I am a Marine Officer and aviator and have been stripped of both flight operations and leadership responsibilities simply for having pursued a religious accommodation as my faith requires.

11. I submitted a separate, but related request for early retirement on 25 October 2021 through my eligibility for the Temporary Early Retirement Authority

program authorized by Congress and in effect until 2025 in the Marine Corps. **My request was forwarded by my immediate superior "*recommending disapproval,*" yet he cited no reasoning.** On 26 October 2021, this request arrived at the final level of routing before proceeding on to its Headquarters Marine Corps (HQMC) destination. **This level happens to require forwarding from the very same Commanding General who grounded me.** My request remains stalled at this level as of 5 Nov 2021 despite my repeated efforts to follow up with its progression. It appears to me that the Marine Corps is not going to let me simply leave with retirement intact, as a punitive measure for having requested an accommodation from the COVID shot.

12. I have done nothing wrong, although these circumstances show that exercising the administrative process made available to me by DoD Instruction and Marine Corps Order is invitation for discriminatory treatment.

13. I have been stripped of my command with no due process, and no finding of wrongdoing, simply for requesting an accommodation for my sincerely-held religious beliefs. My alternative request for early retirement, a means of avoiding the conflict between the COVID shot orders, and my faith, has been non-recommended.

14. Given that these injustices are being carried out against a Lieutenant Colonel, I fear that much worse is occurring at the expense of our junior Marines.

/S Lieutenant Colonel

LIEUTENANT COLONEL, UNITED STATES MARINE CORPS

9 November 2021

VERIFICATION

I, Lieutenant Colonel, am over the age of eighteen years and a Declarant in this action. The statements and allegations that pertain to me or which I make in this DECLARATION are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: November 9, 2021

/S Lieutenant Colonel

LIEUTENANT COLONEL, UNITED STATES MARINE CORPS

(Original Signature retained by Counsel)

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

NAVY SEAL 1, et al.,	)	
	)	
Plaintiffs,	)	
v.	)	No. 8:21-cv-2429-SDM-TGW
	)	
JOSEPH R. BIDEN, et al.,	)	
	)	
Defendants.	)	

DECLARATION OF FEDERAL CONTRACTOR EMPLOYEE

1. I, FEDERAL CONTRACTOR EMPLOYEE, am over the age of eighteen years, have personal knowledge and exposure to the matters set forth in this Declaration, and if called to testify to them, I would and could do so competently.

2. I am an employee of federal contractor United Launch Alliance (ULA) and have worked as an Aerospace Technician/Welder since 2020. I worked for ULA for six years in the past, and I was laid off for a time from 2017 to 2020. I love my job.

3. ULA is a joint venture headquartered in Centennial, Colorado, between private space companies Lockheed Martin and Boeing that provides launch vehicles to NASA, the Department of Defense and other organizations.

4. ULA provides rocket launch services to the government, with primarily DoD-related contracts (USSF/NRO), but also non-military government missions (Lucy, LandSat-9, Parker Solar Probe, ICESat) as well as commercial programs (Sierra Space Dream Chaser, Boeing Starliner).

5. ULA's rockets are among the largest and most powerful in the industry.

6. My job provides mission-critical skills in support of ULA missions by means of fabricating and building the structure of the Centaur Upper Stage Rocket Booster. My skillset is very difficult to replace due to the tedious and critical nature of the parts I weld together for the Centaur rocket booster.

7. The first stage of the rocket is the Atlas booster. This gets the rocket and its payload into orbit.

8. The Centaur III is the upper and final stage of the booster that delivers the satellite payload into its final orbital path. I fabricate and weld the second stage of the booster, using high-grade stainless steel. Stainless steel is typically more difficult to weld, in general, but the stainless steel that I weld for the Centaur is .016 (sixteen thousandths of an inch) thick (or thin, as it were). If this weld fails, the typical multi-million-dollar payload will be destroyed or not delivered to its destination, wasting the costs of the rocket itself as well. The rockets are valued between $100,000,000 and $160,000,000 each.

9. I have helped complete approximately 60 to 70 Centaur rocket boosters. The booster is powered by liquid hydrogen (LH^2) and liquid oxygen (LOX). The booster component we fabricate is the main structure, in which there are two cavities. My specialty is building the vacuum cavity. The vacuum cavity separates the forward and aft ends of the rocket. These ends hold different fuels, and there is a temperature difference between LH^2 and the LOX. The temperature difference is such that a

failure to keep the fuels separate will result in failure. My component is critical during launch, because a failure in it will result in a launch failure.

10. A launch failure could result in either an explosion on the pad, on liftoff, or a failure of the payload to reach its orbit.

11. One coworker and I are the only two aerospace welders (rocket welders) at ULA who are certified to weld the critical parts that we fabricate. The critical nature of our work is such that where others' welds have failed inspection in the past, the rockets must be cut apart and redone at an estimated cost of at least $500,000 per failure.

12. I have personally helped improve the processes involved in manufacturing the parts on which I weld from better weld quality to more timely completion dates which in turn significantly reduce the cost of the rocket.

13. The next generation Centaur is currently in development. It is known as the "Centaur V." The project lead often consults me and utilizes me to do repairs and to guide novice aerospace welders, and to perform repairs where their work needs improvement so that all of their work is not wasted. Whenever there is a repair to be done on a Centaur III or a Centaur V, I am typically the one who does it.

14. I have an associate's degree from Southern Union State Community College for Welding Technology and many years of training and expertise in the welding field.

15. I love my Country and love being a part of the industry that builds equipment to protect it.

16. I first began my welding career in high school and in turn it has become a lifelong passion of mine to perfect my skillset and to be the best I can be. I am now able to apply those skills to my position with ULA.

17. ULA's launch vehicle services are essential to our nation's critical defense missions, and to Earth and planetary exploration.

18. As the employee of a federal contractor, I am personally affected by Joseph R. Biden's order for mandatory vaccinations and this order severely conflicts with my sincerely-held religious beliefs.

19. Our union opposed this mandate. The deadline was extended from September 29 to October 29, for the requirement of the first shot, and ULA stated it would allow religious and medical exemptions. Only a few medical exemptions have been allowed temporarily, with all religious exemption requests denied. I turned in both a religious and a medical exemption, and was denied on both.

20. Based on my religious beliefs, I submitted a religious exemption request from having to receive any of the COVID shots, using ULA's COVID-19 Religious Accommodation Request Form, attached hereto as Exhibit [A]. This was submitted to ULA HR on October 1, 2021.

21. During the next several weeks that followed, there was little to no discussion of accommodations.

22. I thought a possible accommodation would be similar to the work environment of 2020: self-assessment for symptoms, physical distancing, and other potential measures to include possibly masking and testing.

23. On October 22nd, 2021, I received an email which referred to a form by which ULA had denied my accommodation request. ULA's reasons for denial made little sense, and everything contradicted what has occurred since early 2020.

24. The full denial form is attached as Exhibit [B].

25. In applicable part, ULA stated the reasons for denial as:

> This request is being denied because the accommodation would result in an undue hardship to ULA. Factors that contribute to the undue hardship include, but are not limited to: **the high volume of requests to accommodate that qualified under the sincerely held belief prong of the analysis**; the need to ensure a healthy and safe workplace; the time, cost, and administration burden associated with weekly testing; potential issues with the availability of testing; **ULA's requirements as a federal government contractor, including NRO requirements to staff contracts with vaccinated workers**; the need to comply with strict contract requirements, including launch schedules, and the potential financial risks of failure to satisfy such requirements; **the nature of our workplace and business, including the need for on-site work**; the need for employees to interact with others, travel, and access customer facilities, including federal facilities with strict access requirements; the number of prior COVID cases and quarantines at ULA, including multiple hospitalizations and deaths; and the presence of continued active COVID-19 cases and quarantines at ULA despite prior safety measures. (Emphasis added).

26. ULA claims that accommodation of my request would result in an undue hardship are false and contradict ULA's practices by which we continued operations on schedule for the past year.

27. **ULA has accepted medical accommodations, however, religious accommodation requests, including my own, have been blatantly and uniformly rejected**.

28. **I understand that currently no religious accommodations have been approved, however, medical accommodations requests are being approved**. A number of medical approvals have been granted without providing employees with any proposed accommodations, which will be determined later by HR.

29. ULA claims to allow an appeal process, and I timely requested that the Appeal through the Union grievance process. I do not see this going anywhere considering that ULA has denied the religious exemptions and most medical exemptions of everyone with whose situation I am familiar.

30. I and those in this situation are not resigning, we are being forced, under duress, to take the vaccine or lose our employment with ULA.

31. By close of business October 29, 2021 ULA employees were to have received the shot or an approved exemption. I remain unable to receive the shot, per my sincerely-held religious beliefs, and my medical condition, I do not have an approved exemption.

32. ULA states I will be compliant with ULA's COVID-19 Vaccination policy if one of the following happens:

A. proof of vaccination is emailed to ULA Medical;

B. an accommodation request is approved by ULA Medical for medical requests; or

C. an accommodation request is approved by ULA HR for religious requests.

33. If none of the above occur, I will be forced into "unpaid leave" until I am informed of the appeal decision outcome.

34. I fully expect to be terminated although ULA is falsely calling my termination a "voluntarily resignation."

35. I am not resigning and I am not quitting my position.

36. I estimate that between 20%-25% of ULA combined workforce will potentially be dismissed due to the vaccine mandates. As I mentioned previously *all religious accommodation requests within my personal knowledge have been denied*, while few medical accommodations are being approved.

37. I cannot afford to lose my job. I have a wife who stays home with my two children ages 2 and 5 and I am the only financial support for this family.

38. However, I cannot comprise my faith in God, my commitment to acting consistent with His will, and my beliefs even if it means losing this great position working on technology that is critical to our nation's defense and way of life, and the income source that it is.

39. I just want to continue using the gifts and skills that God has granted me stewardship of while on this Earth, working for ULA, which in turn provides launch

services that our vital to the national security for the safety of our country and the men and women who serve.

VERIFICATION

I, FEDERAL CONTRACTOR EMPLOYEE, am over the age of eighteen years and a Declarant in this action. The statements and allegations that pertain to me or which I make in this DECLARATION are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: November 8, 2021

S/ FEDERAL CONTRACTOR EMPLOYEE

Exhibit A

ULA

COVID-19 RELIGIOUS ACCOMMODATION REQUEST FORM

Policy Statement & Instructions:

Consistent with federal, state and local law, United Launch Alliance ("ULA") provides reasonable accommodation for employees' sincerely held religious beliefs, practices, and observances unless providing a reasonable accommodation would result in undue hardship to ULA. If you are seeking an accommodation from the ULA's COVID-19 Vaccination Policy (the "Policy") due to religious reasons, please complete this form and return it to your Human Resources Business Partner.

We request that you complete this form because, in some cases, a person's religious beliefs may be more subjective than objective. If your religious accommodation is not required by the tenets of a specific religion, ULA will need to understand the basis and source of your religious beliefs to reasonably assess whether your request qualifies for a religious accommodation. This is the reason for many of the questions below. The information you provide will allow us to evaluate your request and decide whether we can grant an accommodation in this instance. It is possible that more information will be necessary to evaluate your request, and if so, we will follow up with you for more information. Requests will be processed pursuant to ULA's Reasonable Accommodation Policy, HR-126, and we will inform you once a decision is made on your request.

Company Expectations for Cooperation and Honesty:

As COVID-19 continues to significantly challenge our employees, customers and business, it is more important than ever to work cooperatively with one another. ULA respects employee religious and personal beliefs but also expects employees to cooperate as ULA evaluates accommodation requests, including but not limited to providing true and accurate information in furtherance of accommodation requests. ULA also expects compliance with the United Launch Alliance Code of Conduct. If ULA determines employees have failed to cooperate with its reasonable information requests or employees have acted dishonestly in advancing such requests, it may deny the accommodation request and, if appropriate, take disciplinary action including potentially terminating an employee's employment.

Employee Name: _____

Position: Welder

Supervisor: Jason Smith

1. Please describe in detail the provision(s) of ULA's COVID-19 Vaccination Policy from which you are seeking accommodation and the accommodation you are requesting.

I am requesting to be exempt from the Covid 19 vaccination due to my religious beliefs. I am requesting to be tested periodically vs taking the Covid 19 vaccination.

2. Please identify the religious belief, practice, or observance that is causing you to seek the accommodation identified in response to Question No. 1.

Please see my attached letter in regards to my religious beliefs.

3. Please describe the conflict between such religious belief, practice, or observance and the provision(s) of the COVID-19 Vaccination Policy identified in response to Question No. 1.

Please see my attached letter in regards to my religious beliefs.

4. Is the religious belief, practice, or observance you identified in response to Question No. 2 based on an organized religious faith to which you belong, and if so, please describe?

It is based on my sincerely held religious beliefs, please see my attached letter.

5. If your request for accommodation is not based on an organized religious faith to which you belong, please describe the basis for the religious belief, practice, or observance you have identified in response to Question No. 2.

6. Have you received other vaccinations previously? If so, please describe why the religious belief, practice, or observance you have identified did not prevent you from getting that vaccination(s).

I have received vaccinations as a child, however this was prior to my salvation or my ability to say no. This was also prior to my understanding that these vaccinations utilize fetal cells for development. Therefore this completely conflicts with my beliefs.

7. Would receiving a COVID-19 vaccine interfere with your ability to practice your religion? If so, please explain.

Yes, please see my attached letter.

8. Please describe how the religious belief, practice, or observance you have identified in response to Question No. 2 effects other aspects of your life, such as if it prevents you from receiving certain medical care. (Please do **not** share any medical information, including without limitation

any diagnosis or treatment information.)

As I stated I do not take vaccines that utilize aborted fetuses for development because I do not support abortion and I seek to honor God with my body, by avoiding things that support abortion and Gene therapy.

9. Is there anything else you would like the company to know about your request for accommodation? If so, please provide that information here or attach any documents you wish to provide.

I work in an area where I have limited contact with other individuals and I comply with all safety requirements. Therefore I do not see where my refusal to this vaccine would cause any sort of undue hardship for the company.

Employee Acknowledgment: I acknowledge that I have read and understand this request form and that all statements made above are complete and accurate to the best of my knowledge. I understand that any intentional misrepresentation contained in this request may result in disciplinary action. I understand that the accommodation requested above may not be granted if I have not identified a religious belief, practice, or observance that conflicts with the COVID-19 Vaccination Policy or if the accommodation is not reasonable or imposes an undue hardship.

Date: 9/30/21 Signature: ____

Name: ____

September 30, 2021

HR Business Partner
United Launch Alliance, Inc.
1001 Red Hat Road
Decatur, Alabama 35601

Re: Request for Religious Exemption from Vaccination Policy

Dear Sir or Madam:

I am requesting a religious exemption from the Covid 19 Vaccination policy, specifically, that I not be required to take the vaccine.

I was raised in a Christian household but it wasn't until a few years ago that I became born again. (John 3:7). At that point, I grasped and adopted not only the lifestyle that Christ commanded, but also the heart and mind of a believer in Christ. My Christian beliefs and actions do not come without much faith, Bible study and prayer in order to come to decisions that I make, including this one.

The Bible says that God created the body both "fearfully and wonderfully" (Psalm 139: 13 – 16). The Covid-19 shots insert MRNA processes, which is injection of gene therapy. That process interferes with my God-given natural protective response, and causes genetic changes to my body. To alter myself in this way is a sinful practice to my beliefs, and because of that, I cannot take the vaccine.

The Bible tells us "God blessed them and said be fruitful and multiply." (Genesis 1:28). "In a public comment to the CDC, molecular biologist and toxicologist, Janci Chunn Lindsay, Ph.D. in formed the CDC that …"there is a credible reason to believe that the Covid vaccines will cross-react with the syncytin and reproductive proteins in sperm, ova, and placenta, leading to impaired fertility and impaired reproductive and gestational outcomes." https://www.jennifer margulis.net/halt-covid-vaccine-research-scientist-urges-cdc/. In addition, "respected virologist Dr. Bill Gallaher, made excellent arguments to the CDC as to why you would expect such cross reaction, due to beta sheet conformation similarities between spike proteins and syncytin-1 and syncytin-2." Id. Because of this very real potential for harm, which has not been disproven by any immunological study, (id.) I am to follow the Lord's command and not take any action that would disable or adversely impact my ability to reproduce as I am in my reproductive years, and because of that, I cannot take the vaccine.

One of the basic principles of my faith is that life begins at conception. As stated in Psalm 139:13 "For You created my innermost being. You knit me together in my mother's womb." As a Christian, I believe in the Ten Commandments, among them that "You shall not murder. Exodus 20:13. I both believe in and observe those Christian principles that life is sacred and that life begins at conception. I have a sincerely held religious belief that abortion is murder, and I cannot participate in anything that comes from or uses an abortion.

All of the Covid-19 vaccines use aborted fetuses or parts of aborted fetuses in the testing or initial development of the vaccines. The policy of ULA that I take the vaccine would violate my belief against abortion. I cannot be a participant in an act that offends my sincerely held religious belief, and I cannot in good conscience take any such Covid vaccine.

Also, it is my sincerely held religious belief and practice that I honor God with my body. As stated in I Corinthians 6:19, "Do you not know that your body is a temple of the Holy Spirit, who is in you, whom you have received from God? You are not your own; you were bought at a price. Therefore honor God with your body." As I said above, the Covid-19 vaccines came from the aborted fetuses or parts of aborted fetuses in the testing or manufacture, the gene therapy alters and interferes with the way God made me, and the shot could interfere with fertility or interfere with my baby forming. Due to each of these reasons which go counter to my sincerely held religious belief and practice and my conscience, I cannot take the vaccine.

In short, it violates my sincerely held religious beliefs and conscience to take the vaccine into my body, and I cannot take the vaccine.

Sincerely,

Exhibit 9

From: [redacted]
Sent:
To:
Cc:
Subject: Notification of Vaccine Accommodation Request Status

Sensitive Internal Information

United Launch Alliance (ULA) Proprietary Information

This notice is to inform you that your Medical Vaccine Accommodation request has been denied. The denial was based on the CDC "Interim Clinical Considerations for Use of COVID-19 Vaccines". The Medical Accommodations committee (Dr. David Cole and Dr. Waynett Boyd, Chair) reviewed all documents submitted by you. If you have questions regarding your next steps, please speak with your Human Resources Business Partner.

Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC

Regards,

[redacted]

[redacted]

SAFETY FOR LIFE Living Injury Free Every Day

"Ownership Is The Heart Of Performance"

Exhibit B

REASONABLE ACCOMMODATION DECISION FORM

COVID-19 Vaccine Policy

Reasonable Accommodation Decision Form	
The chair of the Accommodation Committee must complete this form and submit copies of all information reviewed, considered and / or gathered in making a decision to the Talent Management Department within five days of completion.	
Chair Person's Name: [redacted]	Phone Number: [redacted]
Position Title: HRBP	E-mail: [redacted]
Site: Decatur	

List the names of the Accommodation Committee members consulted in this case, including the employee:

Name	Site	Function	Phone Number	E-mail
[redacted]	Denver	Legal	[redacted]	[redacted]
[redacted]	CCSFS	HR	[redacted]	[redacted]
[redacted]	Decatur	HR	[redacted]	[redacted]
[redacted]	Decatur	HR	[redacted]	[redacted]
[redacted]	Denver	HR	[redacted]	[redacted]
[redacted]	Harlingen	HR	[redacted]	[redacted]
[redacted]	Denver	HR	[redacted]	[redacted]
[redacted]	VSFB	HR	[redacted]	[redacted]
[redacted]	Denver	HR	[redacted]	[redacted]
[redacted]	CCSFS	HR	[redacted]	[redacted]

Answer the following questions:

Name of the person requesting the reasonable accommodation: [redacted]

Site and name of business group of requestor: [redacted]

Job title of the requestor: Aerospace Production Technician

Name of leader of requestor: [redacted]

Describe the accommodation requested and the reason for the request:
Exemption from the COVID-19 vaccination mandate for religious reasons

If accommodation is approved, describe the accommodation granted and the reason for approval:

If accommodation is granted, describe any conditions on approval:

If accommodation is denied, provide the reason for denial:
This request is being denied because the accommodation would result in an undue hardship to ULA. Factors that contribute to the undue hardship include, but are not limited to: the high volume of requests to accommodate that qualified under the sincerely held belief prong of the analysis; the need to ensure a healthy and safe workplace; the time, cost, and administration burden associated with weekly testing; potential issues with the availability of testing; ULA's requirements as a federal government contractor, including NRO requirements to staff contracts with vaccinated workers; the need to comply with strict contract requirements, including launch schedules, and the potential financial risks of failure to satisfy such requirements; the nature of our workplace and business, including the need for on-site work; the need for employees to interact with others, travel, and access customer facilities, including federal facilities with strict access requirements; the number of prior COVID cases and quarantines at ULA, including multiple

REASONABLE ACCOMMODATION DECISION FORM

hospitalizations and deaths; and the presence of continued active COVID-19 cases and quarantines at ULA despite prior safety measures.
Date requestor was notified of decision: 10/25/2021

[redacted]	HRBP	10/25/2021
Signature	Title	Date

Reasonable accommodation approvals to the COVID-19 vaccine policy are **provisional** and not considered permanent. Employees with an approved accommodation will be required to complete regular COVID-19 testing, in lieu of receiving the vaccine. Testing will be done weekly, at minimum, and customer requirements may require more frequent testing in some situations, which may apply to the employee. Failure to comply with the testing requirements will result in revocation of the accommodation.

Approvals may be reassessed and/or revoked by ULA at any time. Reasons that may result in discontinuing the accommodation include, but are not limited to: ULA determines it is an undue hardship to continue the accommodation, customer requirements change, there is a change in the employee's job, a new vaccine is developed that does not conflict with the employee's sincerely held religious beliefs, or the approval was based on untruthful or inaccurate information provided by the employee. ULA will re-engage the employee in the interactive process prior to reassessing or revoking the approved accommodation.

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

NAVY SEAL 1, et al.,	)	
	)	
Plaintiffs,	)	
v.	)	
	)	No. 8:21-cv-2429-SDM-TGW
JOSEPH R. BIDEN, et al.,	)	
	)	
Defendants.	)	
	)	

DECLARATION OF FEDERAL CONTRACTOR EMPLOYEE

1. I, Field Test Technician, am over the age of eighteen years, have personal knowledge and exposure to the matters set forth in this Declaration, and if called to testify to them, I would and could do so competently.

2. I am an employee of federal contractor United Launch Alliance (ULA) and have worked as a Quality Inspector since 2006. I was previously with the Boeing Company from November 1985 to 2005 (36 years total).

3. ULA is a joint venture between private space companies Lockheed Martin and Boeing that provides launch vehicles to NASA, the Department of Defense, and other organizations.

4. ULA provides rocket launch services to the government, with primarily DoD-related contracts (USSF/NRO), but also non-military government missions (Lucy, LandSat 9, Parker Solar Probe, ICESat) as well as commercial programs (Sierra Space Dream Chaser, Boeing Starliner).

9. My job provides mission-critical skills in support of ULA missions. I oversee

the work done by technicians, to ensure conformity with engineering procedural specifications. I ensure conformity with engineering procedures. I serve as a witness for procedures and final inspections in various compartments of the launch vehicle, prior to rollout to pad for launch. I'm the second set of eyes to make sure nothing has been missed that would potentially destroy the rocket and its payload. I ensure integrity and mission success. My past work with the Shuttle's payloads assured mission success and ultimately, Shuttle crew safety. If I am not terminated from ULA, I will be working on additional manned missions of Boeing Starliner, a reusable crew transport vehicle to and from the Space Station..

10. With Boeing and ULA, I have worked on Atlas rocket missions, several shuttle missions for science, DOD and commercial. I have worked on the buildup and launch of almost all the space station components. With ULA I have been directly involved in ALL of their launches to date and have served my company proudly with many awards and special honors.

11. The work I have done for both Boeing and now ULA throughout the years reflects my pride for this country and my personal importance to directly supporting our service men and women. We have launched payloads that not only protect and guide our military but also do the same for America and in many cases, the world. I've been very blessed to serve my country in the position that I hold while working for ULA, before being put on unpaid administrative leave.

12. Right out of high school, I began supporting Boeing space shuttle integration

in their logistics group. Early on I was fortunate enough to move into the quality control world; that experience helped me transition onto the Delta IV contract with Boeing. Our joint venture with Lockheed Martin led us to become ULA. I worked on both the Delta IV program and the Atlas V program. We support both launch sites at the Cape and at Vandenberg Space Force base in California. I have spent many months total in California to support their launches, at the cost of being away from my family. But I did it with the pride and understanding that the job we do not only supports so many, but countless lives have been saved and constantly protected by the payloads that our rockets have delivered for our many customers, much of which is classified.

13. ULA's launch vehicle services are essential to our nation's critical defense missions, and to Earth and planetary exploration. We have delivered payloads into orbit and on time with 145 consecutive launches with 100% mission success.

14. I am personally affected by Joseph R. Biden's order for mandatory vaccinations, and this order severely conflicts with my sincerely held religious beliefs. I had previously recovered from COVID, and had serological proof of the recovery, with strong antibodies, ULA originally said that this proof was acceptable. ULA changed positions, stating that the White House and the CDC did not recognize antibodies as an alternative to the COVID vaccine. I also held strong religious beliefs about not getting the shot.

15. Based on my religious beliefs, I submitted a request for exemption from

having to receive any of the COVID shots, using ULA's COVID-19 Religious Accommodation Request Form. I submitted this to ULA HR on October 12, 2021.

16. During the weeks that followed, there was no discussion of accommodations.

17. Based on our past practices, I anticipated that possible accommodation would be similar to the office environment of 2020: self-assessment for symptoms, physical distancing, and possibly masking and testing.

18. On October 20, 2021, I received an email with an attached Attestation Form, listing approximately 30 over-the-counter and prescription medications claiming to have some type of connection with tests that used fetal cell lines. I signed the form, because I do not knowingly use products using aborted fetal cell lines.

19. I later received a company-wide email on October 21, 2021, that ULA had made a decision to refuse or deny all religious exemption requests. ULA's reasons for denial made little sense, and everything contradicted what has occurred since early 2020.

20. In applicable part, ULA stated the reasons for denial as:

> This request is being denied because the accommodation would result in an undue hardship to ULA. Factors that contribute to the undue hardship include, but are not limited to: **the high volume of requests to accommodate that qualified under the sincerely held belief prong of the analysis**; the need to ensure a healthy and safe workplace; the time, cost, and administration burden associated with weekly testing; potential issues with the availability of testing; **ULA's requirements as a federal government contractor, including NRO requirements to staff contracts with vaccinated workers**; the need to comply with strict contract requirements, including launch schedules, and the potential financial risks of failure to satisfy such requirements; **the nature of our workplace and business, including**

> **the need for on-site work**; the need for employees to interact with others, travel, and access customer facilities, including federal facilities with strict access requirements; the number of prior COVID cases and quarantines at ULA, including multiple hospitalizations and deaths; and the presence of continued active COVID-19 cases and quarantines at ULA despite prior safety measures. (Emphasis added).
>
> (Emphasis added).

21. Many of ULA's claims that accommodation would result in an undue hardship are specious and contradict ULA's practices by which we continued operations on schedule for the past year.

22. I was told by my Union steward that they have had many meetings with ULA HR and legal reps, and their decision to reject ALL religious exemptions was final. The Union has filed a grievance on behalf of all Cape hourly (Bargaining Unit represented hourly employees), and my being "processed out" is currently pending the results of that grievance.

23. Those of us in this situation are not resigning; we are being forced, under duress, to take the vaccine or lose our employment with ULA.

24. By close of business October 29, 2021, ULA employees were to have received the shot or an approved exemption. I remain unable to receive the shot, per my sincerely held religious beliefs, and I do not have an approved exemption.

25 I have been forced into "unpaid leave" until I am informed of the grievance decision outcome. My union steward said this was only the process running its course, and ULA would be contacting me to out-process me.

26. I fully expect to be terminated at any time, pending final results of the union

grievanc, although ULA is falsely calling my termination a "voluntarily resignation." ULA has emailed us **that we "will NOT be eligible for unemployment benefits" due to our "voluntary resignation."**

27. I am not resigning, and I am not quitting my position.

28. As I mentioned previously *all religious accommodation requests to my knowledge, have been denied*.

29. I cannot afford to lose my job. I am the sole caregiver for my disabled 86-year-old mother, who lives with me. Also my 19-year-old son (who is on my insurance) is in dire need of several ankle surgeries, due to a severe high school football injury in 2019. I am proud of my work with ULA, and those with whom I work I consider family.

30. However, I cannot compromise my faith in God, my commitment to acting consistent with His will, and my beliefs, even if it means losing the job that I love.

31. I love my God, my country, and those who have and do serve in the military.

32. I just want to continue using the gifts and skills that God has granted me, working for ULA, which in turn provides launch services that our vital to the national security for the safety of our country and the men and women who serve.

Dated: November 10, 2021

/S Field Test Technician

FIELD TEST TECHNICIAN

VERIFICATION

I, Field Test Technician, am over the age of eighteen years and a Declarant in this action. The statements and allegations that pertain to me or which I make in this DECLARATION are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: November 10, 2021

/S Field Test Technician

FIELD TEST TECHNICIAN

(Original Signature retained by Counsel)

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

NAVY SEAL 1, et al.,	)	
	)	
Plaintiffs,	)	
v.	)	
	)	No. 8:21-cv-2429-SDM-TGW
JOSEPH R. BIDEN, et al.,	)	
	)	
Defendants.	)	
	)	

DECLARATION OF FEDERAL CONTRACTOR EMPLOYEE

1. I, Network Services Level 3, am over the age of eighteen years, have personal knowledge and exposure to the matters set forth in this Declaration, and if called to testify to them, I would and could do so competently.

2. Since June 2, 2000 to the present, I have been employed with federal contractor United Launch Alliance (ULA) as a Network Designer Level 3.

3. I previously worked as a Network Designer Level 3 with Boeing, before I was included in the merger of Boeing and Lockheed Martin to form United Launch

4. I have worked for ULA for 21 years. I have loved my job.

5. As a federal contractor, I am personally affected by Joseph R. Biden's various COVID vaccination mandates.

6. My employer put me on administrative leave on October 29, 2021, denying access to perform my job, while I appealed ULA's denial of my religious exemption request regarding the COVID shot.

7. ULA denied my appeal on November 4, 2021, with ULA providing me until the November 7, 2021 to get vaccinated because of President Biden's orders.

8. I was not able to receive the shot, based on my religious beliefs.

9. **Accordingly, termination of my employment will become final at 2:00 PM on Monday, November 15, when I turn in my company laptop and RSA tokens, absent intervention of this court.**

10. ULA is a joint venture between private space companies Lockheed Martin and Boeing.

11. ULA provides launch vehicles to NASA, the Department of Defense and other organizations.

12. ULA provides rocket launch services to the government, with primarily DoD-related contracts (USSF/NRO), but also non-military government missions (Lucy, LandSat-9, Parker Solar Probe, ICESat) as well as commercial programs (Sierra Space Dream Chaser, Boeing Starliner).

13. My job has morphed many times during my 21 year stay at ULA. I designed and built the corporate network supporting the build out to launch of the first Boeing Delta IV rocket in November 20, 2002.

14. During the first few years of working for Boeing, I also inherited the engineering responsibilities for the safety critical public address system and all conference rooms.

15. After the joint venture of Boeing and Lockheed Martin ULA went through a series of very stressful and painful RIFs and employees changing jobs internally. Through those changes I became the video system responsible engineer of the critical system of video engineering for the Delta program.

16. I retained full responsible engineering of all video systems for Cape Canaveral Space Force Station and Vandenberg Space Force Base in 2015. I retained this position up until my unplanned termination of my employment which will become final next week.

17. Upon my transition to full engineering responsibility of the video systems, I went into a full scale project of upgrading the HD video systems on all four ULA launch pads. Those launch PADS are Vandenberg ASFB SLC6 Delta and SLC3 Atlas. The launch PADS on Cape Canaveral Space Force Station are SLC37 Delta and SLC41 Atlas.

18. During the early transitions of the years 2017 and 2018, I worked a significant overtime which at the time was unpaid. In 2017, I worked 440 hours of unpaid OT and in 2018 I worked 574 hours of unpaid OT.

19. Only once did my manager ever make mention of my excessive OT or my lack of taking vacation time. My last true vacation was in March of 2018, my 2nd wedding anniversary. In recognition of the vast amount of people not being able to take their vacation, twice a year ULA offered us the ability to request a 40 hour pay

out. I took every opportunity to do so since my vacation has been tapped out at the maximum hours for years.

20. I have spent 21 years of my life at ULA, and at the expense of personal health, have fought to make every mission of ULA a success. I am not receiving that same level of commitment from ULA, with regard to a simple accommodation request for my sincere religious beliefs.

21. My commitment to ULA is evidenced by other facts as well.

22. During my time spent with Boeing and ULA, I engineered design and completed implementation on more projects than I list in this document. My job was always considered "mission essential." Being "mission essential" to launch support and being on the hurricane response team meant I was required for each launch.

23. During each hurricane event, I was on the DART team, which means we were the last to leave and first to return to base. I stayed in the area to support restoration of CCSFS after all hurricanes. As mission essential, the culture expects significantly above average dedication, which is why vacations are missed, holidays are optional, and family events often missed.

24. Not only have I been "mission essential" to the ULA launch program, ULA's launch vehicle services have been and are essential to our nation's critical defense missions, and to Earth and planetary exploration.

25. As the employee of a federal contractor, I am personally affected by Joseph R. Biden's order for mandatory vaccinations and this order severely conflicts with my sincerely-held religious beliefs.

26. Based on my religious beliefs, I submitted a religious exemption request from having to receive any of the COVID shots, using ULA's COVID-19 Religious Accommodation Request Form. This was submitted to ULA HR on September 21, 2021.

27. During the next several weeks that followed, there was little no discussion of accommodations. I was asked to complete an attestation form stating I would not take a long list of medicine that also were researched using aborted fetal tissue. I DID. They even told me that a decision might not be known until October 22, 2021 leaving only 7 days to file an appeal or make the gut wrenching decision to take the vaccine. Although, my choice on this was already made – I must remain true to my faith.

28. I thought a possible accommodation would be similar to the work environment of 2020: self-assessment for symptoms, physical distancing, and other potential measures to include possibly masking and testing. I also thought the list of accommodations I presented was more than adequate.

29. On October 21, 2021, I received an email which referred to a form by which ULA had denied my accommodation request. ULA's reasons for denial made little sense, and everything contradicted what has occurred since early 2020.

30. In applicable part, ULA stated the reasons for denial as:

> This request is being denied because the accommodation would result in an undue hardship to ULA. Factors that contribute to the undue hardship include, but are not limited to: **the high volume of requests to accommodate that qualified under the sincerely held belief prong of the analysis**; the need to ensure a healthy and safe workplace; the time, cost, and administration burden associated with weekly testing; potential issues with the availability of testing; **ULA's requirements as a federal government contractor, including NRO requirements to staff contracts with vaccinated workers**; the need to comply with strict contract requirements, including launch schedules, and the potential financial risks of failure to satisfy such requirements; **the nature of our workplace and business, including the need for on-site work**; the need for employees to interact with others, travel, and access customer facilities, including federal facilities with strict access requirements; the number of prior COVID cases and quarantines at ULA, including multiple hospitalizations and deaths; and the presence of continued active COVID-19 cases and quarantines at ULA despite prior safety measures. (Emphasis added).

31. ULA claims that accommodation of my request would result in an undue hardship are false and contradict ULA's practices by which we continued operations on schedule for the past year.

32. On the web site "For Federal Contractors | Safer Federal Workforce" available at https://www.saferfederalworkforce.gov/contractors/, the NRO and Air Force encourage contractors to ensure safe COVID-19 work place rules, but clearly state that accommodations, although limited, should be considered: "COVID-19 vaccination of covered contractor employees, except in limited circumstances **where an employee is legally entitled to an accommodation**."

33. **ULA may have accepted soon medical accommodations, however, religious accommodation requests, including my own, have been blatantly and uniformly rejected**.

34. **I aware of no peers at Cape Canaveral who have received a requested medial exemption, either**.

35. ULA claims to allow an appeal process, although mine was aggressively denied.

36. I and those in this situation are not resigning, we are being forced, under duress, to take the vaccine or lose our employment with ULA.

37. By close of business October 29, 2021 ULA employees were to have received the shot or an approved exemption. I remain unable to receive the shot, per my sincerely-held religious beliefs, and my medical condition, I do not have an approved exemption.

38. I will be terminated on Monday, November 15, although ULA is falsely calling my termination a "voluntarily resignation."

39. I am not resigning and I am not quitting my position.

40. As I mentioned previously *all religious accommodation requests within my personal knowledge have been denied*, while few medical accommodations are being approved.

41. I cannot afford to lose my job. I am 59 years old and turn 60 in December. This is the worst age to not only retire but to expect to start another career job. I

should be in the glory days of my career enjoying my successes with my peers and training my replacements. Instead, I am left pondering how to respond in my defense. I will lean on my faith in a Holy God that his will and purpose for me will continue, no matter what the struggles lie ahead.

42. However, I cannot comprise my faith in God, my commitment to acting consistent with His will, and my beliefs even if it means losing this great position working on technology that is critical to our nation's defense and way of life, and the income source that it is.

43. I just want to continue using the gifts and skills that God has given me, working for ULA, which in turn provides launch services that our vital to the national security for the safety of our country and the men and women who serve.

44. I must finally note that ULA has not missed any scheduled prelaunch testing, prelaunch processing (WDR, Centaur stacking, Space Craft Mate), or any launch event timeline "due to COVID." The precautions we took were sufficient for ULA to continue successful launch operations since 2020. I am part of the reason for this success.

Dated: November 10, 2021

/S Network SRV Level 3

NETWORK SRV LEVEL 3

VERIFICATION

I, Network Services Level 3, am over the age of eighteen years (59) and a Declarant in this action. The statements and allegations that pertain to me or which I make in this DECLARATION are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: November 9, 2021

/S Network Services Level 3

NETWORK SERVICES LEVEL 3

(Original Signature retained by Counsel)

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

NAVY SEAL 1, et al,	)	
	)	
Plaintiffs,	)	
v.	)	
	)	No. 8:21-cv-2429-SDM-TGW
JOSEPH R. BIDEN, et al.,	)	
	)	
Defendants.	)	

DECLARATION OF AIR FORCE CIVILIAN REGISTERED NURSE

I, Air Force Civilian Registered Nurse, do hereby declare as follows:

1. I am over the age of 18 years, have personal knowledge of the matters set forth in this Declaration, and if called upon to testify to them, I would and could do so competently.

2. I am a civilian nurse with the US Air Force.

3. I have served on active duty for 1 tour, and as a civilian GS and contractor for 17 years.

4. I am personally affected by the SECDEF's order for mandatory vaccinations.

5. I've been a nurse for over 14 years and in healthcare for over 30.

6. Since the advent of the COVID shot, I've had coworkers and patients alike speak with me about their concerns surrounding the push for them to take the COVID shot.

7. Many took it due to fear of loss of their employment.

8. Two of my active duty coworkers succumbed to the pressure after being told they would be dishonorably discharged if they refused.

9. One has 17 years of honorable service and a newborn, the other is 1.5 years shy of the end of this first enlistment. They anguished over the thought of a choice between the COVID shot, and their deeply-held, sincere beliefs that taking the COVID shot violated their conscience as well as bodily autonomy.

10. In my 30 years of healthcare experience, I've never seen anything like this. The threats, coercion and demonizing of patients and employees who decline to take the COVID Shots is disheartening, ethically wrong and immoral.

11. I've had pregnant patients ask me whether they should take this vaccine, as they were being pressured by their obstetrician to take it. As a nurse it is my responsibility to first do no harm. I take my pledge, as follows, seriously and personally.

12. *I solemnly pledge myself before God and in the presence of this assembly, to pass my life in purity and to practice my profession faithfully. I will abstain from whatever is deleterious and mischievous, and will not take or knowingly administer any harmful drug. I will do all in my power to maintain and elevate the standard of my profession, and will hold in confidence all personal matters committed to my keeping and all family affairs coming to my*

knowledge in the practice of my calling. With loyalty will I endeavor to aid the physician in his work, and devote myself to the welfare of those committed to my care.

13. Advising a young mother to take into her body a substance for which I have no knowledge of ingredients, adverse- or long-term effects violates my oath.

14. This also requires me to refer the patient back to the provider for more information, while educating them on best practices to prevent disease transmission in their daily lives.

15. I have chosen not to receive this injection due to medical concerns and conviction that this is morally, ethically and spiritually wrong.

16. To be forced to choose between my profession or financial ruin, I feel, is demonically driven.

17. Satan offered Jesus the world if he would just submit and follow him. Matthew 4:8-9

18. Forcing this COVID shot in order to keep one's job is the same quid pro quo proposal in different packaging.

19. I cannot submit to demands against what I believe Christ would have me do.

20. I cannot agree to accept the products of a newly delivered infant whose kidney cells were harvested, without anesthesia, at time of birth and resulted in this child's death (HEK 293).

21. Each one of the available injections used or contains these cells and other aborted fetal cells in their testing and/or formulation.

22. It is my sincerely held religious belief that putting these injections into my body fully defiles it in the eyes of God, as I would then knowingly be complicit in the murder of the infant and preborn children whose cells were used in the testing and/or manufacture of these shots.

23. On October 21, 2021, my coworkers spoke with me regarding the active shooter exercise planned for the day. One supervisor (a civilian psychologist) stated **the exercise scenario is based on a person who is upset that they are being forced to take the Covid injection against their will. They become violent and enter the clinic shooting and killing many staff members**.

24. She vocalized a concern that "We don't need to give people any ideas".

25. As the only unvaccinated person in my clinic, I felt singled out and ostracized, as everyone knows I am the hold out.

26. It is unconscionable for this base to hold an exercise characterizing a person who is declining the COVID shot as someone who is unhinged, mentally unstable and violent due to their opposition to the COVID shot mandate.

27. The "anti-vax active shooter" scenario shows the tone from the top down, that the unvaccinated should be viewed and treated with suspicion because they are "a threat" in more ways than "spreading COVID."

28. Beginning November 22, 2021, only the unvaccinated will be required to test weekly as a new "condition of employment."

29. This is intrusive, ineffective and unnecessary, as both vaccinated and unvaccinated can experience active Covid infection and shed the virus to others.

30. Where the vaccinated are just as likely to get COVID and transmit it (perhaps more so, due to potentially milder symptoms) singling out only those who have not taken the shot for testing mask wearing both in and out of doors is discriminatory.

31. It is the equivalent of having us wear the Star of David on our sleeve for all to see.

32. It is a divisive and harassing action meant to force compliance.

33. It creates a hostile work environment for myself and others who are declining at this time.

34. Since Spring 2021, the focus has been "diversity, equity, and inclusion" ("DEI"), and "extremism" training.

35. DEI training continues weekly here with today's narrative focusing on high-ranking white males making all decisions.

36. The "extremism" training was extremely divisive. It was entirely anti-Republican, anti-Conservative, anti-Christian, and anti-white male training. It created a hostile environment and directly undermined our Oath to the Constitution and protection of our country against all enemies foreign and domestic.

37. Our suicide prevention training did not touch on the realities of the stressors our military, civilian and contract workforce is experiencing due to Covid and the vaccine mandates.

38. I have spoken with Airmen, Soldiers, Marines, Sailors, Guardsmen, civilians and contractors who have expressed great stress and harm to their mental health, as a result of the SECDEF's COVID vaccination orders.

39. I am being forced to choose between my faith in God, as informed by my conscience, and service to the military and their families.

40. On October 5, 2021, I received a timeline for compliance with the October 1, 2021, SECDEF's COVID vaccination orders.

41. All shots must be completed by November 8 to meet the "fully vaccinated" requirement by November 22.

42. As of October 5, 2021 no guidance is available on requesting an accommodation for medical or religious exemption.

43. On October 25, 2021, I was required to complete DD Form 3175 DOD Employee Certification of Vaccination and email to my supervisor for completion.

44. This was also required of my civilian colleagues who have been vaccinated and they were required to provide a copy of their vaccination cards, even though they had received the vaccine in the clinic and it is part of their personnel record.

45. This DD Form 3175 DOD Employee Certification of Vaccination form was completed and forwarded to my supervisor on October 25, 2021.

46. My supervisor forwarded my DD Form 3175 to my CNO on October 26, 2021, and notified me via email, but did not provide a copy of his completed portion to me.

47. Our Wing Commander sent emailed information on applying for accommodation on Friday, October 29 at 0702 to all us.af.mil addresses.

48. I did not receive this communication and I was at work all day.

49. On Monday, November 1, 2021, The Wing Commander's email was forwarded from my clinic Chief.

50. I was on leave from November 1-2, 2021, and did not receive this information until Wednesday, November 3, 2021.

51. This email clearly states "Supervisors should take no action on these requests until further guidance is received".

52. On November 2, 2021, my Chief Nursing Officer (CNO) emailed instruction, dated November 1, 2021, to complete the DD Form 3175 again on MilConnect.

53. The email stated "the supervisor function in MilConnect is not available with no ETA on completion".

54. On November 2, 2021, my CNO sent email instructing me to complete DD Form 3177 and stating he had attached the Secretary of Defense guidance for me.

55. Nowhere in the body of this email did it state the date when this form was due.

56. I found the due date buried in the 23-page memorandum from Senior Pentagon Leadership titled "Force Health Protection Guidance (Supplement 23) Revision 2 – Department of Defense Guidance for Coronavirus Disease 2019 Vaccination Attestation, Screening Testing and Vaccination Verification dated October 29, 2021.

57. This is not transparency and further serves to foster division and mistrust of my senior leadership.

58. Despite requesting Religious exemption on August 5, 2021, which was returned with the verbal message, "it's not time", followed by a resubmission on October 4, 2021, that has been sitting in Public Health with no news on status, I

completed and returned DD Form 3177, "Request for A Religious Exemption to the Covid-19 Vaccination Requirement" on November 5, 2021.

59. Requesting the same information over and over again.

60. Not sending information out to everyone in a timely manner and deliberately hiding information is harassment.

61. This is negatively impacting the cohesiveness of our healthcare team.

62. The stress I am experiencing is often overwhelming.

63. I cannot focus or concentrate.

64. I have a continuous headache.

65. I am unable to sleep at night and am experiencing nightmares when I do fall asleep.

66. I fully expect to be terminated after the Department of the Air Force deadline of November 22, 2021, for civilian employees.

67. I am not resigning, and I am not quitting my position.

68. I continue to plan events and offer supports to military families with young children, but it is incredibly difficult to press on not knowing if I will be there to support them.

69. Those who lose as result of this unnecessary choice will be all of the Sailors, Soldiers, Airmen, Marines and their families whom I would have continued to faithfully serve.

Dated: November 9, 2021

S/ Air Force Civilian Registered Nurse

VERIFICATION

I, Air Force Civilian Registered Nurse, am over the age of eighteen years and a Declarant in this action. The statements and allegations that pertain to me or which I make in this DECLARATION are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: November 9, 2021

S/ Air Force Civilian Registered Nurse

(Original Signature retained by Counsel)

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

NAVY SEAL 1, et al., Plaintiffs, v. JOSEPH R. BIDEN, et al., Defendants.	)	Case No. 8:21-cv-02429-SDM-TGW

DECLARATION OF ROBERT MALONE, MD, MS, IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

Dr. Robert Malone declares under penalty of perjury:

1. I am over the age of eighteen years, have personal knowledge and exposure to the matters set forth in this Declaration, and if called to testify to them, I would and could do so competently.

2. I am an original inventor of core mRNA and DNA vaccination technology; have been involved in developing, designing, and providing oversight of approximately forty phase 1 clinical trials and twenty phase 2 clinical trials, as well as five phase 3 clinical trials; have been involved in infectious disease pathogen advanced development oversight of HIV, Influenza, Plague, Anthrax, VEE/EEE/WEE, Tularemia, Tuberculosis, Ebola, Zika, Ricin toxin, and Engineered pathogens; and, since January 2020, have been leading a large team focused on clinical research design, drug development, computer modeling, and mechanisms of action of repurposed drugs for COVID-19 treatment.

3. I submit this declaration in support of Plaintiffs' arguments that (a) the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY COVID-19 Vaccine are legally distinct; and (b) there are

no licensed SARS-CoV-2 vaccines currently available in the US. Rather, all currently available doses of SARS-CoV-2 vaccines are experimental medical products made available under the Emergency Use Statutes and Authorizations (EUA).

Education and Professional Experience

4. I graduated from the University of California, Davis with a Bachelor of Science degree in Biochemistry in 1984. I graduated from the University of California, San Diego with a Master's degree in Biology in 1989. I graduated from Northwestern University Medical School, Feinburg School of Medicine, in 1991.

5. I received one year of pathology residence training at University of California, Davis Sacramento Medical Center. I completed a Masters' Degree in Biology from University of California, San Diego in 1989 for work performed primarily at the Salk Institute in the Molecular Biology and Virology Laboratories and Laboratory of Dr. Inder Verma. This and subsequent work at the San Diego corporation "Vical" resulted in nine issued domestic US patents describing mRNA and DNA vaccine platform technology.

6. I completed a Giannini post-doctoral research fellowship at University of California, Davis Department of Pathology in 1992. I completed a Harvard Medical School Global Clinical Research Scholars fellowship in 2016. This fellowship included an emphasis on regulatory affairs, clinical development, bioethics, epidemiology and biostatistics.

7. I am currently licensed to practice medicine in the State of Maryland.

8. I have been extensively and repeatedly trained in clinical research bioethics over many years at a variety of institutions including intensive training by Dr. Adil Shamoo of the University of Maryland, Baltimore.

9. I served as Assistant and Associate Professor of Surgery and/or Pathology at University of California, Davis School of Medicine, University of Maryland School of Medicine, and the Uniformed University of the Health Sciences between 1992 and 2001. During this period, I was awarded numerous peer-reviewed and industrial grants and contracts relating to gene delivery technology, genetic vaccine development, the chemistry and formulation of gene delivery reagents such as those used for mRNA vaccines, mucosal genetic vaccine development and other related topics. This work resulted in numerous additional granted US Patents in these fields and the incorporation of biotechnology companies based on these discoveries including Inovio vaccines.

10. I served as Associate Director, Clinical Research at Dynport Vaccine Company LLC from 2002-2003, supporting the prime systems US DoD contract for all biodefense products under advanced development by the Department of Defense. I also served as Director, Business Development and Program Management for the Bill and Melinda Gates funded Aeras Global TB Vaccine Foundation from 2004-2005; Senior Medical Director, Summit Drug Development Services (a Regulatory Affairs and Clinical Research specialty contract research organization) from 2005-2006; Director, Clinical Development & Medical Affairs, Influenza for Solvay Pharmaceuticals (currently Abbvie) from 2006-2008; and Medical Director, Vaccines for the Beardsworth Consulting Group from 2010 – 2013.

11. I currently serve as CEO and Principal Consultant for RW Malone MD LLC, primarily supporting the US Department of Defense, Defense Threat Reduction Agency (via contracts held by Leidos and MIT-Lincoln Lab). I have been leading or serving as a principal consultant for teams developing both repurposed drugs or vaccines since January 4, 2020, resulting in multiple novel findings, published and pending manuscripts, three clinical trials involving repurposed drugs

(two in USA under DoD funding, one in India under funding from Reliance Healthcare) and one Phase 1 clinical trial for a novel SARS-CoV-2 vaccine.

12. I have a history of over a decade of service to the NIAID as either reviewer or study section chairperson for evaluating large contract bids for development of Biodefense and other Medical Countermeasures against emerging infectious diseases and biothreat agents.

13. I currently sit on the NIH/FNIH ACTIV COVID-19 Drug development panel.

14. I co-authored a book entitled "NOVEL CORONAVIRUS: A Practical Guide for Preparation and Protection (originally published Feb 2020).

15. I played a key role in the discovery and clinical development of the repurposed drugs Famotidine and Famotidine + Celecoxib as treatment for both outpatient and inpatient COVID-19 disease, and have academic publications relating to this work. This work has yielded FDA and Indian health authority approved INDs for clinically testing these agents in outpatient and inpatient randomized controlled trials.

16. I supported the Indian corporation Reliance in development of a second-generation SARS-CoV-2 vaccine that is now IND approved by the Indian health authority for initiation of clinical trials which are anticipated for Q4 2021.

17. I have previously served as an expert witness in cases relating to vaccine development, COVID-19, and related topics.

18. Together with Dr. Peter Navarro, I developed and published (lay press, Washington times) public policy recommendations involving targeting SARS-CoV-2 vaccine deployment to high risk groups (elderly, morbidly obese, immunodeficient and others), providing early COVID-19 treatment options (including antibody therapies), home diagnostic tests, and computational algorithms enabling individual assessment of COVID-19 risks.

19. Attached as **Exhibit A** is a true and correct copy of my curriculum vitae.

BioNTech's COMIRNATY Vaccine is distinct from the Pfizer-BioNTech Vaccine

20. Defendants' argument that the Pfizer-BioNTech vaccine is fully interchangeable with BioNTech's COMIRNATY is incorrect. Even if the vaccines might be produced at the same facilities or with the "same formulation," as defendants assert, does not mean they are fully interchangeable. The Pfizer-BioNTech vaccine is only authorized under the Emergency Use Authorization provision while the BioNTech vaccine received FDA approval. However, as will be addressed below, there is no FDA approved SARS-CoV-2 vaccine available. That is to say, the FDA approved BioNTech COMIRNATY vaccine is not available.

21. Although the FDA has stated that the two vaccines have the "same formulation . . . and can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns," that does not mean they are the same vaccine. In fact, the FDA has explained that the two "products are legally distinct" but "with certain differences that do not impact safety or effectiveness." *See* Letter United States Food and Drug Administration to Pfizer at 3, n. 10 (Sept. 22, 2021) (A true and correct copy of the letter is attached as **Exhibit B**); Letter United States Food and Drug Administration to Pfizer at 3, n. 11 (Oct. 20, 2021) (A true and correct copy of the letter is attached as **Exhibit C**); Letter United States Food and Drug Administration to Pfizer at 3 (A true and correct copy of the letter is attached as **Exhibit D**); CDC COVID-19 Vaccine Related Codes at 4 (A true and correct copy of the document is attached as **Exhibit E**).

22. The notion that the two legally distinct products are wholly interchangeable appears to be based on an incorrect understanding that a regulated product authorized for marketing by the FDA consists only of the active drug substance as delivered into a vial or other container in the case of

an injectable vaccine. However, the Pfizer-BioNTech vaccine and BioNTech COMIRNATY vaccine are legally distinct products, as described by the FDA documents available at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine. These vaccines and any other FDA regulated medicinal product consists of the entirety of the data supporting the safe and effective use of the product, as well as the quality systems, production methods and processes, laboratory assays (including in-process and release assays), materials, facilities & equipment, and packaging & labeling of the product. Packaging and labeling specifically includes a package insert summarizing the data supporting the intended safe and effective use, and also describing the risks associated with the medical product.

23. These packaging and labeling aspects for the Pfizer-BioNTech vaccine and BioNTech's COMIRNATY, which are intrinsic aspects of the regulated product, are explicitly not identical between these two legally distinct products. For example, BioNTech's COMIRNATY includes FDA approved labeling and a package insert designed to inform the recipient of the (incomplete, as recognized by the FDA) list of risks and benefits of the product, whereas the Pfizer-BioNTech vaccine does not. Therefore, the Pfizer-BioNTech vaccine and BioNTech's COMIRNATY are neither identical legally nor functionally.

24. There may be other differences between the Pfizer-BioNTech vaccine and BioNTech's COMIRNATY in the totality of the products in terms of quality systems, production methods and processes, laboratory assays (including in-process and release assays), materials, facilities & equipment. The provided FDA communication appears to assert that the materials used and final formulation is essentially identical, but potential differences in addition to the differences in packaging and labeling are not explicitly addressed.

25. On the basis of these facts and observations, it is my expert opinion that the Pfizer-BioNTech vaccine and BioNTech's COMIRNATY are not identical, and that the FDA has appropriately identified them as legally separate and distinct products. The assertions that the Pfizer-BioNTech vaccine and BioNTech's COMIRNATY are identical is not based in regulatory or legal fact.

BioNTech's COMIRNATY Vaccine is not available in the US

26. It is my expert opinion, based on the aforementioned FDA letters dated September 22, 2021 (Exhibit B at 6, n.12), October 20, 2021 (Exhibit C at 7, n. 13) , and October 29, 2021 (Exhibit D at 9, n. 17), as well as the September 13, 2021 National Institutes of Health news release (Exhibit F), and a CDC release of COVID-19 Vaccine Related Codes (Exhibit E), **that the FDA regulated product labeled COMIRNATY is the only FDA licensed SARS-CoV-2 vaccine** (A true and correct copy of the NIH press release is attached hereto as Exhibit F) **but it is not yet available for use in the U.S.** In the FDA letters dates September 22, 2021 and October 20, 2021 (both cited above), the FDA expressly states: "Although COMIRNATY (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, **there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA**." (emphasis added).

27. As stated in the CDC COVID-19 Vaccine Related Codes document (Exhibit E), "**COMINARTY products are not orderable at this time. NDCs are listed per FDA Structured Product Label (SPL) document for the BLA licensed product. These codes are not included in CDC Vaccine Code Set files at this time. Pfizer has provided the following statement regarding the COMINARTY branded NDCs and labels:** 'Pfizer received FDA BLA license on 8/23/2021 for its COVID-19 vaccine for use in individuals 16 and older (COMIRNATY). 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. **At present, Pfizer does not plan to produce any product with these new NDCs and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution. As such, the CDC, AMA, and drug compendia may not publish these new codes until Pfizer has determined when the product will be produced with the BLA labels**.'" (Exhibit E) (first bolding in original, second bolding emphasis added).

28. On September 13, 2021, the NIH published the identical Pfizer statement: "**At present, Pfizer does not plan to produce any product with these new NDCs and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution. As such, the CDC, AMA, and drug compendia may not publish these new codes until Pfizer has determined when the product will be produced with the BLA labels**." (Exhibit. F) (emphasis added).

29. Based on all information available to me, it is my expert opinion that **none** of the SARS-CoV-2 vaccines currently available in the U.S. are FDA approved and licensed for use. All doses currently available (Pfizer-BioNTech, Moderna, and Johnson & Johnson) are experimental medical products made available as such by the FDA and the Department of Health and Human Services under the Emergency Use Statutes and Authorizations (EUA). Under the EUA, and the FDA Fact Sheets for Pfizer-BioNTech, Moderna, and Johnson & Johnson, individuals have the "option to accept or refuse" the products.

VERIFICATION

I, Robert Malone, MD, MS, am over the age of eighteen years and a Declarant in this action. The statements and allegations that pertain to me or which I make in this DECLARATION are true and correct, and based upon my personal knowledge (unless otherwise indicated). If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

Dated: November 9, 2021

Robert Malone, MD, MS

EXHIBIT A

Robert W. Malone, MD, MS
Madison, VA 22727
rwmalonemd@gmail.com
(434) 979-0090

PROFESSIONAL EXPERIENCE

The original inventor of mRNA and DNA vaccination technologies (1989); including in-vitro and in-vivo RNA transfection. Dr. Malone is a specialist in clinical research, medical affairs, regulatory affairs, project management, proposal management (large grants and contracts), vaccines and biodefense. This includes writing, developing, reviewing and managing vaccine, bio-threat and biologics clinical trials and clinical development strategies. He has been involved in developing, designing, and providing oversight of approximately forty phase 1 clinical trials and twenty phase 2 clinical trials, as well as five phase 3 clinical trials. He has served as medical director/medical monitor on both phase 1, phase 2 and phase 3 clinical trials, including those run at a well-known vaccine-focused Clinical Contract Research Organizations. He has served as principal investigator on some of these. Examples of his infectious disease pathogen advanced (clinical phase) development oversight experience include HIV, Influenza (seasonal and pandemic), Plague, Anthrax, VEE/EEE/WEE, Tularemia, Tuberculosis, Ebola, Zika, Ricin toxin, Botulinum toxin, and Engineered pathogens. In many cases, this experience has included vaccine product development, manufacturing, regulatory compliance, and testing (manufacturing release and clinical) aspects. In most cases, his oversight responsibilities have included clinical trial design, regulatory and ethical compliance, and laboratory assay strategy, design, testing and performance.

Dr. Malone has a history of assembling and managing expert teams that focus on solving complicated biodefense challenges to meet US Government requirements. He was instrumental in enabling the PHAC/rVSV ZEBOV ("Merck Ebola") vaccine to move forward quickly towards BLA and (now recently granted) licensure. Dr. Malone got the project on track in support of DoD/DTRA and NewLink Genetics, recruited organizations to team with USAMRIID/WRAIR to develop the immunoassays, put WHO and Norwegian government philanthropic leadership in touch with Pentagon leadership to expedite the initial WRAIR clinical and ring vaccination trials, recruited a management team, recruited Merck vaccines to purchase the product candidate from NewLink, helped write and edit the clinical trials developed by the World Health Organization and lead the development of the BARDA and DTRA contracts - yielding over 200M$ in resources. Dr. Malone's early involvement in this project allowed for the Merck vaccine to be developed very rapidly.

Currently, Dr. Malone is leading a large team since January 10, 2020, focused on clinical research design, drug development, computer modeling and mechanisms of action of repurposed drugs for COVID-19 treatment. This work has included multiple manuscripts summarizing most recent findings relating to famotidine and overall insights into the mechanism of COVID-19 disease, and others focused on celecoxib and famotidine are being reviewed for publication. He has developed and wrote the initial clinical trial design: A Single Center, Randomized, Double Blinded Controlled Crossover Observational Outpatient Trial of the Safety and Efficacy of Oral Famotidine for the Treatment of COVID-19 in Non-Hospitalized Symptomatic Adults. Another project he has been involved with is a DTRA/DOMANE-funded development and performance of a virtual outpatient clinical trial designed to test new monitoring and data capture technology while using COVID19 as a live-fire example. He has helped open two IND for famotidine and celecoxib use for treatment and prevention of COVID19 disease including an associated

drug master file, and has enabled teaming/pharmaceutical supply arrangements with two major pharmaceutical firms.

Dr. Malone is an internationally recognized scientist and is the original inventor of mRNA Vaccination, DNA Vaccination, and multiple non-viral DNA and RNA/mRNA delivery technologies. Dr. Malone holds numerous fundamental domestic and foreign patents in the fields of gene delivery, delivery formulations, and vaccines: including DNA and RNA/mRNA vaccines. His expertise includes virology, immunology, molecular biology, pathology and pharmacology.

Scientifically trained at UC Davis, UC San Diego, and at the Salk Institute Molecular Biology and Virology laboratories, Dr. Malone received his medical training at Northwestern University (MD) and Harvard University (Clinical Research Post Graduate Fellowship) medical schools, and in Pathology at UC Davis.

He has extensive research and development experience (bench to bedside) in the areas of pre-clinical discovery research, clinical trials, vaccines, gene therapy, bio-defense, repurposing drugs for infectious diseases, high throughput screening and immunology. He has over twenty years of management and leadership experience in academia, pharmaceutical and biotechnology industries, as well as in governmental and non-governmental organizations. He often serves as study section chairperson for NIAID contract study sections relating to biodefense medical product development. He is currently a topic editor for the journal Frontiers in Pharmacology, in the area of "Treating COVID-19 With Currently Available Drugs."

Dr. Malone has approximately 100 peer-reviewed publications and published abstracts and has about 12,000 citations of his peer reviewed publications and patents, as verified by Google Scholar. His google scholar ranking is "outstanding" for impact factors. He has been an invited speaker at over 50 conferences, has chaired numerous conferences and he has sat on or served as chairperson on numerous NIAID and DoD study sections.

SUMMARY OF ACCOMPLISHMENTS / SKILLS

- Inventor of mRNA and DNA vaccination.
- Inventor of lipid mediated and naked mRNA delivery (transfection).
- Inventor of in-vivo electroporation (particularly for skin delivery).
- A senior executive and scientist with a highly successful track record of leading bench and discovery research through FDA Phase I, II, and III clinical trials, protocol development and submission, and related regulatory submissions including pIND and IND.
- Significant expertise in drug development and delivery.
- Specialist in Medical Affairs.
- Special in Regulatory Affairs.
- Domestically trained, Maryland Licensed Physician/Scientist.
- Experienced capturing and managing large federal contracts (including BARDA) with over 9 billion in ID/IQ awards and almost a billion USD in government contracts won and/or managed in the last decade.
- Expertise in pathology, infectious disease, pandemic clinical trials, influenza, regulatory affairs, project management, biodefense, HIV and Ebola. A verified list of capture is available upon request.
- Significant expertise with federal contracting, grants, international NGO health related research and development coupled with professional relationships at CDC, DoD, HHS (BARDA, CDC, FDA and NIAID).
- Prior and current service on many federal study sections and oversight boards involving infectious disease, vaccine, and biodefense.
- Experienced and formally trained as a Business Development Professional, project manager, capture/proposal manager, color team reviewer and editor for projects valued from 10M$ up to 1B$ US, with experience managing processes and teams in a wide variety of non-profit and for-profit corporate cultures including both matrix and traditional environments.
- Highly skilled in fostering a culture of innovative problem solving within project teams.
- DoD Secret Clearance authorized.
- Expert witness experience, with extensive training from some of the top attorneys/law firms in the USA.
- Rated outstanding for impact factors, by Google scholar.
- Graduated from the Harvard Medical School Global Clinical Scholars Research Training Program with distinction, a year-long program focused on international clinical research. This program combines on-site (London & Boston) as well as distance learning, with an average of 15h per week lecture and practicum exercises.

RW Malone MD, LLC
CEO and Principal Consultant: 2001-Present

Dr. Malone has been involved in developing, designing, and providing oversight of approximately forty phase-1 clinical trials and twenty phase-2 clinical trials, as well as five phase 3 clinical trials. He has served as medical director/medical monitor on approximately forty phase-1 clinical trials, and on twenty phase-2 clinical trials, including those run at vaccine-focused Clinical Research Organizations. He has served as principal investigator on some of these. Providing business development, proposal management, clinical trials development, expert witness, regulatory and medical affairs support for pharmaceutical, vaccines-related and biologics companies as well as related regulatory submissions including pIND and IND.

Projects include:

- Working with Reliance Life Sciences (India) to develop RelCovax™, a second-generation multivalent SARS-CoV-2 vaccine candidate designed to meet global vaccination demands. 2020-present.
  Led a large team since January 10, 2020, focused on drug development, computer modeling and mechanisms of action for COVID-19 and is now preparing a manuscript summarizing most recent findings relating to famotidine and overall insights into the mechanism of COVID-19 disease.
- Accelerated COVID-19 Therapeutic Interventions and Vaccines:
  ACTIV Therapeutics Clinical Working Group, NIH. Invited Participant. June, 2020-present.
- Clinical trials protocol development: Developed and wrote initial clinical trial design: A Single Center, Randomized, Double Blinded Controlled Crossover Observational Outpatient Trial of the Safety and Efficacy of Oral Famotidine for the Treatment of COVID-19 in Non-Hospitalized Symptomatic Adults.
- Proposed is a DOMANE/WRAIR joint development and performance of outpatient clinical trial designed to test new monitoring and data capture technology while using COVID19 as a live-fire example.
- Opening IND for famotidine use for treatment and prevention of COVID19 disease with associated drug master file.
- Principal Regulatory Consultant, Clinical Network Services (CNS)/Novotech, 2018-2019. Regulatory, clinical and business development support.
- Served as an expert witness with specialized training, 2017 - present.
- Ebola vaccine project for NewLink/Bioprotection Systems (rVSVdG ZEBOV Ebola vaccine project), resulting in well over 100M USD non-dilutive capital to NL/BPS. This also included working with the World Health Organization as well as initial set up of the licensing deal to Merck Vaccines of the Ebola vaccine.
- Served as Medical Director, Beardsworth, half time position on retainer, 2010 – 2013.
- Service on federal biotechnology/vaccines proposal study sections (multiple).
- Served as Editor-In-Chief of Journal of Immune Based Therapies and Vaccines 2007-2012
- Service on Safety Monitoring Committee, Phase 1 safety/immunogenicity of novel Influenza vaccine
- Consulting support for multiple vaccine-focused clinical sites in US and Latin America.
- Served as Medical Director, Vaccines with Accelovance, Inc. (2008 – 2009).
- Served as medical monitor for multiple seasonal and pandemic (H1N1) studies.

- Review and edit clinical protocols.
- Examples of multi-year contract clients include Accelovance, Alchem Laboratories, Avancer, Beardsworth, Chesapeake Perl, Corium, DOAR, ITS, ITT-Exelis, EpiVax, Jean Brown Research, Opgen, Quest Diagnostics (Focus), PaxVax, SAI, Soligenix, TASC, Univ of MA.
- Commercial intelligence work for two of the largest pharmaceutical companies in the world (sub-contractor).
- Partnering with Galloway and Associates (Darrell Galloway) 2012-2014.
- Acting as *Managing Director, Clinical Development and Government Affairs* for the Avancer Group. April 2012 – 2016.
- Proposal development (patch-based vaccine delivery, Tularemia vaccine, CDC contract for clinical trials site development, international government and NGO contract and grant solicitations) – Aeras Global TB Vaccine Foundation 2003-2005.
- Proposal development (plague vaccine- HHS), Technical diligence – VaxGen Corporation.
- Consulting services for EpiVax, 2005-2018 (member, Scientific Advisory Board), 2020.
- Consulting services for Aldevron, LLC.
  2001-2005 (operating as Gene Delivery Alliance).
- Business and proposal development in the areas of Bioinformatics and Life Sciences (including telemedicine) and research at the University of Bern, Switzerland.
- Consulting services for Molecular Histology, Inc. with the title of Medical Director.
- Collaboration with Inovio, including incorporation of company in the USA.
- Consulting services for MSD, Inc. for business/ technology development planning.

Alchem Laboratories
Chief Medical Officer

This position was as a consultant, but then full time FTE. Consulting for Alchem and/or its CEO: 2012 – 2019. CMO 11/2019 to 4/2020.

- Led a high through-put screening and research team for drug development 2019-2020.
- Dr. Malone began modeling and focusing on the Plpro (papain-like protease) and Mpro (main protease) of then novel coronavirus (now SARS-CoV-2) using computational tools including Modeller to generate homology-modeled crystal structures for the SARS-CoV-2 Plpro and Mpro. Which generated a candidate list for COVID-19, which was reduced to a few candidates, based on binding sites, safety, licensure, efficacy, bioavailability of drug candidates.
- Lead the discovery and development of famotidine for the Treatment of COVID-19.
- Technical Lead/writer for funded full proposal under BAA-18-100-SOL-00003 Amendment 15 entitled: "A Multi-site, Randomized, Double-Blind, Multi-Arm Historical Control, Comparative Trial of the Safety and Efficacy of Hydroxychloroquine, and the Combination of Hydroxychloroquine and Famotidine for the Treatment of COVID-19 in Hospitalized Adults."
- Developed and wrote initial clinical trial design for a comparative trial of the safety and efficacy of hydroxychloroquine, and the combination of hydroxychloroquine and famotidine for the treatment of COVID-19 in hospitalized adults.

Atheric Pharmaceutical, LLC
CEO, and Co-founder.
Feb 2016-Dec 2017. Atheric™ Pharmaceutical LLC was a biopharmaceutical company focused on the rapid development and commercialization of re-purposed drugs to prevent and treat Zika and other Flavivirus disease. Optimization of high through-put screening techniques for anti-viral drug development.

Kennesaw State University
Adjunct Associate Professor 2009-2013

Beardsworth Consulting Group, Inc
Medical Director, Vaccines (RW Malone MD, LLC under contract to Beardsworth)
2010-2013
Dr. Malone functioned as the in-house medical vaccine expert for medical monitoring and Scientific Liaison

- Medical liaison to investigator sites including oversight of clinical monitoring
- Provided medical monitoring input including CRF review, 24x7 accessibility to site personnel, assess enrollment waiver requests, SAE review, etc.
- Safety Officer and Medical Representative on project teams
- Medical consultant to clients
- Business development/proposal writing/government contracting

Solvay Pharmaceuticals, Inc (currently Abbvie)
Director, Clinical Development & Medical Affairs, Influenza 2006-2008
Led an extended clinical team (both internal and CRO components), providing project and clinical trials management oversight, serving as primary author on clinical protocols, strategic documents including clinical development plans, DSMB/SMC charters, and all clinical documents required to support IND filing. Support and review of outcomes including safety data assessment
Generated and managed cost projections and budgetary oversight, providing strategic management and serving as a communication hub for clinical aspects of a $300 million USD federal contract to develop and license a cell-based influenza vaccine
Solvay's US Government contract for cell-based influenza vaccine was terminated around the end of 2007. At which point the cell-based influenza vaccine project was dissolved.

Summit Drug Development Services
Senior Medical Director 2005-2006
Directed due diligence assessments and strategic drug development planning and prepared regulatory submissions and implemented, monitored, and analyzed clinical trials for clients (oncology, vaccines, biologicals, cell/stem cell therapies). Primary author of three pIND, two IND, an Appendix M submission. Served as proposal manager and primary author for a 129M USD federal contract submission focused on pandemic influenza.

AERAS Global TB Vaccine Foundation
Director, Business Development and Program Management 2004-2005
Initially serving as consultant, provided leadership primarily focused on tuberculosis vaccine development and proposal development to NGO (B&M Gates), USG (CDC, NIH, DoD).

Dynport Vaccine Company, LLC
Associate Director, Clinical Research 2002-2003

- Served as liaison between product development teams and clinical research support groups.
- Prepared planning documents and product development plans.
- Participated in and supported safety review and assessment of smallpox vaccine product.
- Identified new technologies relevant to product development teams, facilitating integration of same in product development plans.
- Created documents for clinical trials including investigator brochures. Prepared proposal solicitations, technical review of subcontractor proposals. Performed technical review of potential subcontractors, new technologies.
- Assisted business development group in strategic evaluation and planning concerning new business opportunities and managed in-house Publication.

Intradigm, Corp
Co-Founder (one of three co-founders), CSO, Board of Director Member 2000-2001
Intradigm was a biotechnology company that develops gene therapeutic technology based on RNA interference. Intradigm merged with Silence Technologies in 2009 and the merged company is now publicly traded. Silence Technologies is involved in developmental research of targeted RNAi therapeutics for the treatment of serious diseases.
Dr. Malone co-founded and helped to secure $2.3 million in V.C. funding, including monies from the Novartis Venture Fund, ETP Venture Capital Fund and the State of Maryland. Performed facilities set-up, infrastructure set-up and Intellectual Property Development. Business and technology development planning, including in-depth business and scientific plan.

Uniformed Services University of the Health Sciences
Dept of Surgery, Clinical Breast Care Program (CBCP) through the Henry M. Jackson Foundation
Adjunct Associate Professor
Chief of Laboratory Science and Director of Tissue Banking 2000-2001

- Worked closely with architect firm to design space, set-up laboratory facilities for the Clinical Breast Care Project, including new facilities design (tissue banking facilities, laboratory, animal rooms, animal surgical suite, office suites) at USUHS and Windber Medical Center, PA
- Hired faculty, technicians, staff for CBCP at both sites, including writing and initiating job descriptions, job interviews, hiring decisions, set-up for re-locations
- Laboratory Supervisor: Tissue banking immunology, cell culture, gene transfer, genetic vaccination research, animal research.

University of Maryland, Baltimore School of Medicine, Dept. of Pathology
Assistant Professor 1997-2000
Set-up and ran successful research laboratory in immunology (genetic vaccination) and gene transfer.

University of California, Davis Department of Medical Pathology
1991-1997
Assistant Professor 1993-1997
Director and Founder, Gene Therapy Program (pulmonary, dermal, heart, liver, mucosal and parenteral vaccines).
Research Fellow, Pathology Resident 1991-1993

Vical, Inc
Research Scientist 1989

- Set up Vical's molecular biology laboratory.
- Initiated and carried out research in non-viral gene therapy and DNA vaccination.
- Inventor of "naked DNA" gene therapy. (see issued patents for details).
- Inventor of DNA vaccination (see issued patents for details).
- Inventor of "mRNA" gene therapy. Salk institute.
- Inventor of mRNA vaccination. Salk institute.
- Inventor of "mRNA as a drug" or "transient gene therapy", terms both coined by Dr. Malone. Salk Institute.

LICENSURE / CERTIFICATIONS
Physician and Surgeon, State of Maryland License 1997-present. #DOO55466

BOARD OF DIRECTOR POSITIONS:
Discovery Cure, Inc. Founding Board of Director. 2018-2020
Epivax, Scientific Advisory Board, 2012-2019.

EDUCATION

- **HARVARD MEDICAL SCHOOL** *Global Clinical Scholars Research Training Program (fellowship)* A year-long comprehensive program that combines on-site (London, Boston) and distance learning, with an average of 15h per week lecture and practicum exercises. 2015-2016. Graduation with distinction (top 5% of graduating class).

- **UNIVERSITY OF CALIFORNIA, DAVIS:** RESEARCH FELLOWSHIP, 1992 – 1993
  Postgraduate Fellowship Award

- **UNIVERSITY OF CALIFORNIA, DAVIS MEDICAL CENTER**: 1992
  Clinical Pathology Internship

- **NORTHWESTERN UNIVERSITY MEDICAL SCHOOL**: 1991
  Doctor of Medicine

- **UNIVERSITY OF CALIFORNIA, SAN DIEGO**: 1988
  Master of Science, Biology

- **UNIVERSITY OF CALIFORNIA, DAVIS**: 1984
  Bachelor of Science, Biochemistry

TEACHING EXPERIENCE

Kennesaw State University
Associate Professor:
BTEC 4490 Experimental Design and Analysis (2009): Survey course focused on advanced product development and regulatory aspects of biotechnology and vaccines products.
University of Maryland, Medical School
Assistant Professor:
Fundamentals of Molecular Biology (Graduate Course, Winter 2000)
Host defenses and Infectious Diseases, small group instructor Year 2 Medical School core curriculum. 1998, 1999
University of California, Davis
Assistant Professor:
MD 410A/410B. General Systemic Pathology (1992, 1993, 1994, 1995, 1996)
PTX 202. Principles of Pharmacology and Toxicology-Lecturer (1995, 1996)
BCM 214-414. Molecular Medicine-Lecturer (1995, 1996)
IM 295 Cytokines-Lecturer (1996), IDI 280. Molecular Basis of Disease-Lecturer (1996)
University of California, San Diego
Biology 111. Cell Biology (Fall 1988). Teaching Assistant under Dr. M. Montal
Biology 123. Embryology laboratory (Spring 1988). Teaching Assistant under Dr. C.Holt
Santa Barbara City College
Computer Laboratory (Spring 1981) Teaching Assistant

PROFESSIONAL OFFICES AND MEMBERSHIPS

- Royal Society of Medicine, Fellow 2021-Present.
- Harvard Medical School Alumni, 2016- present.
- American Society of Tropical Medicine and Hygiene Member (ASTMH): 2016-2018.
- Virginia Bio: 2016-2018
- IEEE Genomics and Bioinformatics Working Group Member: 2002
- Northern Virginia Technology Council BioMedTech Committee: Co-chair: 2002 – 2003
- Intradigm, Corp. – a new start-up from Novartis, Inc.: Scientific Advisory Board: 2000 – 2001
- Novartis, Inc. (GTI/Systemix & Pharmacokinetics): Scientific Advisory Board and External Portfolio Reviewer: 1999 – 2001
- University of Maryland, Medical School: Pathology Education Policy Committee: 1999 – 2000
- UC Davis:
  - Education Policy Committee Graduate Group in Comparative Pathology: 1996 – 1/1997
  - Member, Biochemistry and Molecular Biology Graduate Group: 1993 – 1/1997
  - Member, Comparative Pathology Graduate Group: 1995 – 1/1997
- Boehringer Mannheim: Scientific Advisory Board: 1992 – 1993

EDITORIAL BOARDS

- Topic Editor, Frontiers in Pharmacology (Respiratory Pharmacology): "Treating COVID-19 with Currently Available Drugs," 2020-2021.
- Editor-In-Chief, Journal of Immune Based Therapies and Vaccines. 2009 – 2012, Editor: 2012.
- Gene Therapy/Molecular Biology International Society. 1997 – 2014.
- Reviewer for: Numerous peer-reviewed journals on infectious disease, public health 2016 to present.
- Nucleic Acids Research: 2001 – 2002.
- Molecular Therapy: 1999 – 2001.

ACADEMIC HONORS

- Harvard Medical School, Global Clinical Scholar Post Graduate: graduation with distinction (top 5% of graduating class).
- "DNA Vaccine" Recognizes Robert W. Malone, MD, MS, 2013.
- Trainee Investigator Award, American Federation for Clinical Research: 1993.
- Bank of America – Giannini Foundation Medical Research Fellow: 1992 – 1993.
- Henry Christian Award for Excellence in Research, American Federation for Clinical Research: 1992.
- UCDMC Medical Scholars Grant: 1992 – 1993.
- DNA and RNA Transfection and Vaccination (Abstract). First Place, Northwestern AOA Research Symposium Competition for Medical Students: 1989.
- USPHS Pre-Doctoral Fellowship: 1986 – 1988.
- San Diego Supercomputer Grant for RNA Structure Modeling: 1988.
- Northwestern University MD/ PhD Scholarship: 1984 – 1986.
- Dean's List, UC Davis: 1982 – 1984.
- President's Undergraduate Fellowship Grant for Investigation of Oncogene Expression in Breast Tumor Tissue: 1983 – 1984.
- Edmonson Summer Fellowship, Department of Pathology, UC Davis Medical School: 1984.

PATENTS ISSUED:

1. Lipid-mediated polynucleotide administration to deliver a biologically active peptide and to induce a cellular immune response. Assigned to Vical, Inc and licensed to Merck. No. 7,250,404, date of issue: 7/31/07. Priority date 3/21/1989. **Citations: 105 articles.**
2. Lipid-mediated polynucleotide administration to reduce likelihood of subject's becoming infected. Assigned to Vical, Inc and licensed to Merck. US Pat. Ser. No. 6,867,195 B1, date of issue: 3/15/05. Priority date 3/21/1989.
3. Generation of an immune response to a pathogen. Assigned to Vical, Inc and licensed to Merck. US Pat. Ser. No. 6,710,035, date of issue: 3/23/04. Priority date 3/21/1989. **Citations: 37 articles.**

4. Expression of exogenous polynucleotide sequences in a vertebrate, mammal, fish, bird or human Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 6,673,776, date of issue: 1/6/04. Priority date 3/21/1989.
5. Methods of delivering a physiologically active polypeptide to a mammal. Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 6.413.942, date of issue: 7/2/02. Priority date 3/21/1989. **Citations: 150 articles.**
6. Induction of a protective immune response in a mammal by injecting a DNA sequence (includes mRNA). Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 6,214,804, date of issue: 4/10/01. Priority date 3/21/1989. **Citations: 359 articles.**
7. DNA vaccines for eliciting a mucosal immune response (includes mRNA). US Pat. Ser. No. 6,110,898, date of issue: 8/29/00. Priority date 1996. **Citations: 40 articles.**
8. Formulations and methods for generating active cytofectin: polynucleotide transfection complexes. US Pat. Ser. No. 5,925,623 7/20/99.
9. Cationic Transport Reagents. US Pat. Ser. No. 5,892,071 issued 4/06/99.
10. Polyfunctional cationic cytofectins, formulations and methods for generating active cytofectin: polynucleotide transfection complexes. US Pat. Ser. No. 5,824,812 issued 10/20/98.
11. Cationic Transport Reagents. US Pat. Ser. No. 5,744,625 issued 4/28/98.
12. Generation of antibodies through lipid mediated DNA delivery. Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 5,703,055, date of issue: 12/30/97. Priority date 3/21/1989. **Citations: 463 articles.**
13. Induction of a protective immune response in a mammal by injecting a DNA sequence (includes mRNA). Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 5,589,466, date of issue: 12/31/96. Priority date 3/21/1989. **Citations: 889 articles.**
14. Delivery of exogenous DNA sequences in a mammal (includes mRNA). Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 5,580,859, date of issue: 12/3/96. Priority date 3/21/1989. **Citations: 1234 articles.**
15. Cationic Transport Reagents. US Pat. Ser. No. 5,527,928, date of issue: 6/18/96.

Of note: Cationic Lipid-Mediated RNA and DNA Transfection ("RNA as a Drug). 1988 patent application, Salk institute assignee, patent abandoned without inventor permission or knowledge. Inventor: Robert Malone. Available upon request.

PUBLICATIONS (selected)

COVID-19 Disease, Women's Predominant Non-Heparin Vaccine-Induced Thrombotic Thrombocytopenia and Kounis Syndrome: A Passepartout Cytokine Storm Interplay. Kounis, N.G.; Koniari, I.; … Malone, R.W. *Biomedicines* 2021, *9*, 959. https://doi.org/10.3390/biomedicines9080959

Famotidine and Celecoxib COVID-19 Treatment Without and With Dexamethasone; Retrospective Comparison of Sequential Continuous Cohorts, Submitted to Nature, Scientific Reports, May 2021. Robert W Malone, Kevin M Tomera, Leo Egbujiobi, Joseph K Kittah
Preprint at Research Square https://www.researchsquare.com/article/rs-526394/v1

More Than Just Heartburn: Does Famotidine Effectively Treat Patients with COVID-19? Malone RW. Dig Dis Sci. 2021 Feb 24:1–2. doi: 10.1007/s10620-021-06875-w. PMID: 33625612; PMCID: PMC7903029.

COVID-19: Famotidine, Histamine, Mast Cells, and Mechanisms.
Malone RW, et. al. Frontiers in Pharmacololgy, 23 March 2021. https://doi.org/10.3389/fphar.2021.633680
Cited in 46 articles.

COVID-19: Famotidine, Histamine, Mast Cells, and Mechanisms.
Malone RW, et al DO.Res Sq. 2020 Jun 22:rs.3.rs-30934. doi: 10.21203/rs.3.rs-30934/v2. Preprint.PMID: 32702719 https://www.researchsquare.com/article/rs-30934/v2 Cited in 26 articles.

Hospitalized COVID-19 Patients Treated With Celecoxib and High Dose Famotidine Adjuvant Therapy Show Significant Clinical Responses (July 8, 2020). Tomera, K, Malone, R and kittah, J.
Available at SSRN: https://ssrn.com/abstract=3646583 or http://dx.doi.org/10.2139/ssrn.3646583
Cited in 10 articles.

Medical Countermeasures Analysis of 2019-nCoV and Vaccine Risks for Antibody-Dependent Enhancement (ADE). Ricke, D.O.; Malone, R.W. Preprints 2020, 2020030138 (doi: 10.20944/preprints202003.0138.v1). May, 2020
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3646583 Cited in 32 articles.

Molecular evolution of Zika virus as it crossed the Pacific to the Americas. Schneider AB, Malone RW, et al. Cladistics. 2017; 12: 10.1111/cla.12178

Zika Virus: Medical Countermeasure Development Challenges. Malone RW, et al. PLoS Negl Trop Dis. 2016;10(3):e0004530. **Citations: 212 articles.**

Zika Fetal Neuropathogenesis: Etiology of a Viral Syndrome. Klase ZA, Khakhina S, Schneider Ade B, Callahan MV, Glasspool-Malone J, Malone R. PLoS Negl Trop Dis. 2016;10(8):e0004877. **Citations: 97 articles.**

Antibody mediated epitope mimicry in the pathogenesis of Zika virus related disease. Homan J, Malone RW, et al. BioRxiv. 2016.

Making vaccines "on demand": a potential solution for emerging pathogens and biodefense? De Groot AS, Einck L, Moise L, Chambers M, Ballantyne J, Malone RW Hum Vaccin Immunother. 2013;9(9):1877-84.

Electroporation enhances transfection efficiency in murine cutaneous wounds. Byrnes CK, Malone RW, et al. Wound Repair Regen. 2004;12(4):397-403.

DNA transfection of macaque and murine respiratory tissue is greatly enhanced by use of a nuclease inhibitor. Glasspool-Malone J, …, Malone RW. J Gene Med. 2002;4(3):323-2.

Marked enhancement of macaque respiratory tissue transfection by aurintricarboxylic acid. Glasspool-Malone J, …, Malone RW. Gene Med. 2002;4(3):323-2.

Enhancing direct in vivo transfection with nuclease inhibitors and pulsed electrical fields. Glasspool-Malone J, Malone RW. In Gene Therapy Methods: Methods Enzymol. 2002;346:72-91

Cutaneous transfection and immune responses to intradermal nucleic acid vaccination are significantly enhanced by in vivo electropermeabilization. Drabick JJ, Glasspool-Malone J, …, Malone RW. Mol Ther. 2001;3(2):249-55. Citations: 192 articles.

Theory and in vivo application of electroporative gene delivery. Somiari S, Glasspool-Malone J, … Malone RW. Mol Ther. 2000;2(3):178-87. Citations: 345 articles.

Nucleic acid vaccination with a single SIV can protect rhesus macaques from oral challenge with pathogenic SIVMAC239. Gary Rhodes, … Robert Malone, et al. *Journal of Medical Primatology* 29.3-4 (2000).

Efficient nonviral cutaneous transfection. Glasspool-Malone J, …, Malone RW. Mol Ther. 2000;2(2):140-6. Citations:138 articles.

Transfer and expression of foreign genes in mammalian cells. Colosimo A, …, Malone RW, et al. Biotechniques. 2000;29(2):314-8, 20-2, 24 passim. Citations: 188 articles.

Specific inhibition of macrophage TNF-alpha expression by in vivo ribozyme treatment. Kisich KO, Malone RW, …, Erickson KL. J Immunol. 1999;163(4):2008-16. Citations:131 Articles.

Marked enhancement of direct respiratory tissue transfection by aurintricarboxylic acid. Glasspool-Malone J, Malone RW. Hum Gene Ther. 1999;10(10):1703-13

Developing dendritic cell polynucleotide vaccination for prostate cancer immunotherapy. Berlyn KA, …, Malone RW J Biotechnol. 1999;73(2-3):155-79

Models of Cationic Liposome Mediated Transfection. Gene Therapy and Molecular Biology. Ahearn A, Malone RW. Vol 4. Gene Therapy and Molecular Biology 1999;4

Feline dendritic-like cells: Isolation, culture, and genetic modification using monocytic precursors. Malone, J. G., Watts, T. L., Hale, A., & Malone, R. W. (1998, January). In *JOURNAL OF LEUKOCYTE BIOLOGY* (pp. 63-63): FEDERATION AMER SOC EXP BIOL.

Mucosal immune responses associated with polynucleotide vaccination. Malone JG, …, Malone RW. Behring Inst Mitt. 1997(98):63-72

Delivery of exogenous DNA sequences in a mammal. P Felgner, …, R Malone, D Carson. Biotechnology Advances. 1997 15 (3-4), 763-763

Cationic lipid-mediated gene delivery to murine lung: correlation of lipid hydration with in vivo transfection activity. Bennett MJ, …, Malone RW, Nantz MH. J Med Chem. 1997;40(25):4069-78

Improved method for the removal of endotoxin from DNA. Montbriand PM, Malone RW. J Biotechnol. 1996;44(1-3):43-6. Citations: 43 articles

Toxicity of cationic lipid-ribozyme complexes in human prostate tumor cells can mimic ribozyme activity.Freedland SJ, Malone RW, et al. Biochem Mol Med. 1996;59(2):144-53

Considerations for the design of improved cationic amphiphile-based transfection reagents. Bennett MJ, …, Malone RW. Journal of Liposome Research 1996;6(3):545-65

Escherichia coli beta-glucuronidase and Photinus pyralis luciferase reporter. Ayar, S. F., & Malone, R. W. (1996, November). In *CLINICAL CHEMISTRY* (Vol. 42, No. 11, pp. 35-35).

Structural and functional analysis of cationic transfection lipids: the hydrophobic domain. Balasubramaniam RP, …, Malone RW. Gene Ther. 1996;3(2):163-72. Citations: 172 articles.

The counterion influence on cationic lipid-mediated transfection of plasmid DNA.Aberle AM, Bennett MJ, Malone RW, Nantz MH. Biochim Biophys Acta. 1996;1299(3):281-3

Direct gene transfer into mouse muscle in vivo. N Shafee, ..., RW Malone, et al. International Journal of Virology 2 (1), 33-38

A flexible approach to synthetic lipid ammonium salts for polynucleotide transfection. MJ Bennett, RW Malone, MH Nantz. Tetrahedron letters 36 (13), 2207-2210

Tfx-50 Reagent, a new transfection reagent for eukaryotic cells. Schenborn E, …, Malone RW, et al. 1995

Hepatic gene expression after direct DNA injection. Hickman MA, Malone RW, et al. Advanced Drug Delivery Reviews. 1995;17(3):265-71

Ribozyme and messenger-RNA delivery using cationic liposomes RW MALONE 1995/1/5 Conference JOURNAL OF CELLULAR BIOCHEMISTRY Pages 206 Publisher WILEY-LISS

Cholesterol enhances cationic liposome-mediated DNA transfection of human respiratory epithelial cells. Bennett MJ, …, Malone RW. Biosci Rep. 1995;15(1):47-53

Dexamethasone enhancement of gene expression after direct hepatic DNA injection. Malone RW, et al. J Biol Chem. 1994;269(47):29903-7

Gene expression following direct injection of DNA into liver. Hickman MA, Malone RW, et al. Hum Gene Ther. 1994;5(12):1477-83. Citations: 306 articles.

Cationic liposome-mediated RNA transfection. Dwarki VJ, Malone RW, Verma IM. Methods Enzymol. 1993;217:644-54. Citations: 88 articles.

Successful gene transfection of respiratory epithelium invitro using polyamine containing cationic lipids. CB Robinson, RW Malone, J Jessee, G Gebeyehu, R Wu AMERICAN REVIEW OF RESPIRATORY DISEASE 147 (4), A546-A546

Direct gene transfer into mouse muscle in vivo. Wolff JA, Malone RW, et al. Science. 1990;247(4949 Pt 1):1465-8. **Citations: 4,695 articles.**

Cationic liposome-mediated RNA transfection. Malone RW, Felgner PL, Verma IM. Proc Natl Acad Sci U S A. 1989;86(16):6077-81. **Citations: 717 articles.**

mRNA Transfection of cultured eukaryotic cells and embryos using cationic liposomes. Malone RW. Focus. 1989;11:61-8

High levels of messenger RNA expression following cationic liposome mediated transfection tissue culture cells. Malone R, Kumar R, Felgner P. NIH Conference: "Self-Cleaving RNA as an Anti-HIV Agent" (Abstract). Washington, DC June 1989.

A novel approach to study packaging of retroviral RNA by RNA transfection (Abstract). RW Malone, P. Felgner, I. Verma. RNA Tumor Viruses, May 17-18, 1988. Cold Spring Harbor

Mammary tumors in feral mice lacking MuMTV DNA. Gardner MB, Malone RW, …, Cardiff RD, et al. J Exp Pathol. 1985;2(2):93-8

Hyperplastic and neoplastic changes in the mammary glands of feral mice free of endogenous mouse mammary tumor virus provirus. Faulkin LJ, …, Malone RW, et al. J Natl Cancer Inst. 1984;73(4):971-82.

PUBLISHED ABSTRACTS: **Over 50 published**

CHAIRPERSON/ORAL PRESENTATIONS BY INVITATION: **Over 40 Invitations**
(Only the most recent events listed)

- Vaccines R&D, 2021. Keynote Speaker. September, 2021
- International Covid-19 Summit, Keynote speaker and chair. Rome, Italy, September, 2021
- Vaccines R&D, 2019. Keynote Speaker, Panel Moderator: Boston, MA. 18-20 November, 2019.
- Repurposing drugs for Infectious Disease Outbreaks. International Conference on Zika Virus. Washington, DC Feb 22-25, 2017 (Chairperson)
- Accelerated Discovery and Development of re-purposed licensed drugs for Zika virus outbreak antiviral prophylaxis and therapy. International Conference on Zika Virus. Washington, DC Feb 22-25, 2017. (Oral Presentation)
- Zika Virus: Accelerating Development of Medical Countermeasures by Re-purposing Licensed Drugs. Bridging the Sciences: Zika Virus. Emery, Atlanta, GA 1-3 May, 2016. (Oral Presentation)

- Speaker/Round table- Zika virus: Challenges for Medical Countermeasure Development. World Vaccine Conference. Washington, DC. 29-31 March, 2016.

- The World Health Organization (WHO) Consultation for Zika Virus: Research and Development. Presentation of Drug Development TPP. Geneva, Switzerland. 12-14 March, 2016. (Oral Presentation)

- Keynote Speaker: Ebola Vaccine in 12 months, Global Village, and the Need for Speed. Vaccines R&D, Baltimore, MD. 2-4 November, 2015. (Keynote Speaker)

- Current USG contracting Opportunities and Initiatives from the point of View of Vaccine Developers. World Vaccine Conference, Washington, DC. 24-26 March, 2014. (Oral Presentation)

- World Vaccine Conference, Washington, DC. 24-26 March, 2014 Preclinical and Clinical Vaccine Research. (Session Chair)

- PHEMCE Modeling Workshop "Operational Decision Making using Innovative Modeling, Analysis, and Visualization Tools", Sponsored by Deloitte. 2013 (Conference Co-Organizer and Coordinator/Oral Presentation)

- "Vaccine Production Strategies: Ensuring Alignment and Sustainability" The World Health Organization (WHO) Global Action Plan for Influenza Vaccines. Geneva, Switzerland. 12-14 July 2011 (Oral Presentation)

RECENT STUDY SECTIONS (selected):

- Accelerated COVID-19 Therapeutic Interventions and Vaccines:
  ACTIV Therapeutics Clinical Working Group, NIH. Invited Participant. June, 2020-present.
- Chairperson, NIH/NIAID/DMID Special Emphasis Panel, Development of Vaccines to Combat Antibiotic Resistant Bacteria September 2019.
- Chairperson, NIH/NIAID Special Emphasis Panel, December 2018.
- Reviewer, NIH/NIAID Special Emphasis Panel, December 2017.
- Chairperson and scientific reviewer for Department of Defense, U.S. Army Medical Research and Materiel Command, for "Congressionally Directed Medical Research Programs (DMRDP), 2012.
- Committee member and reviewer for NIH/NIAID Committee for Development of Technologies that Accelerate the Immune Response to BioDefense Vaccines. 2011
- Chair and reviewer for NIH/NIAID: Partnerships in Biodefense Immunotherapeutics. 2011
- NIH/NIAID Committee member and reviewer for Development of Technologies to Facilitate the Use of, and Response to Biodefense Vaccines," Special Emphasis panel. 2010
- Chairperson and scientific reviewer for NIH/NIAID Omnibus BAA 2017-1: Research Area 5 (N01) ZAI1-KP- M-C6 (Topic 5: Advanced Development of Vaccine Candidates for Biodefense and Emerging Infectious Diseases), September 2017.
- Scientific reviewer for NIH/NIAID Special Emphasis Panel/Scientific Review Group 2017/08 ZRG1 IMM-R (12) B (Non-HIV Microbial vaccines), June 2017.

- Chairperson and scientific reviewer for Department of Defense, U.S. Army Medical Research and Materiel Command, "CDMRP: Defense Medical Research & Development Program (DMRDP), 2012.
- Chairperson and scientific reviewer for NIH/NIAID Committee on Partnerships in Biodefense Immunotherapeutics, Fall 2011.
- Committee member and reviewer for NIH/ NIAID Committee for Development of Technologies that Accelerate the Immune Response to BioDefense Vaccines, Fall 2011.
- NIH/ NIAID Committee member and reviewer for Development of Technologies to Facilitate the Use of, and Response to Biodefense Vaccines," Special Emphasis panel, 2010.
- NIH Study Section K01 Breast Cancer Study Section: July 1997
- NIDDK Special Emphasis Panel Review Committee for Competing Continuation Program Project: April 1999 and April 1998
- NIAID Study Section "Innovative Grant Program for Approaches in HIV Vaccine Research": 1998

BOOKS AND BOOK CHAPTERS

- *Molecular Virology of COVID-19.* Glasspool-Malone, J, Malone RW. In "*COVID-19 for Health Care."* In press.

- Malone RW. *"Present and Future Status of Gene Therapy.' Intro Chapter in Advanced Gene Delivery: From Concepts to Pharmaceutical Products*." Editor: Allain Rolland. Harwood Academic Pub. 1998, republished 2014.

- *Enhancing direct in vivo transfection with nuclease inhibitors and pulsed electrical fields***.** Glasspool-Malone J, Malone RW. In *Gene Therapy Methods: Methods Enzymol.* 2002;346:72-91

- Malone RW. *"Toxicology of non-viral gene transfer".* Editor, Walsh B. In*: "Non-Viral Therapeutics: Advances, Challenges and Applications for Self-Assembling Systems*." IBC's Biomedical Library Series. (1996) 4.1

NATIONAL NEWSPAPER ARTICLES

Sorry Facebook, forced universal vaccinations are not the answer
All the science should be considered, not censored
Washington Times, September 1, 2021.
By: Dr. Robert Malone and Peter Navarro
https://www.washingtontimes.com/news/2021/sep/1/sorry-facebook-forced-universal-vaccinations-are-n/

Biden team's misguided and deadly COVID-19 vaccine strategy
Vaccination 'arms race' could prove dangerous to the American public
Dr. Robert Malone and Peter Navarro,
Washington Times, August 5, 2021.
https://www.washingtontimes.com/news/2021/aug/5/biden-teams-misguided-and-deadly-covid-19-vaccine-/
Online and print editions

NATIONAL PODCASTS AND DOCUMENTARIES

Dr. Malone has been featured on many TV shows and podcasts, including Fox News with Tucker Carlson, the War Room with Steve Bannon, Mercola, Glen Beck, Laura Ingraham, News Max, Russia Times, The Dark Horse Studio and dozens more. Please search Spotify or Apple Podcasts ("Robert Malone") for listings.

FDA U.S. FOOD & DRUG ADMINISTRATION

EXHIBIT B

September 22, 2021

Pfizer Inc.
Attention: Mr. Amit Patel
235 East 42nd St
New York, NY 10017

Dear Mr. Patel:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus Disease 2019 (COVID-19).[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.[2]

On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 for individuals 16 years of age and older pursuant to Section 564 of the Act. FDA reissued the letter of authorization on: December 23, 2020,[3] February 25, 2021,[4] May

[1] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the FD&C Act, 21 U.S.C. § 360bbb-3, February 4, 2020.

[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020).

[3] In the December 23, 2020 revision, FDA removed reference to the number of doses per vial after dilution from the letter of authorization, clarified the instructions for vaccination providers reporting to VAERS, and made other technical corrections. FDA also revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to clarify the number of doses of vaccine per vial after dilution and the instructions for reporting to VAERS. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers were revised to include additional information on safety monitoring and to clarify information about the availability of other COVID-19 vaccines.

[4] In the February 25, 2021 revision, FDA allowed flexibility on the date of submission of monthly periodic safety reports and revised the requirements for reporting of vaccine administration errors by Pfizer Inc. The Fact Sheet for Health Care Providers Administering Vaccine (Vaccination Providers) was revised to provide an update to the storage and transportation temperature for frozen vials, direct the provider to the correct CDC website for information on monitoring vaccine recipients for the occurrence of immediate adverse reactions, to include data from a developmental toxicity study, and add adverse reactions that have been identified during post authorization use. The Fact Sheet for Recipients and Caregivers was revised to add adverse reactions that have been identified during post authorization use.

10, 2021,[5] June 25, 2021,[6] August 12, 2021,[7] and on August 23, 2021, FDA approved COMIRNATY (COVID-19 Vaccine, mRNA)[8] and reissued the letter in its entirety for both Pfizer-BioNTech COVID-19 Vaccine and certain uses of COMIRNATY (COVID-19 Vaccine, mRNA).[9]

On September, 22 2021, having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA is reissuing the August 23, 2021 letter of authorization in its entirety with revisions incorporated to authorize for emergency use the administration of a single booster dose of COMIRNATY (COVID-19 Vaccine, mRNA) or Pfizer-BioNTech COVID-19 Vaccine at least 6 months after completing the primary series of this vaccine in individuals: 65 years of age and older;18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

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[5] In the May 10, 2021 revision, FDA authorized Pfizer-BioNTech Vaccine for the prevention of COVID-19 in individuals 12 through 15 years of age, as well as for individuals 16 years of age and older. In addition, FDA revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to include the following Warning: "Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting." In addition, the Fact Sheet for Recipients and Caregivers was revised to instruct vaccine recipients or their caregivers to tell the vaccination provider about fainting in association with a previous injection.

[6] In the June 25, 2021 revision, FDA clarified terms and conditions that relate to export of Pfizer-BioNTech COVID-19 Vaccine from the United States. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to include a Warning about myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine. The Fact Sheet for Recipients and Caregivers was updated to include information about myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine.

[7] In the August 12, 2021 revision, FDA authorized a third dose of the Pfizer-BioNTech COVID-19 Vaccine administered at least 28 days following the two dose regimen of this vaccine in individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

[8] COMIRNATY (COVID-19 Vaccine, mRNA) was approved for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

[9] In the August 23, 2021 revision, FDA clarified that, subsequent to the FDA approval of COMIRNATY (COVID-19 Vaccine, mRNA) for the prevention of COVID-19 for individuals 16 years of age and older, this EUA would remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously-authorized indication and uses. It also authorized COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved biologics license application (BLA). In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to provide updates on expiration dating of the authorized Pfizer-BioNTech COVID-19 Vaccine and updated language regarding warnings and precautions related to myocarditis and pericarditis. The Fact Sheet for Recipients and Caregivers was updated as the Vaccine Information Fact Sheet for Recipients and Caregivers, which comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA).

COMIRNATY (COVID-19 Vaccine, mRNA) is the same formulation as the Pfizer-BioNTech COVID-19 Vaccine and can be used interchangeably with the Pfizer-BioNTech COVID-19 Vaccine to provide the COVID-19 vaccination series.[10]

For the December 11, 2020 authorization for individuals 16 years of age and older, FDA reviewed safety and efficacy data from an ongoing Phase 1/2/3 trial in approximately 44,000 participants randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline control. The trial has enrolled participants 12 years of age and older. FDA's review at that time considered the safety and effectiveness data as they relate to the request for emergency use authorization in individuals 16 years of age and older. FDA's review of the available safety data from 37,586 of the participants 16 years of age and older, who were followed for a median of two months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of the available efficacy data from 36,523 participants 12 years of age and older without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirmed that the vaccine was 95% effective (95% credible interval 90.3, 97.6) in preventing COVID-19 occurring at least 7 days after the second dose (with 8 COVID-19 cases in the vaccine group compared to 162 COVID-19 cases in the placebo group). Based on these data, and review of manufacturing information regarding product quality and consistency, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective. Additionally, FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 16 years of age and older. Finally, on December 10, 2020, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

For the May 10, 2021 authorization for individuals 12 through 15 years of age, FDA reviewed safety and effectiveness data from the above-referenced, ongoing Phase 1/2/3 trial that has enrolled approximately 46,000 participants, including 2,260 participants 12 through 15 years of age. Trial participants were randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline control. FDA's review of the available safety data from 2,260 participants 12 through 15 years of age, who were followed for a median of 2 months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of SARS-CoV-2 50% neutralizing antibody titers 1 month after the second dose of Pfizer-BioNTech COVID-19 Vaccine in a subset of participants who had no serological or virological evidence of past SARS-CoV-2 infection confirm that the geometric mean antibody titer in participants 12 through 15 years of age was non-inferior to the geometric mean antibody titer in participants 16 through 25 years of age. FDA's analysis of available descriptive efficacy data from 1,983 participants 12 through 15 years of age without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirm that the vaccine was 100% effective (95% confidence interval 75.3, 100.0) in preventing COVID-19 occurring at least 7 days after the second dose

[10] 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.

(with no COVID-19 cases in the vaccine group compared to 16 COVID-19 cases in the placebo group). Based on these data, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in individuals 12 through 15 years of age. Additionally, FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 12 through 15 years of age.

For the August 12, 2021 authorization of a third dose of the Pfizer-BioNTech COVID-19 Vaccine in individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise, FDA reviewed safety and effectiveness data reported in two manuscripts on solid organ transplant recipients. The first study was a single arm study conducted in 101 individuals who had undergone various solid organ transplant procedures (heart, kidney, liver, lung, pancreas) a median of 97±8 months earlier. A third dose of the Pfizer-BioNTech COVID-19 Vaccine was administered to 99 of these individuals approximately 2 months after they had received a second dose. Levels of total SARS-CoV-2 binding antibodies meeting the pre-specified criteria for success occurred four weeks after the third dose in 26/59 (44.0%) of those who were initially considered to be seronegative and received a third dose of the Pfizer-BioNTech COVID-19 Vaccine; 67/99 (68%) of the entire group receiving a third vaccination were subsequently considered to have levels of antibodies indicative of a significant response. In those who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 events were reported. A supportive secondary study describes a double-blind, randomized-controlled study conducted in 120 individuals who had undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver, lung, pancreas) a median of 3.57 years earlier (range 1.99-6.75 years). A third dose of a similar mRNA vaccine (the Moderna COVID-19 vaccine) was administered to 60 individuals approximately 2 months after they had received a second dose (i.e., doses at 0, 1 and 3 months); saline placebo was given to 60 individuals for comparison. The primary outcome was anti-RBD antibody at 4 months greater than 100 U/mL. This titer was selected based on NHP challenge studies as well as a large clinical cohort study to indicate this antibody titer was protective. Secondary outcomes were based on a virus neutralization assay and polyfunctional T cell responses. Baseline characteristics were comparable between the two study arms as were pre-intervention anti-RBD titer and neutralizing antibodies. Levels of total SARS-CoV-2 binding antibodies indicative of a significant response occurred four weeks after the third dose in 33/60 (55.0%) of the Moderna COVID-19 vaccinated group and 10/57 (17.5%) of the placebo individuals. In the 60 individuals who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 adverse events were reported. Despite the moderate enhancement in antibody titers, the totality of data (i.e., supportive paper by Hall et al. demonstrated efficacy of the product in the elderly and persons with co-morbidities) supports the conclusion that a third dose of the Pfizer-BioNTech COVID-19 Vaccine may be effective in this population, and that the known and potential benefits of a third dose of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine for immunocompromised individuals at least 12 years of age who have received two doses of the Pfizer-BioNTech COVID-19 Vaccine and who have undergone solid organ

transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

For the September 22, 2021 authorization of a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine administered at least 6 months after completing the primary series in individuals: 65 years of age and older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19, FDA reviewed safety and effectiveness data from the above-referenced, ongoing Phase 1/2/3 trial in which 329 participants 18 through 75 years of age received a booster dose of the Pfizer-BioNTech COVID-19 Vaccine approximately 6 months (range 4.8 to 8.8 months) after completion of the primary series. FDA's review of the available safety data from 329 participants 18 through 75 years of age, who had been followed for a median of 2.6 months after receiving the booster dose, did not identify specific safety concerns that would preclude issuance of an EUA. The effectiveness of the booster dose of the Pfizer-BioNTech COVID-19 Vaccine is based on an assessment of 50% neutralizing antibody titers (NT50) against SARS-CoV-2 (USA_WA1/2020). FDA's analysis of SARS-CoV-2 NT50 one month after the booster dose compared to 1 month after the primary series in study participants 18 through 55 years of age who had no serological or virological evidence of past SARS-CoV-2 infection up to 1 month after the booster dose confirmed noninferiority for both geometric mean ratio and difference in seroresponse rates. Based on the totality of the scientific evidence available, including data from the above-referenced clinical trial, FDA concluded that a booster dose the Pfizer-BioNTech COVID-19 Vaccine may be effective, and that the known and potential benefits of a single booster dose at least 6 months after completing the primary series outweigh the known and potential risks for individuals 65 years of age and older; individuals 18 through 64 years of age at high risk of severe COVID-19; and individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization. Additionally, as specified in subsection III.BB, I am authorizing use of Pfizer-BioNTech COVID-19 Vaccine and of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA when used to provide: a two-dose regimen for individuals aged 12 through 15 years; a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise; or a single booster dose at least 6 months after completing the primary series to individuals: 65 years of age and older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Pfizer-BioNTech COVID-19 Vaccine[11] for the prevention of COVID-19 when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

A. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

B. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks; and

C. There is no adequate, approved, and available alternative[12] Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19.[13]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Pfizer Inc. will supply Pfizer-BioNTech COVID-19 Vaccine either directly or through authorized distributor(s),[14] to emergency response stakeholders[15] as directed by the U.S.

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[11] In this section (Section I), references to Pfizer-BioNTech COVID-19 Vaccine also apply to COMIRNATY (COVID-19 Vaccine, mRNA).

[12] Although COMIRNATY (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA. Additionally, there are no products that are approved to prevent COVID-19 in individuals age 12 through 15, or to provide: an additional dose to the immunocompromised population, or a booster dose to the authorized population described in this EUA.

[13] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

[14] "Authorized Distributor(s)" are identified by Pfizer Inc. or, if applicable, by a U.S. government entity, such as the Centers for Disease Control and Prevention (CDC) and/or other designee, as an entity or entities allowed to distribute authorized Pfizer-BioNTech COVID-19 Vaccine.

[15] For purposes of this letter, "emergency response stakeholder" refers to a public health agency and its delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, tribal, territorial, State, or Federal), or functional (e.g., law enforcement or public health range) or sphere of authority to administer, deliver, or distribute vaccine in an emergency situation. In some cases (e.g., depending on a state or local jurisdiction's COVID-19 vaccination response organization and plans), there might be overlapping roles and responsibilities among "emergency response stakeholders" and "vaccination providers" (e.g., if a local health department is administering COVID-19 vaccines; if a pharmacy is acting in an official capacity under the authority of the state health department to administer COVID-19 vaccines). In such cases, it is expected that the conditions of authorization that apply to emergency response stakeholders and vaccination providers will all be met.

government, including the Centers for Disease Control and Prevention (CDC) and/or other designee, for use consistent with the terms and conditions of this EUA;

- The Pfizer-BioNTech COVID-19 Vaccine covered by this authorization will be administered by vaccination providers[16] and used only to prevent COVID-19 in individuals ages 12 and older with a two-dose regimen, to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise, and to provide a single booster dose at least 6 months after completing the primary series of the vaccine to individuals: 65 years of age or older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19; and
- Pfizer-BioNTech COVID-19 Vaccine may be administered by a vaccination provider without an individual prescription for each vaccine recipient.

This authorization also covers the use of the licensed COMIRNATY (COVID-19 Vaccine, mRNA) product when used to provide: a two-dose regimen for individuals aged 12 through 15 years; a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise; or a single booster dose at least 6 months after completing the primary series to individuals: 65 years of age and older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

Product Description[17]

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. The Pfizer-BioNTech COVID-19 Vaccine does not contain a preservative.

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[16] For purposes of this letter, "vaccination provider" refers to the facility, organization, or healthcare provider licensed or otherwise authorized by the emergency response stakeholder (e.g., non-physician healthcare professionals, such as nurses and pharmacists pursuant to state law under a standing order issued by the state health officer) to administer or provide vaccination services in accordance with the applicable emergency response stakeholder's official COVID-19 vaccination and emergency response plan(s) and who is enrolled in the CDC COVID-19 Vaccination Program. If the vaccine is exported from the United States, a "vaccination provider" is a provider that is authorized to administer this vaccine in accordance with the laws of the country in which it is administered. For purposes of this letter, "healthcare provider" also refers to a person authorized by the U.S. Department of Health and Human Services (e.g., under the PREP Act Declaration for Medical Countermeasures against COVID-19) to administer FDA-authorized COVID-19 vaccine (e.g., qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist). See, e.g., HHS. *Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration*. 85 FR 79190 (December 9, 2020).

[17] For COMIRNATY (COVID-19 Vaccine, mRNA) product description, please see the COMIRNATY (COVID-19 Vaccine, mRNA) prescribing information, found here: *https://www.fda.gov/media/151707/download*.

Each 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2. Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection) contributes an additional 2.16 mg sodium chloride per dose.

The dosing regimen is a primary series of two doses of 0.3 mL each, 3 weeks apart. A third primary series dose may be administered at least 28 days following the second dose to individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. A single booster dose (0.3 mL) may be administered at least 6 months after completing the primary series to individuals: 65 years of age or older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

The manufacture of the authorized Pfizer-BioNTech COVID-19 Vaccine is limited to those facilities identified and agreed upon in Pfizer's request for authorization.

The Pfizer-BioNTech COVID-19 Vaccine vial label and carton labels are clearly marked for "Emergency Use Authorization." The Pfizer-BioNTech COVID-19 Vaccine is authorized to be distributed, stored, further redistributed, and administered by emergency response stakeholders when packaged in the authorized manufacturer packaging (i.e., vials and cartons), despite the fact that the vial and carton labels may not contain information that otherwise would be required under the FD&C Act.

Pfizer-BioNTech COVID-19 Vaccine is authorized for emergency use with the following product-specific information required to be made available to vaccination providers and recipients, respectively (referred to as "authorized labeling"):

- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)

- Vaccine Information Fact Sheet for Recipients and Caregivers About COMIRNATY (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease (COVID-19).

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine,[18] when used to prevent COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that Pfizer-BioNTech COVID-19 Vaccine (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of Pfizer-BioNTech COVID-19 Vaccine under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), Pfizer-BioNTech COVID-19 Vaccine is authorized to prevent COVID-19 in individuals 12 years of age and older as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

Pfizer Inc. and Authorized Distributor(s)

A. Pfizer Inc. and authorized distributor(s) will ensure that the authorized Pfizer-BioNTech COVID-19 Vaccine is distributed, as directed by the U.S. government, including CDC and/or other designee, and the authorized labeling (i.e., Fact Sheets) will be made available to vaccination providers, recipients, and caregivers consistent with the terms of this letter.

B. Pfizer Inc. and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until delivered to emergency response stakeholders' receipt sites.

C. Pfizer Inc. will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., emergency response stakeholders, authorized distributors, and vaccination providers) involved in distributing or receiving authorized Pfizer-BioNTech COVID-19 Vaccine. Pfizer Inc. will provide to all relevant stakeholders a

[18] The conclusions supporting authorization stated in this Section (Section II) also apply to COMIRNATY (COVID-19 Vaccine, mRNA).

copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized labeling.

D. Pfizer Inc. may develop and disseminate instructional and educational materials (e.g., video regarding vaccine handling, storage/cold-chain management, preparation, disposal) that are consistent with the authorized emergency use of the vaccine as described in the letter of authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs during an emergency. Any instructional and educational materials that are inconsistent with the authorized labeling are prohibited.

E. Pfizer Inc. may request changes to this authorization, including to the authorized Fact Sheets for the vaccine. Any request for changes to this EUA must be submitted to Office of Vaccines Research and Review (OVRR)/Center for Biologics Evaluation and Research (CBER). Such changes require appropriate authorization prior to implementation.[19]

F. Pfizer Inc. will report to Vaccine Adverse Event Reporting System (VAERS):
- Serious adverse events (irrespective of attribution to vaccination);
- Cases of Multisystem Inflammatory Syndrome in children and adults; and
- Cases of COVID-19 that result in hospitalization or death, that are reported to Pfizer Inc.

These reports should be submitted to VAERS as soon as possible but no later than 15 calendar days from initial receipt of the information by Pfizer Inc.

G. Pfizer Inc. must submit to Investigational New Drug application (IND) number 19736 periodic safety reports at monthly intervals in accordance with a due date agreed upon with the Office of Biostatistics and Epidemiology (OBE)/CBER beginning after the first full calendar month after authorization. Each periodic safety report is required to contain descriptive information which includes:
- A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest;
- A narrative summary and analysis of vaccine administration errors, whether or not associated with an adverse event, that were identified since the last reporting interval;
- Newly identified safety concerns in the interval; and

[19] The following types of revisions may be authorized without reissuing this letter: (1) changes to the authorized labeling; (2) non-substantive editorial corrections to this letter; (3) new types of authorized labeling, including new fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing processes, including tests or other authorized components of manufacturing; (7) new conditions of authorization to require data collection or study. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), or (7), review and concurrence is required from the Preparedness and Response Team (PREP)/Office of the Center Director (OD)/CBER and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS).

- Actions taken since the last report because of adverse experiences (for example, changes made to Healthcare Providers Administering Vaccine (Vaccination Providers) Fact Sheet, changes made to studies or studies initiated).

H. No changes will be implemented to the description of the product, manufacturing process, facilities, or equipment without notification to and concurrence by FDA.

I. All manufacturing facilities will comply with Current Good Manufacturing Practice requirements.

J. Pfizer Inc. will submit to the EUA file Certificates of Analysis (CoA) for each drug product lot at least 48 hours prior to vaccine distribution. The CoA will include the established specifications and specific results for each quality control test performed on the final drug product lot.

K. Pfizer Inc. will submit to the EUA file quarterly manufacturing reports, starting in July 2021, that include a listing of all Drug Substance and Drug Product lots produced after issuance of this authorization. This report must include lot number, manufacturing site, date of manufacture, and lot disposition, including those lots that were quarantined for investigation or those lots that were rejected. Information on the reasons for lot quarantine or rejection must be included in the report.

L. Pfizer Inc. and authorized distributor(s) will maintain records regarding release of Pfizer-BioNTech COVID-19 Vaccine for distribution (i.e., lot numbers, quantity, release date).

M. Pfizer Inc. and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

N. Pfizer Inc. will conduct post-authorization observational studies to evaluate the association between Pfizer-BioNTech COVID-19 Vaccine and a pre-specified list of adverse events of special interest, including myocarditis and pericarditis, along with deaths and hospitalizations, and severe COVID-19. The study population should include individuals administered the authorized Pfizer-BioNTech COVID-19 Vaccine under this EUA in the general U.S. population (12 years of age and older), individuals that receive a booster dose, populations of interest such as healthcare workers, pregnant women, immunocompromised individuals, subpopulations with specific comorbidities. The studies should be conducted in large scale databases with an active comparator. Pfizer Inc. will provide protocols and status update reports to the IND 19736 with agreed-upon study designs and milestone dates.

Emergency Response Stakeholders

O. Emergency response stakeholders will identify vaccination sites to receive authorized Pfizer-BioNTech COVID-19 Vaccine and ensure its distribution and administration, consistent with the terms of this letter and CDC's COVID-19 Vaccination Program.

P. Emergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of this letter of authorization, and the terms herein and any subsequent amendments that might be made to the letter of authorization, instruct them about the means through which they are to obtain and administer the vaccine under the EUA, and ensure that the authorized labeling [i.e., Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Vaccine Information Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website).

Q. Emergency response stakeholders receiving authorized Pfizer-BioNTech COVID-19 Vaccine will ensure that appropriate storage and cold chain is maintained.

Vaccination Providers

R. Vaccination providers will administer the vaccine in accordance with the authorization and will participate and comply with the terms and training required by CDC's COVID-19 Vaccination Program.

S. Vaccination providers will provide the Vaccine Information Fact Sheet for Recipients and Caregivers to each individual receiving vaccination and provide the necessary information for receiving their second dose and/or third dose.

T. Vaccination providers administering the vaccine must report the following information associated with the administration of the vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):
   - Vaccine administration errors whether or not associated with an adverse event
   - Serious adverse events (irrespective of attribution to vaccination)
   - Cases of Multisystem Inflammatory Syndrome in children and adults
   - Cases of COVID-19 that result in hospitalization or death

   Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. The VAERS reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report. More information is available at vaers.hhs.gov or by calling 1-800-822-7967. To the extent feasible, report to Pfizer Inc. by contacting 1-800-438-1985 or by providing a copy of the VAERS form to Pfizer Inc.; Fax: 1-866-635-8337.

U. Vaccination providers will conduct any follow-up requested by the U.S government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.

V. Vaccination providers will monitor and comply with CDC and/or emergency response stakeholder vaccine management requirements (e.g., requirements

concerning obtaining, tracking, and handling vaccine) and with requirements concerning reporting of vaccine administration data to CDC.

W. Vaccination providers will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to CDC, and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising, and Promotion

X. All descriptive printed matter, advertising, and promotional material, relating to the use of the Pfizer-BioNTech COVID-19 Vaccine shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in section 502(a) and (n) of the FD&C Act and FDA implementing regulations.

Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Pfizer-BioNTech COVID-19 Vaccine clearly and conspicuously shall state that:
- This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

Condition Related to Export

Z. If the Pfizer-BioNTech COVID-19 Vaccine is exported from the United States, conditions C, D, and O through Y do not apply, but export is permitted only if 1) the regulatory authorities of the country in which the vaccine will be used are fully informed that this vaccine is subject to an EUA and is not approved or licensed by FDA and 2) the intended use of the vaccine will comply in all respects with the laws of the country in which the product will be used. The requirement in this letter that the authorized labeling (i.e., Fact Sheets) be made available to vaccination providers, recipients, and caregivers in condition A will not apply if the authorized labeling (i.e., Fact Sheets) are made available to the regulatory authorities of the country in which the vaccine will be used.

Conditions With Respect to Use of Licensed Product

AA. COMIRNATY (COVID-19 Vaccine, mRNA) is now licensed for individuals 16 years of age and older. There remains, however, a significant amount of Pfizer-BioNTech COVID-19 Vaccine that was manufactured and labeled in accordance with this emergency use authorization. The authorization remains in place with respect to the Pfizer-BioNTech COVID-19 Vaccine.

BB. This authorization also covers the use of the licensed COMIRNATY (COVID-19 Vaccine, mRNA) product when used to provide: a two-dose regimen for individuals aged 12 through 15 years; a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise; or a single booster dose at least 6 months after completing the primary series to individuals: 65 years of age or older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19. Conditions A through W in this letter apply when COMIRNATY (COVID-19 Vaccine, mRNA) is provided for the uses described in this subsection III.BB, except that product manufactured and labeled in accordance with the approved BLA is deemed to satisfy the manufacturing, labeling, and distribution requirements of this authorization.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

--/S/--

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

U.S. FOOD & DRUG ADMINISTRATION

EXHIBIT C

October 20, 2021

Pfizer Inc.
Attention: Mr. Amit Patel
235 East 42nd St
New York, NY 10017

Dear Mr. Patel:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus Disease 2019 (COVID-19).[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.[2]

On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 for individuals 16 years of age and older pursuant to Section 564 of the Act. FDA reissued the letter of authorization on: December 23, 2020,[3] February 25, 2021,[4] May

[1] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the FD&C Act, 21 U.S.C. § 360bbb-3, February 4, 2020.

[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020).

[3] In the December 23, 2020 revision, FDA removed reference to the number of doses per vial after dilution from the letter of authorization, clarified the instructions for vaccination providers reporting to VAERS, and made other technical corrections. FDA also revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to clarify the number of doses of vaccine per vial after dilution and the instructions for reporting to VAERS. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers were revised to include additional information on safety monitoring and to clarify information about the availability of other COVID-19 vaccines.

[4] In the February 25, 2021 revision, FDA allowed flexibility on the date of submission of monthly periodic safety reports and revised the requirements for reporting of vaccine administration errors by Pfizer Inc. The Fact Sheet for Health Care Providers Administering Vaccine (Vaccination Providers) was revised to provide an update to the storage and transportation temperature for frozen vials, direct the provider to the correct CDC website for information on monitoring vaccine recipients for the occurrence of immediate adverse reactions, to include data from a developmental toxicity study, and add adverse reactions that have been identified during post authorization use. The Fact Sheet for Recipients and Caregivers was revised to add adverse reactions that have been identified during post authorization use.

10, 2021,[5] June 25, 2021,[6] August 12, 2021,[7] and on August 23, 2021, FDA approved COMIRNATY (COVID-19 Vaccine, mRNA)[8] and reissued the letter in its entirety for both Pfizer-BioNTech COVID-19 Vaccine and certain uses of COMIRNATY (COVID-19 Vaccine, mRNA).[9] Subsequently, FDA reissued the letter of authorization on September 22, 2021.[10]

On October 20, 2021, having concluded that revising this EUA is appropriate to protect the public health or safety under Section 564(g)(2) of the Act, FDA is reissuing the September 22, 2021 letter of authorization in its entirety with revisions incorporated to clarify eligibility for the booster dose of COMIRNATY (COVID-19 Vaccine, mRNA) or Pfizer-BioNTech COVID-19 Vaccine and to authorize for emergency use the administration of a single booster dose of Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA) as a heterologous booster dose following completion of primary vaccination with another authorized COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster

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[5] In the May 10, 2021 revision, FDA authorized Pfizer-BioNTech Vaccine for the prevention of COVID-19 in individuals 12 through 15 years of age, as well as for individuals 16 years of age and older. In addition, FDA revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to include the following Warning: "Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting." In addition, the Fact Sheet for Recipients and Caregivers was revised to instruct vaccine recipients or their caregivers to tell the vaccination provider about fainting in association with a previous injection.

[6] In the June 25, 2021 revision, FDA clarified terms and conditions that relate to export of Pfizer-BioNTech COVID-19 Vaccine from the United States. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to include a Warning about myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine. The Fact Sheet for Recipients and Caregivers was updated to include information about myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine.

[7] In the August 12, 2021 revision, FDA authorized a third dose of the Pfizer-BioNTech COVID-19 Vaccine administered at least 28 days following the two dose regimen of this vaccine in individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

[8] COMIRNATY (COVID-19 Vaccine, mRNA) was approved for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

[9] In the August 23, 2021 revision, FDA clarified that, subsequent to the FDA approval of COMIRNATY (COVID-19 Vaccine, mRNA) for the prevention of COVID-19 for individuals 16 years of age and older, this EUA would remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously-authorized indication and uses. It also authorized COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved biologics license application (BLA). In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to provide updates on expiration dating of the authorized Pfizer-BioNTech COVID-19 Vaccine and updated language regarding warnings and precautions related to myocarditis and pericarditis. The Fact Sheet for Recipients and Caregivers was updated as the Vaccine Information Fact Sheet for Recipients and Caregivers, which comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA).

[10] In the September 22, 2021 revision, FDA authorized the administration of a single booster dose of COMIRNATY (COVID-19 Vaccine, mRNA) or Pfizer-BioNTech COVID-19 Vaccine at least 6 months after completing the primary series of this vaccine in individuals: 65 years of age and older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.

COMIRNATY (COVID-19 Vaccine, mRNA) is the same formulation as the Pfizer-BioNTech COVID-19 Vaccine and can be used interchangeably with the Pfizer-BioNTech COVID-19 Vaccine to provide doses for COVID-19 primary vaccination or a booster dose.[11]

For the December 11, 2020 authorization for individuals 16 years of age and older, FDA reviewed safety and efficacy data from an ongoing Phase 1/2/3 trial in approximately 44,000 participants randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline control. The trial enrolled participants 12 years of age and older. FDA's review at that time considered the safety and effectiveness data as they relate to the request for emergency use authorization in individuals 16 years of age and older. FDA's review of the available safety data from 37,586 of the participants 16 years of age and older, who were followed for a median of two months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of the available efficacy data from 36,523 participants 12 years of age and older without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirmed that the vaccine was 95% effective (95% credible interval 90.3, 97.6) in preventing COVID-19 occurring at least 7 days after the second dose (with 8 COVID-19 cases in the vaccine group compared to 162 COVID-19 cases in the placebo group). Based on these data, and review of manufacturing information regarding product quality and consistency, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective. Additionally, FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 16 years of age and older. Finally, on December 10, 2020, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

For the May 10, 2021 authorization for individuals 12 through 15 years of age, FDA reviewed safety and effectiveness data from the above-referenced, ongoing Phase 1/2/3 trial that enrolled approximately 46,000 participants, including 2,260 participants 12 through 15 years of age. Trial participants were randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline control. FDA's review of the available safety data from 2,260 participants 12 through 15 years of age, who were followed for a median of 2 months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of SARS-CoV-2 50% neutralizing antibody titers 1 month after the second dose of Pfizer-BioNTech COVID-19 Vaccine in a subset of participants who had no serological or virological evidence of past SARS-CoV-2 infection confirm that the geometric mean antibody titer in participants 12 through 15 years of age was non-inferior to the geometric mean antibody titer in participants 16 through 25 years of age. FDA's analysis of available descriptive efficacy data from 1,983 participants 12 through 15 years of age without evidence of SARS-CoV-2 infection

[11] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide doses for primary vaccination or a booster dose without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

prior to 7 days after dose 2 confirm that the vaccine was 100% effective (95% confidence interval 75.3, 100.0) in preventing COVID-19 occurring at least 7 days after the second dose (with no COVID-19 cases in the vaccine group compared to 16 COVID-19 cases in the placebo group). Based on these data, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in individuals 12 through 15 years of age. Additionally, FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 12 through 15 years of age.

For the August 12, 2021 authorization of a third primary series dose in individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise, FDA reviewed safety and effectiveness data reported in two manuscripts on solid organ transplant recipients. The first study was a single arm study conducted in 101 individuals who had undergone various solid organ transplant procedures (heart, kidney, liver, lung, pancreas) a median of 97±8 months earlier. A third dose of the Pfizer-BioNTech COVID-19 Vaccine was administered to 99 of these individuals approximately 2 months after they had received a second dose. Levels of total SARS-CoV-2 binding antibodies meeting the pre-specified criteria for success occurred four weeks after the third dose in 26/59 (44.0%) of those who were initially considered to be seronegative and received a third dose of the Pfizer-BioNTech COVID-19 Vaccine; 67/99 (68%) of the entire group receiving a third vaccination were subsequently considered to have levels of antibodies indicative of a significant response. In those who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 events were reported. A supportive secondary study describes a double-blind, randomized-controlled study conducted in 120 individuals who had undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver, lung, pancreas) a median of 3.57 years earlier (range 1.99-6.75 years). A third dose of a similar messenger RNA vaccine (the Moderna COVID-19 vaccine) was administered to 60 individuals approximately 2 months after they had received a second dose (i.e., doses at 0, 1 and 3 months); saline placebo was given to 60 individuals for comparison. The primary outcome was anti-RBD antibody at 4 months greater than 100 U/mL. This titer was selected based on NHP challenge studies as well as a large clinical cohort study to indicate this antibody titer was protective. Secondary outcomes were based on a virus neutralization assay and polyfunctional T cell responses. Baseline characteristics were comparable between the two study arms as were pre-intervention anti-RBD titer and neutralizing antibodies. Levels of total SARS-CoV-2 binding antibodies indicative of a significant response occurred four weeks after the third dose in 33/60 (55.0%) of the Moderna COVID-19 vaccinated group and 10/57 (17.5%) of the placebo individuals. In the 60 individuals who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 adverse events were reported. Despite the moderate enhancement in antibody titers, the totality of data (i.e., supportive paper by Hall et al. demonstrated efficacy of the product in the elderly and persons with co-morbidities) supports the conclusion that a third dose of the Pfizer-BioNTech COVID-19 Vaccine may be effective in this population, and that the known and potential benefits of a third dose of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine for immunocompromised individuals at least 12 years of age who have received two

doses of the Pfizer-BioNTech COVID-19 Vaccine and who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

For the September 22, 2021 authorization of a single booster dose administered at least 6 months after completing the primary series in individuals: 65 years of age and older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19, FDA reviewed safety and effectiveness data from the above-referenced, ongoing Phase 1/2/3 trial in which 329 participants 18 through 75 years of age received a booster dose of the Pfizer-BioNTech COVID-19 Vaccine approximately 6 months (range 4.8 to 8.8 months) after completion of the primary series. FDA's review of the available safety data from 329 participants 18 through 75 years of age, who had been followed for a median of 2.6 months after receiving the booster dose, did not identify specific safety concerns that would preclude issuance of an EUA. The effectiveness of the booster dose of the Pfizer-BioNTech COVID-19 Vaccine is based on an assessment of 50% neutralizing antibody titers (NT50) against SARS-CoV-2 (USA_WA1/2020). FDA's analysis of SARS-CoV-2 NT50 one month after the booster dose compared to 1 month after the primary series in study participants 18 through 55 years of age who had no serological or virological evidence of past SARS-CoV-2 infection up to 1 month after the booster dose confirmed noninferiority for both geometric mean ratio and difference in seroresponse rates. Based on the totality of the scientific evidence available, including data from the above-referenced clinical trial, FDA concluded that a booster dose the Pfizer-BioNTech COVID-19 Vaccine may be effective, and that the known and potential benefits of a single booster dose at least 6 months after completing the primary series outweigh the known and potential risks for individuals 65 years of age and older; individuals 18 through 64 years of age at high risk of severe COVID-19; and individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

For the October 20, 2021 authorization of a single booster dose as a heterologous booster dose following completion of primary vaccination with another authorized COVID-19 vaccine, FDA reviewed data from an ongoing Phase1/2 clinical trial in participants 19-85 years of age. In this trial, adults who had completed primary vaccination with a Moderna COVID-19 Vaccine 2-dose series (N=151), a Janssen COVID-19 Vaccine single dose (N=156), or a Pfizer-BioNTech COVID-19 Vaccine 2-dose series (N=151) at least 12 weeks prior to enrollment and who reported no history of SARS-CoV-2 infection were randomized 1:1:1 to receive a booster dose of one of three vaccines: Moderna COVID-19 Vaccine, Janssen COVID-19 Vaccine, or Pfizer-BioNTech COVID-19 Vaccine. Adverse events were assessed through 28 days after the booster dose. An overall review of adverse reactions reported following the Pfizer-BioNTech COVID-19 Vaccine heterologous booster dose did not identify any new safety concerns, as compared with adverse reactions reported following Pfizer-BioNTech COVID-19 Vaccine primary series doses or homologous booster dose. Neutralizing antibody titers, as measured by a pseudovirus neutralization assay using a lentivirus expressing the SARS-CoV-2 Spike protein with D614G

mutation, were assessed on Day 1 prior to administration of the booster dose and on Day 15 after the booster dose. A booster response to the Pfizer-BioNTech COVID-19 Vaccine was demonstrated regardless of primary vaccination. Based on the on the totality of the scientific evidence available, including data from the above-referenced clinical trial, FDA concluded that a heterologous booster dose of the Pfizer-BioNTech COVID-19 Vaccine may be effective, and that the known and potential benefits of a heterologous booster dose of the Pfizer-BioNTech COVID-19 Vaccine following completion of primary vaccination with another authorized COVID-19 vaccine outweigh the known and potential risks.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization. Additionally, as specified in subsection III.BB, I am authorizing use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA when used to provide: (1) a two-dose regimen for individuals aged 12 through 15 years; (2) a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise; (3) a single homologous booster dose at least 6 months after completing a primary series to individuals 65 years of age and older, 18 through 64 years of age at high risk of severe COVID-19, and 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2; and (4) a heterologous booster dose to certain individuals who have completed primary vaccination with a different authorized COVID-19 vaccine as described in the Scope of Authorization section of this letter (Section II).

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Pfizer-BioNTech COVID-19 Vaccine[12] for the prevention of COVID-19 when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

A. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

B. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks; and

[12] In this section (Section I), references to Pfizer-BioNTech COVID-19 Vaccine also apply to COMIRNATY (COVID-19 Vaccine, mRNA).

C. There is no adequate, approved, and available alternative[13] Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19.[14]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Pfizer Inc. will supply Pfizer-BioNTech COVID-19 Vaccine either directly or through authorized distributor(s),[15] to emergency response stakeholders[16] as directed by the U.S. government, including the Centers for Disease Control and Prevention (CDC) and/or other designee, for use consistent with the terms and conditions of this EUA;
- The Pfizer-BioNTech COVID-19 Vaccine covered by this authorization will be administered by vaccination providers[17] and used only to prevent COVID-19 in individuals ages 12 and older with a two-dose primary regimen and to provide:

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[13] Although COMIRNATY (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA. Additionally, there are no COVID-19 vaccines that are approved to provide: COVID-19 vaccination in individuals age 12 through 15; a third primary series dose to certain immunocompromised populations described in this EUA; a homologous booster dose to the authorized population described in this EUA; or a heterologous booster dose following completion of primary vaccination with another authorized COVID-19 vaccine.

[14] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

[15] "Authorized Distributor(s)" are identified by Pfizer Inc. or, if applicable, by a U.S. government entity, such as the Centers for Disease Control and Prevention (CDC) and/or other designee, as an entity or entities allowed to distribute authorized Pfizer-BioNTech COVID-19 Vaccine.

[16] For purposes of this letter, "emergency response stakeholder" refers to a public health agency and its delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, tribal, territorial, State, or Federal), or functional (e.g., law enforcement or public health range) or sphere of authority to administer, deliver, or distribute vaccine in an emergency situation. In some cases (e.g., depending on a state or local jurisdiction's COVID-19 vaccination response organization and plans), there might be overlapping roles and responsibilities among "emergency response stakeholders" and "vaccination providers" (e.g., if a local health department is administering COVID-19 vaccines; if a pharmacy is acting in an official capacity under the authority of the state health department to administer COVID-19 vaccines). In such cases, it is expected that the conditions of authorization that apply to emergency response stakeholders and vaccination providers will all be met.

[17] For purposes of this letter, "vaccination provider" refers to the facility, organization, or healthcare provider licensed or otherwise authorized by the emergency response stakeholder (e.g., non-physician healthcare professionals, such as nurses and pharmacists pursuant to state law under a standing order issued by the state health officer) to administer or provide vaccination services in accordance with the applicable emergency response stakeholder's official COVID-19 vaccination and emergency response plan(s) and who is enrolled in the CDC COVID-19 Vaccination Program. If the vaccine is exported from the United States, a "vaccination provider" is a provider that is authorized to administer this vaccine in accordance with the laws of the country in which it is administered. For purposes of this letter, "healthcare provider" also refers to a person authorized by the U.S. Department of Health and Human Services (e.g., under the PREP Act Declaration for Medical Countermeasures against COVID-19) to administer FDA-authorized COVID-19 vaccine (e.g., qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist). See, e.g., HHS. *Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration*. 85 FR 79190 (December 9, 2020).

  - a third primary series dose to individuals 12 years of age or older who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise;
  - a single booster dose at least 6 months after completion of a primary series of the vaccine to individuals: 65 years of age or older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2; and
  - a single booster dose as a heterologous booster dose following completion of primary vaccination with another authorized COVID-19 vaccine, where the eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.
- Pfizer-BioNTech COVID-19 Vaccine may be administered by a vaccination provider without an individual prescription for each vaccine recipient.

This authorization also covers the use of the licensed COMIRNATY (COVID-19 Vaccine, mRNA) product when used to provide: (1) a two-dose primary regimen (0.3 mL each, 3 weeks apart) for individuals aged 12 through 15 years; (2) a third primary series dose at least 28 days following the second dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise; (3) a single booster dose (0.3 mL) at least 6 months after completion of the primary series to individuals 65 years of age and older, 18 through 64 years of age at high risk of severe COVID-19, and 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2; and (4) a single booster dose (0.3 mL) as a heterologous booster dose following completion of primary vaccination with another authorized COVID-19 vaccine, where the eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.

Product Description[18]

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. The Pfizer-BioNTech COVID-19 Vaccine does not contain a preservative.

Each 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2. Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic

[18] For COMIRNATY (COVID-19 Vaccine, mRNA) product description, please see the COMIRNATY (COVID-19 Vaccine, mRNA) prescribing information, found here: *https://www.fda.gov/media/151707/download*.

potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection) contributes an additional 2.16 mg sodium chloride per dose.

The manufacture of the authorized Pfizer-BioNTech COVID-19 Vaccine is limited to those facilities identified and agreed upon in Pfizer's request for authorization.

The Pfizer-BioNTech COVID-19 Vaccine vial label and carton labels are clearly marked for "Emergency Use Authorization." The Pfizer-BioNTech COVID-19 Vaccine is authorized to be distributed, stored, further redistributed, and administered by emergency response stakeholders when packaged in the authorized manufacturer packaging (i.e., vials and cartons), despite the fact that the vial and carton labels may not contain information that otherwise would be required under the FD&C Act.

Pfizer-BioNTech COVID-19 Vaccine is authorized for emergency use with the following product-specific information required to be made available to vaccination providers and recipients, respectively (referred to as "authorized labeling"):

- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)
- Vaccine Information Fact Sheet for Recipients and Caregivers About COMIRNATY (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease (COVID-19)

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine,[19] when used to prevent COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that Pfizer-BioNTech COVID-19 Vaccine (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of Pfizer-BioNTech COVID-19 Vaccine under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and

[19] The conclusions supporting authorization stated in this section (Section II) also apply to COMIRNATY (COVID-19 Vaccine, mRNA).

under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), Pfizer-BioNTech COVID-19 Vaccine is authorized to prevent COVID-19 in individuals 12 years of age and older as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

Pfizer Inc. and Authorized Distributor(s)

A. Pfizer Inc. and authorized distributor(s) will ensure that the authorized Pfizer-BioNTech COVID-19 Vaccine is distributed, as directed by the U.S. government, including CDC and/or other designee, and the authorized labeling (i.e., Fact Sheets) will be made available to vaccination providers, recipients, and caregivers consistent with the terms of this letter.

B. Pfizer Inc. and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until delivered to emergency response stakeholders' receipt sites.

C. Pfizer Inc. will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., emergency response stakeholders, authorized distributors, and vaccination providers) involved in distributing or receiving authorized Pfizer-BioNTech COVID-19 Vaccine. Pfizer Inc. will provide to all relevant stakeholders a copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized labeling.

D. Pfizer Inc. may develop and disseminate instructional and educational materials (e.g., video regarding vaccine handling, storage/cold-chain management, preparation, disposal) that are consistent with the authorized emergency use of the vaccine as described in the letter of authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs during an emergency. Any instructional and educational materials that are inconsistent with the authorized labeling are prohibited.

E. Pfizer Inc. may request changes to this authorization, including to the authorized Fact Sheets for the vaccine. Any request for changes to this EUA must be submitted to Office of Vaccines Research and Review (OVRR)/Center for Biologics Evaluation and Research (CBER). Such changes require appropriate authorization prior to implementation.[20]

[20] The following types of revisions may be authorized without reissuing this letter: (1) changes to the authorized labeling; (2) non-substantive editorial corrections to this letter; (3) new types of authorized labeling, including new fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing

F. Pfizer Inc. will report to Vaccine Adverse Event Reporting System (VAERS):
- Serious adverse events (irrespective of attribution to vaccination);
- Cases of Multisystem Inflammatory Syndrome in children and adults; and
- Cases of COVID-19 that result in hospitalization or death, that are reported to Pfizer Inc.

These reports should be submitted to VAERS as soon as possible but no later than 15 calendar days from initial receipt of the information by Pfizer Inc.

G. Pfizer Inc. must submit to Investigational New Drug application (IND) number 19736 periodic safety reports at monthly intervals in accordance with a due date agreed upon with the Office of Biostatistics and Epidemiology (OBE)/CBER beginning after the first full calendar month after authorization. Each periodic safety report is required to contain descriptive information which includes:
- A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest;
- A narrative summary and analysis of vaccine administration errors, whether or not associated with an adverse event, that were identified since the last reporting interval;
- Newly identified safety concerns in the interval; and
- Actions taken since the last report because of adverse experiences (for example, changes made to Healthcare Providers Administering Vaccine (Vaccination Providers) Fact Sheet, changes made to studies or studies initiated).

H. No changes will be implemented to the description of the product, manufacturing process, facilities, or equipment without notification to and concurrence by FDA.

I. All manufacturing facilities will comply with Current Good Manufacturing Practice requirements.

J. Pfizer Inc. will submit to the EUA file Certificates of Analysis (CoA) for each drug product lot at least 48 hours prior to vaccine distribution. The CoA will include the established specifications and specific results for each quality control test performed on the final drug product lot.

K. Pfizer Inc. will submit to the EUA file quarterly manufacturing reports, starting in July 2021, that include a listing of all Drug Substance and Drug Product lots produced after issuance of this authorization. This report must include lot number, manufacturing site, date of manufacture, and lot disposition, including those lots that

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processes, including tests or other authorized components of manufacturing; (7) new conditions of authorization to require data collection or study. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), or (7), review and concurrence is required from the Preparedness and Response Team (PREP)/Office of the Center Director (OD)/CBER and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS).

were quarantined for investigation or those lots that were rejected. Information on the reasons for lot quarantine or rejection must be included in the report.

L. Pfizer Inc. and authorized distributor(s) will maintain records regarding release of Pfizer-BioNTech COVID-19 Vaccine for distribution (i.e., lot numbers, quantity, release date).

M. Pfizer Inc. and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

N. Pfizer Inc. will conduct post-authorization observational studies to evaluate the association between Pfizer-BioNTech COVID-19 Vaccine and a pre-specified list of adverse events of special interest, including myocarditis and pericarditis, along with deaths and hospitalizations, and severe COVID-19. The study population should include individuals administered the authorized Pfizer-BioNTech COVID-19 Vaccine under this EUA in the general U.S. population (12 years of age and older), individuals who receive a booster dose, populations of interest such as healthcare workers, pregnant women, immunocompromised individuals, subpopulations with specific comorbidities. The studies should be conducted in large scale databases with an active comparator. Pfizer Inc. will provide protocols and status update reports to the IND 19736 with agreed-upon study designs and milestone dates.

Emergency Response Stakeholders

O. Emergency response stakeholders will identify vaccination sites to receive authorized Pfizer-BioNTech COVID-19 Vaccine and ensure its distribution and administration, consistent with the terms of this letter and CDC's COVID-19 Vaccination Program.

P. Emergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of this letter of authorization, and the terms herein and any subsequent amendments that might be made to the letter of authorization, instruct them about the means through which they are to obtain and administer the vaccine under the EUA, and ensure that the authorized labeling [i.e., Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Vaccine Information Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website).

Q. Emergency response stakeholders receiving authorized Pfizer-BioNTech COVID-19 Vaccine will ensure that appropriate storage and cold chain is maintained.

Vaccination Providers

R. Vaccination providers will administer the vaccine in accordance with the authorization and will participate and comply with the terms and training required by CDC's COVID-19 Vaccination Program.

S. Vaccination providers will provide the Vaccine Information Fact Sheet for Recipients and Caregivers to each individual receiving vaccination and provide the necessary information for receiving their second dose and/or third dose.

T. Vaccination providers administering the vaccine must report the following information associated with the administration of the vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):
- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome in children and adults
- Cases of COVID-19 that result in hospitalization or death

Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. The VAERS reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report. More information is available at vaers.hhs.gov or by calling 1-800-822-7967. To the extent feasible, report to Pfizer Inc. by contacting 1-800-438-1985 or by providing a copy of the VAERS form to Pfizer Inc.; Fax: 1-866-635-8337.

U. Vaccination providers will conduct any follow-up requested by the U.S government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.

V. Vaccination providers will monitor and comply with CDC and/or emergency response stakeholder vaccine management requirements (e.g., requirements concerning obtaining, tracking, and handling vaccine) and with requirements concerning reporting of vaccine administration data to CDC.

W. Vaccination providers will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to CDC, and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising, and Promotion

X. All descriptive printed matter, advertising, and promotional material, relating to the use of the Pfizer-BioNTech COVID-19 Vaccine shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in Section 502(a) and (n) of the FD&C Act and FDA implementing regulations.

Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Pfizer-BioNTech COVID-19 Vaccine clearly and conspicuously shall state that:

- This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

Condition Related to Export

Z. If the Pfizer-BioNTech COVID-19 Vaccine is exported from the United States, conditions C, D, and O through Y do not apply, but export is permitted only if 1) the regulatory authorities of the country in which the vaccine will be used are fully informed that this vaccine is subject to an EUA and is not approved or licensed by FDA and 2) the intended use of the vaccine will comply in all respects with the laws of the country in which the product will be used. The requirement in this letter that the authorized labeling (i.e., Fact Sheets) be made available to vaccination providers, recipients, and caregivers in condition A will not apply if the authorized labeling (i.e., Fact Sheets) are made available to the regulatory authorities of the country in which the vaccine will be used.

Conditions With Respect to Use of Licensed Product

AA. COMIRNATY (COVID-19 Vaccine, mRNA) is licensed for individuals 16 years of age and older. There remains, however, a significant amount of Pfizer-BioNTech COVID-19 Vaccine that was manufactured and labeled in accordance with this emergency use authorization. The authorization remains in place with respect to the Pfizer-BioNTech COVID-19 Vaccine for this population.

BB. This authorization also covers the use of the licensed COMIRNATY (COVID-19 Vaccine, mRNA) product when used to provide: (1) a two-dose primary regimen for individuals aged 12 through 15 years; (2) a third primary series dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise; (3) a single booster dose at least 6 months after completing the primary series to individuals 65 years of age or older, 18 through 64 years of age at high risk of severe COVID-19, and 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2; and (4) a heterologous booster dose to certain individuals who have completed primary vaccination with a different authorized COVID-19 vaccine as described in the Scope of Authorization (Section II) under this EUA. Conditions A through W in this letter apply when COMIRNATY (COVID-19 Vaccine, mRNA) is provided for the uses described in this subsection III.BB., except that product manufactured and labeled in accordance with the approved BLA is deemed to satisfy the manufacturing, labeling, and distribution requirements of this authorization.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

--/S/--

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosures

U.S. FOOD & DRUG ADMINISTRATION

EXHIBIT D

October 29, 2021

Pfizer Inc.
Attention: Mr. Amit Patel
235 East 42nd St
New York, NY 10017

Dear Mr. Patel:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus Disease 2019 (COVID-19).[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.[2]

On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 for individuals 16 years of age and older pursuant to Section 564 of the Act. FDA reissued the letter of authorization on: December 23, 2020,[3] February 25, 2021,[4] May

[1] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the FD&C Act, 21 U.S.C. § 360bbb-3, February 4, 2020.

[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020).

[3] In the December 23, 2020 revision, FDA removed reference to the number of doses per vial after dilution from the letter of authorization, clarified the instructions for vaccination providers reporting to VAERS, and made other technical corrections. FDA also revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to clarify the number of doses of vaccine per vial after dilution and the instructions for reporting to VAERS. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers were revised to include additional information on safety monitoring and to clarify information about the availability of other COVID-19 vaccines.

[4] In the February 25, 2021 revision, FDA allowed flexibility on the date of submission of monthly periodic safety reports and revised the requirements for reporting of vaccine administration errors by Pfizer Inc. The Fact Sheet for Health Care Providers Administering Vaccine (Vaccination Providers) was revised to provide an update to the storage and transportation temperature for frozen vials, direct the provider to the correct CDC website for information on monitoring vaccine recipients for the occurrence of immediate adverse reactions, to include data from a developmental toxicity study, and add adverse reactions that have been identified during post authorization use. The Fact Sheet for Recipients and Caregivers was revised to add adverse reactions that have been identified during post authorization use.

10, 2021,[5] June 25, 2021,[6] and August 12, 2021.[7] On August 23, 2021, FDA approved COMIRNATY (COVID-19 Vaccine, mRNA)[8] and reissued the letter in its entirety for both Pfizer-BioNTech COVID-19 Vaccine and certain uses of COMIRNATY (COVID-19 Vaccine, mRNA).[9] Subsequently, FDA reissued the letter of authorization on September 22, 2021[10] and October 20, 2021.[11]

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[5] In the May 10, 2021 revision, FDA authorized Pfizer-BioNTech Vaccine for the prevention of COVID-19 in individuals 12 through 15 years of age, as well as for individuals 16 years of age and older. In addition, FDA revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to include the following Warning: "Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting." In addition, the Fact Sheet for Recipients and Caregivers was revised to instruct vaccine recipients or their caregivers to tell the vaccination provider about fainting in association with a previous injection.

[6] In the June 25, 2021 revision, FDA clarified terms and conditions that relate to export of Pfizer-BioNTech COVID-19 Vaccine from the United States. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to include a Warning about myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine. The Fact Sheet for Recipients and Caregivers was updated to include information about myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine.

[7] In the August 12, 2021 revision, FDA authorized a third dose of the Pfizer-BioNTech COVID-19 Vaccine administered at least 28 days following the two dose regimen of this vaccine in individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

[8] COMIRNATY (COVID-19 Vaccine, mRNA) was approved for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

[9] In the August 23, 2021 revision, FDA clarified that, subsequent to the FDA approval of COMIRNATY (COVID-19 Vaccine, mRNA) for the prevention of COVID-19 for individuals 16 years of age and older, this EUA would remain in place for the Pfizer-BioNTech COVID-19 Vaccine for the previously-authorized indication and uses. It also authorized COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved biologics license application (BLA). In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to provide updates on expiration dating of the authorized Pfizer-BioNTech COVID-19 Vaccine and updated language regarding warnings and precautions related to myocarditis and pericarditis. The Fact Sheet for Recipients and Caregivers was updated as the Vaccine Information Fact Sheet for Recipients and Caregivers, which comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA).

[10] In the September 22, 2021 revision, FDA authorized the administration of a single booster dose of COMIRNATY (COVID-19 Vaccine, mRNA) or Pfizer-BioNTech COVID-19 Vaccine at least 6 months after completing the primary series of this vaccine in individuals: 65 years of age and older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

[11] In the October 20, 2021 revision, FDA clarified eligibility for the booster dose of COMIRNATY (COVID-19 Vaccine, mRNA) or Pfizer-BioNTech COVID-19 Vaccine and authorized the administration of a single booster dose of Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA) as a heterologous booster dose following completion of primary vaccination with another authorized COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.

On October 29, 2021, having concluded that revising this EUA is appropriate to protect the public health or safety under Section 564(g)(2) of the Act, FDA is again reissuing the October 20, 2021 letter of authorization in its entirety with revisions incorporated to:

1) authorize the use of Pfizer-BioNTech COVID-19 Vaccine for children 5 through 11 years of age; and

2) authorize a manufacturing change to include an additional formulation of the Pfizer-BioNTech COVID-19 Vaccine that uses tromethamine (Tris) buffer instead of phosphate buffered saline (PBS) used in the originally authorized Pfizer-BioNTech COVID-19 Vaccine.

The formulation of the Pfizer-BioNTech COVID-19 Vaccine that uses Tris buffer is authorized in two presentations:[12]

1) Multiple dose vials, with gray caps and labels with a gray border, formulated to provide, without need for dilution, doses (each 0.3 mL dose containing 30 µg nucleoside-modified messenger RNA (modRNA)) for individuals 12 years of age and older; and

2) Multiple dose vials, with orange caps and labels with an orange border, formulated to provide, after dilution, doses (each 0.2 mL dose containing 10 µg modRNA) for individuals 5 through 11 years of age.[13]

The Pfizer-BioNTech COVID-19 Vaccine that uses PBS buffer and COMIRNATY (COVID-19 Vaccine, mRNA) have the same formulation. The products are legally distinct with certain differences that do not impact safety or effectiveness. Accordingly, under this EUA, the Pfizer-BioNTech COVID-19 Vaccine that uses PBS buffer and COMIRNATY (COVID-19 Vaccine, mRNA) can be used interchangeably to provide doses for primary vaccination in individuals 12 years of age and older, or to provide a single booster dose in the adult populations described in Section II of this letter of authorization, without presenting any safety or effectiveness concerns.

The Pfizer-BioNTech COVID-19 Vaccine formulations that use Tris and PBS buffers, and which are authorized for use in individuals 12 years of age and older, contain the same modRNA and lipids, and the same quantity of these ingredients, per 0.3 mL dose. The two formulations differ with respect to certain inactive ingredients only and have been shown to be analytically comparable.[14]

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[12] The Pfizer-BioNTech COVID-19 Vaccine that uses PBS buffer is available in multiple dose vials with purple caps, and is formulated to provide, after dilution, doses (each 0.3mL containing 30 µg modRNA) for individuals 12 years of age and older. The formulation that uses PBS buffer is not authorized for use in children 5 through 11 years of age.

[13] The Pfizer-BioNTech COVID-19 Vaccine (0.2 mL dose containing 10 µg modRNA) that uses Tris buffer and is available in multiple dose vials with orange caps and labels with an orange border is the only formulation that is authorized for use in individuals 5 through 11 years of age.

[14] Analytical comparability assessments use laboratory testing to demonstrate that a change in product formulation does not impact a product's safety or effectiveness. For the Pfizer-BioNTech COVID-19 Vaccine, multiple different

Accordingly, under this EUA, for individuals 12 years of age and older, COMIRNATY (COVID-19 Vaccine, mRNA) and these two formulations of the Pfizer-BioNTech COVID-19 Vaccine, when prepared according to their respective instructions for use, can be used interchangeably without presenting any safety or effectiveness concerns.

Therefore, for individuals 12 years of age and older, COMIRNATY (COVID-19 Vaccine, mRNA) is authorized to complete the primary regimen or provide a booster dose for individuals who received their initial primary dose(s) with the Pfizer-BioNTech COVID-19 Vaccine (whether the PBS formulation or Tris formulation), and the Pfizer-BioNTech COVID-19 Vaccine (whether the PBS formulation or Tris formulation) is authorized to complete the primary regimen or provide a booster for individuals who received their initial primary dose(s) with COMIRNATY (COVID-19 Vaccine, mRNA).

For the December 11, 2020 authorization for individuals 16 years of age and older, FDA reviewed safety and effectiveness data from an ongoing Phase 1/2/3 trial in approximately 44,000 participants randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline control. The trial enrolled participants 12 years of age and older. FDA's review at that time considered the safety and effectiveness data as they relate to the request for emergency use authorization in individuals 16 years of age and older. FDA's review of the available safety data from 37,586 of the participants 16 years of age and older, who were followed for a median of two months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of the available efficacy data from 36,523 participants 12 years of age and older without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirmed that the vaccine was 95% effective (95% credible interval 90.3, 97.6) in preventing COVID-19 occurring at least 7 days after the second dose (with 8 COVID-19 cases in the vaccine group compared to 162 COVID-19 cases in the placebo group). Based on these data, and review of manufacturing information regarding product quality and consistency, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective. Additionally, FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 16 years of age and older. Finally, on December 10, 2020, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

For the May 10, 2021 authorization for individuals 12 through 15 years of age, FDA reviewed safety and effectiveness data from the above-referenced, ongoing Phase 1/2/3 trial that enrolled approximately 46,000 participants, including 2,260 participants 12 through 15 years of age.

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release parameters were evaluated to assess the comparability of the modified formulation (the formulation with the Tris buffer) to the originally-authorized formulation (the formulation with the PBS buffer). These release parameters ranged from product appearance to size of the lipid-nanoparticle to the integrity of the modRNA in the product. Additionally, characterization testing was performed to evaluate product composition and purity, including characteristics of the modRNA, as these are characteristics associated with the activity of the vaccine. The combination of release testing and characterization testing demonstrated that the modified formulation is analytically comparable to the original formulation.

Trial participants were randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline control. FDA's review of the available safety data from 2,260 participants 12 through 15 years of age, who were followed for a median of 2 months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of SARS-CoV-2 50% neutralizing antibody titers 1 month after the second dose of Pfizer-BioNTech COVID-19 Vaccine in a subset of participants who had no serological or virological evidence of past SARS-CoV-2 infection confirm that the geometric mean antibody titer in participants 12 through 15 years of age was non-inferior to the geometric mean antibody titer in participants 16 through 25 years of age. FDA's analysis of available descriptive efficacy data from 1,983 participants 12 through 15 years of age without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirm that the vaccine was 100% effective (95% confidence interval 75.3, 100.0) in preventing COVID-19 occurring at least 7 days after the second dose (with no COVID-19 cases in the vaccine group compared to 16 COVID-19 cases in the placebo group). Based on these data, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in individuals 12 through 15 years of age. Additionally, FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 12 through 15 years of age.

For the August 12, 2021 authorization of a third primary series dose in individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise, FDA reviewed safety and effectiveness data reported in two manuscripts on solid organ transplant recipients. The first study was a single arm study conducted in 101 individuals who had undergone various solid organ transplant procedures (heart, kidney, liver, lung, pancreas) a median of 97±8 months earlier. A third dose of the Pfizer-BioNTech COVID-19 Vaccine was administered to 99 of these individuals approximately 2 months after they had received a second dose. Levels of total SARS-CoV-2 binding antibodies meeting the pre-specified criteria for success occurred four weeks after the third dose in 26/59 (44.0%) of those who were initially considered to be seronegative and received a third dose of the Pfizer-BioNTech COVID-19 Vaccine; 67/99 (68%) of the entire group receiving a third vaccination were subsequently considered to have levels of antibodies indicative of a significant response. In those who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 events were reported. A supportive secondary study describes a double-blind, randomized-controlled study conducted in 120 individuals who had undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver, lung, pancreas) a median of 3.57 years earlier (range 1.99-6.75 years). A third dose of a similar messenger RNA vaccine (the Moderna COVID-19 vaccine) was administered to 60 individuals approximately 2 months after they had received a second dose (i.e., doses at 0, 1 and 3 months); saline placebo was given to 60 individuals for comparison. The primary outcome was anti-RBD antibody at 4 months greater than 100 U/mL. This titer was selected based on NHP challenge studies as well as a large clinical cohort study to indicate this antibody titer was protective. Secondary outcomes were based on a virus neutralization assay and polyfunctional T cell responses. Baseline characteristics were comparable between the two study arms as were pre-intervention anti-RBD titer and neutralizing antibodies. Levels of total SARS-CoV-2 binding

antibodies indicative of a significant response occurred four weeks after the third dose in 33/60 (55.0%) of the Moderna COVID-19 vaccinated group and 10/57 (17.5%) of the placebo individuals. In the 60 individuals who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 adverse events were reported. Despite the moderate enhancement in antibody titers, the totality of data (i.e., supportive paper by Hall et al. demonstrated efficacy of the product in the elderly and persons with co-morbidities) supports the conclusion that a third dose of the Pfizer-BioNTech COVID-19 Vaccine may be effective in this population, and that the known and potential benefits of a third dose of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine for immunocompromised individuals at least 12 years of age who have received two doses of the Pfizer-BioNTech COVID-19 Vaccine and who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

For the September 22, 2021 authorization of a single booster dose administered at least 6 months after completing the primary series in individuals: 65 years of age and older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19, FDA reviewed safety and effectiveness data from the above-referenced, ongoing Phase 1/2/3 trial in which 329 participants 18 through 75 years of age received a booster dose of the Pfizer-BioNTech COVID-19 Vaccine approximately 6 months (range 4.8 to 8.8 months) after completion of the primary series. FDA's review of the available safety data from 329 participants 18 through 75 years of age, who had been followed for a median of 2.6 months after receiving the booster dose, did not identify specific safety concerns that would preclude issuance of an EUA. The effectiveness of the booster dose of the Pfizer-BioNTech COVID-19 Vaccine is based on an assessment of 50% neutralizing antibody titers (NT50) against SARS-CoV-2 (USA_WA1/2020). FDA's analysis of SARS-CoV-2 NT50 one month after the booster dose compared to 1 month after the primary series in study participants 18 through 55 years of age who had no serological or virological evidence of past SARS-CoV-2 infection up to 1 month after the booster dose confirmed noninferiority for both geometric mean ratio and difference in seroresponse rates. Based on the totality of the scientific evidence available, including data from the above-referenced clinical trial, FDA concluded that a booster dose the Pfizer-BioNTech COVID-19 Vaccine may be effective, and that the known and potential benefits of a single booster dose at least 6 months after completing the primary series outweigh the known and potential risks for individuals 65 years of age and older; individuals 18 through 64 years of age at high risk of severe COVID-19; and individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

For the October 20, 2021 authorization of a single booster dose as a heterologous booster dose following completion of primary vaccination with another authorized COVID-19 vaccine, FDA reviewed data from an ongoing Phase1/2 clinical trial in participants 19-85 years of age. In this trial, adults who had completed primary vaccination with a Moderna COVID-19 Vaccine 2-dose

series (N=151), a Janssen COVID-19 Vaccine single dose (N=156), or a Pfizer-BioNTech COVID-19 Vaccine 2-dose series (N=151) at least 12 weeks prior to enrollment and who reported no history of SARS-CoV-2 infection were randomized 1:1:1 to receive a booster dose of one of three vaccines: Moderna COVID-19 Vaccine, Janssen COVID-19 Vaccine, or Pfizer-BioNTech COVID-19 Vaccine. Adverse events were assessed through 28 days after the booster dose. An overall review of adverse reactions reported following the Pfizer-BioNTech COVID-19 Vaccine heterologous booster dose did not identify any new safety concerns, as compared with adverse reactions reported following Pfizer-BioNTech COVID-19 Vaccine primary series doses or homologous booster dose. Neutralizing antibody titers, as measured by a pseudovirus neutralization assay using a lentivirus expressing the SARS-CoV-2 Spike protein with D614G mutation, were assessed on Day 1 prior to administration of the booster dose and on Day 15 after the booster dose. A booster response to the Pfizer-BioNTech COVID-19 Vaccine was demonstrated regardless of primary vaccination. Based on the on the totality of the scientific evidence available, including data from the above-referenced clinical trial, FDA concluded that a heterologous booster dose of the Pfizer-BioNTech COVID-19 Vaccine may be effective, and that the known and potential benefits of a heterologous booster dose of the Pfizer-BioNTech COVID-19 Vaccine following completion of primary vaccination with another authorized COVID-19 vaccine outweigh the known and potential risks.

For the October 29, 2021 authorization for the Pfizer-BioNTech COVID-19 Vaccine that uses Tris buffer for individuals 5 through 11 years of age, FDA reviewed safety and effectiveness data from an ongoing Phase 1/2/3 trial that has enrolled 4,695 participants 5 through 11 years of age, of whom 3,109 participants received PfizerBioNTech COVID19 Vaccine (containing 10 μg modRNA) formulated using PBS buffer and approximately 1,538 participants received saline control in Phase 2/3. FDA's review of the available safety data from 3,109 participants 5 through 11 years of age who received Pfizer-BioNTech COVID-19 Vaccine (containing 10 μg modRNA), including 1,444 who were followed for at least 2 months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. SARS-CoV-2 50% neutralizing antibody titers 1 month after the second dose were compared between a subset of participants 5 through 11 years of age who received Pfizer-BioNTech COVID-19 Vaccine (containing 10 μg modRNA) and a subset of participants 16 through 25 years of age who received Pfizer-BioNTech COVID-19 Vaccine (containing 30 μg modRNA) in the above-referenced ongoing Phase 1/2/3 trial that enrolled approximately 46,000 participants. Immunobridging analyses included a subset of participants from each study who had no serological or virological evidence of past SARS-CoV-2 infection. FDA's analyses confirm that immunobridging criteria were met for both geometric mean antibody titers and seroresponse rates. FDA's analysis of available descriptive efficacy data from 1,968 participants 5 through 11 years of age without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirm that the vaccine was 90.7% effective (95% confidence interval 67.7, 98.3) in preventing COVID-19 occurring at least 7 days after the second dose (with 3 COVID-19 cases in the vaccine group compared to 16 COVID-19 cases in the placebo group). Based on these data, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in individuals 5 through 11 years of age. Additionally, FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 5 through 11 years of age. Finally, on

October 26, 2021, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

For the October 29, 2021 authorization of the manufacturing change to include an additional formulation of the Pfizer-BioNTech COVID-19 Vaccine that uses Tris buffer instead of PBS buffer used in the originally authorized Pfizer-BioNTech COVID-19 Vaccine, FDA reviewed data on analytical comparability, which uses laboratory testing to demonstrate that a change in product formulation is not expected to impact safety or effectiveness. In the case of Pfizer-BioNTech COVID-19 Vaccine, multiple different release parameters were evaluated, ranging from product appearance to size of the lipid-nanoparticle to the integrity of the modRNA in the product. Characterization testing included looking at product composition and purity including characteristics of the modRNA, and strength including the lipid-nanoparticle size distribution and shape, as these are characteristics associated with the activity of the vaccine. In this case, analytical comparability to the current PBS formulation of the Pfizer-BioNTech COVID-19 Vaccine was demonstrated for the Tris formulation of the Pfizer-BioNTech COVID-19 Vaccine through a combination of release and characterization testing.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine[15] for the prevention of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization. Additionally, as specified in subsection III.BB, I am authorizing use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA as described in the Scope of Authorization section of this letter (Section II).

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Pfizer-BioNTech COVID-19 Vaccine[16] for the prevention of COVID-19 when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

A. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

B. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks; and

[15] Reference to the Pfizer-BioNTech COVID-19 Vaccine hereinafter refers to both the PBS and Tris formulations, unless specifically delineated otherwise.

[16] In this section (Section I), references to Pfizer-BioNTech COVID-19 Vaccine also apply to COMIRNATY (COVID-19 Vaccine, mRNA).

C. There is no adequate, approved, and available alternative[17] Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19.[18]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Pfizer Inc. will supply Pfizer-BioNTech COVID-19 Vaccine either directly or through authorized distributor(s),[19] to emergency response stakeholders[20] as directed by the U.S. government, including the Centers for Disease Control and Prevention (CDC) and/or other designee, for use consistent with the terms and conditions of this EUA;
- Pfizer-BioNTech COVID-19 Vaccine may be administered by a vaccination provider[21] without an individual prescription for each vaccine recipient.

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[17] Although COMIRNATY (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA. Additionally, there are no COVID-19 vaccines that are approved to provide: COVID-19 vaccination in individuals 5 through 15 years of age; a third primary series dose to certain immunocompromised populations described in this EUA; a homologous booster dose to the authorized population described in this EUA; or a heterologous booster dose following completion of primary vaccination with another authorized COVID-19 vaccine.

[18] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

[19] "Authorized Distributor(s)" are identified by Pfizer Inc. or, if applicable, by a U.S. government entity, such as the Centers for Disease Control and Prevention (CDC) and/or other designee, as an entity or entities allowed to distribute authorized Pfizer-BioNTech COVID-19 Vaccine.

[20] For purposes of this letter, "emergency response stakeholder" refers to a public health agency and its delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, tribal, territorial, State, or Federal), or functional (e.g., law enforcement or public health range) or sphere of authority to administer, deliver, or distribute vaccine in an emergency situation. In some cases (e.g., depending on a state or local jurisdiction's COVID-19 vaccination response organization and plans), there might be overlapping roles and responsibilities among "emergency response stakeholders" and "vaccination providers" (e.g., if a local health department is administering COVID-19 vaccines; if a pharmacy is acting in an official capacity under the authority of the state health department to administer COVID-19 vaccines). In such cases, it is expected that the conditions of authorization that apply to emergency response stakeholders and vaccination providers will all be met.

[21] For purposes of this letter, "vaccination provider" refers to the facility, organization, or healthcare provider licensed or otherwise authorized by the emergency response stakeholder (e.g., non-physician healthcare professionals, such as nurses and pharmacists pursuant to state law under a standing order issued by the state health officer) to administer or provide vaccination services in accordance with the applicable emergency response stakeholder's official COVID-19 vaccination and emergency response plan(s) and who is enrolled in the CDC COVID-19 Vaccination Program. If the vaccine is exported from the United States, a "vaccination provider" is a provider that is authorized to administer this vaccine in accordance with the laws of the country in which it is administered. For purposes of this letter, "healthcare provider" also refers to a person authorized by the U.S. Department of Health and Human Services (e.g., under the PREP Act Declaration for Medical Countermeasures against COVID-19) to administer FDA-authorized COVID-19 vaccine (e.g., qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist). See, e.g., HHS. *Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration*. 85 FR 79190 (December 9, 2020).

For use in individuals 12 years of age and older

- The Pfizer-BioNTech COVID-19 Vaccine formulations that use Tris and PBS buffers (each 0.3 mL dose containing 30 µg modRNA) covered by this authorization will be administered by vaccination providers and used only to prevent COVID-19 in individuals 12 years of age and older with a two-dose primary regimen (3 weeks apart) and to provide:
    - a third primary series dose at least 28 days following the second dose to individuals 12 years of age or older who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise;
    - a single booster dose at least 6 months after completion of a primary series of the vaccine to individuals: 65 years of age or older; 18 through 64 years of age at high risk of severe COVID-19; and 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2;
    - a single booster dose as a heterologous booster dose following completion of primary vaccination with another authorized COVID-19 vaccine, where the eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination; and

For use in individuals 5 through 11 years of age

- The Pfizer-BioNTech COVID-19 Vaccine that uses Tris buffer (each 0.2 mL dose containing 10 µg modRNA) covered by this authorization will be administered by vaccination providers and used only to prevent COVID-19 in individuals 5 through 11 years of age with a two-dose primary regimen (3 weeks apart).

For use in individuals who are 11 years old at the time of the first dose, and turn 12 years old before the second dose:

- Notwithstanding the age limitations for use of the different formulations and presentations described above, individuals who will turn from 11 years to 12 years of age between their first and second dose in the primary regimen may receive, for either dose, either: (1) the Pfizer-BioNTech COVID-19 Vaccine that uses Tris buffer (each 0.2 mL dose containing 10 µg modRNA) covered by this authorization; or (2) the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY formulations provided in one of the presentations for individuals 12 years of age and older (each 0.3 mL dose containing 30 µg modRNA) covered by this authorization.
- The vaccine will be administered by vaccination providers and used only to prevent COVID-19 with a two-dose primary regimen (3 weeks apart).

This authorization also covers the use of the licensed COMIRNATY (COVID-19 Vaccine, mRNA) product when used to provide: (1) a two-dose primary regimen (0.3 mL each, 3 weeks apart) for individuals 12 through 15 years of age; (2) a third primary series dose at least 28 days following the second dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an

equivalent level of immunocompromise; (3) a single booster dose (0.3 mL) at least 6 months after completion of the primary series to individuals 65 years of age and older, 18 through 64 years of age at high risk of severe COVID-19, and 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2; and (4) a single booster dose (0.3 mL) as a heterologous booster dose following completion of primary vaccination with another authorized COVID-19 vaccine, where the eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.

Product Description[22]

The Pfizer-BioNTech COVID-19 Vaccine, supplied in two formulations, is provided in three different vials:

For use in individuals 12 years of age and older

- The Pfizer-BioNTech COVID-19 Vaccine that uses PBS buffer is available in multiple dose vials with purple caps. It is formulated to provide, after dilution, 0.3 mL doses (each containing 30 µg modRNA) and can be used for all authorized indications in individuals 12 years of age and older.
- The Pfizer-BioNTech COVID-19 Vaccine that uses Tris buffer, and is available in multiple dose vials with gray caps and labels with gray borders, is formulated to provide, after dilution, 0.3 mL doses (each containing 30 µg modRNA) and can be used for all authorized indications in individuals 12 years of age and older.

For use in individuals 5 through 11 years of age

- The Pfizer-BioNTech COVID-19 Vaccine that uses Tris buffer, and is available in multiple dose vials with orange caps and labels with orange borders, is formulated to provide, after dilution, 0.2 mL doses (each containing 10 µg modRNA) and can be used for administration to individuals 5 through 11 years of age.

For use in individuals 12 years of age and older

The Pfizer-BioNTech COVID-19 Vaccine that uses PBS buffer (supplied in multiple dose vials with purple caps) is supplied as a frozen suspension; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. The Pfizer-BioNTech COVID-19 Vaccine does not contain a preservative. Each 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 µg of modRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2. Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylee glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg

[22] For COMIRNATY (COVID-19 Vaccine, mRNA) product description, please see the COMIRNATY (COVID-19 Vaccine, mRNA) prescribing information, found here: *https://www.fda.gov/media/151707/download.*

dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection) contributes an additional 2.16 mg sodium chloride per dose.

The Pfizer-BioNTech COVID-19 Vaccine that uses Tris buffer and that is supplied in multiple dose vials with gray caps is supplied as a frozen suspension and should not be diluted. The Pfizer-BioNTech COVID-19 Vaccine does not contain a preservative. Each 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 μg of a modRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2. Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.19 mg cholesterol), 0.06 mg tromethamine, 0.4 mg tromethamine hydrochloride, and 31 mg sucrose.

For use in individuals 5 through 11 years of age

The Pfizer-BioNTech COVID-19 Vaccine that uses Tris buffer and that is supplied in multiple dose vials with orange caps is supplied as a frozen suspension; each vial must be diluted with 1.3 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. Each dose of the Pfizer-BioNTech COVID-19 Vaccine contains 10 μg of a modRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2. Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.14 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.02 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.03 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.06 mg cholesterol), 10.3 mg sucrose, 0.02 mg tromethamine, and 0.13 mg tromethamine hydrochloride. The diluent (0.9% Sodium Chloride Injection, USP) contributes 0.9 mg sodium chloride per dose.

The manufacture of the authorized Pfizer-BioNTech COVID-19 Vaccine is limited to those facilities identified and agreed upon in Pfizer's request for authorization.

The Pfizer-BioNTech COVID-19 Vaccine vial label and carton labels are clearly marked for "Emergency Use Authorization." The Pfizer-BioNTech COVID-19 Vaccine is authorized to be distributed, stored, further redistributed, and administered by emergency response stakeholders when packaged in the authorized manufacturer packaging (i.e., vials and cartons), despite the fact that the vial and carton labels may not contain information that otherwise would be required under the FD&C Act.

Pfizer-BioNTech COVID-19 Vaccine is authorized for emergency use with the following product-specific information required to be made available to vaccination providers and recipients, respectively (referred to as "authorized labeling"):

- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) - For 12 Years of Age and Older Dilute Before Use)

- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) - For 12 Years of Age and Older Do Not Dilute
- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) - For 5 Through 11 Years of Age Dilute Prior To Use
- Vaccine Information Fact Sheet for Recipients and Caregivers About COMIRNATY (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease (COVID-19) For Use Use in Individuals 12 Years of Age and Older
- Vaccine Information Fact Sheet for Recipients and Caregivers About the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease (COVID-19) for Use in Individuals 5 Through 11 Years of Age

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine,[23] when used to prevent COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that Pfizer-BioNTech COVID-19 Vaccine (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of Pfizer-BioNTech COVID-19 Vaccine under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), Pfizer-BioNTech COVID-19 Vaccine is authorized to prevent COVID-19 in individuals 5 years of age and older as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

[23] The conclusions supporting authorization stated in this section (Section II) also apply to COMIRNATY (COVID-19 Vaccine, mRNA).

Pfizer Inc. and Authorized Distributor(s)

A. Pfizer Inc. and authorized distributor(s) will ensure that the authorized Pfizer-BioNTech COVID-19 Vaccine is distributed, as directed by the U.S. government, including CDC and/or other designee, and the authorized labeling (i.e., Fact Sheets) will be made available to vaccination providers, recipients, and caregivers consistent with the terms of this letter.

B. Pfizer Inc. and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until delivered to emergency response stakeholders' receipt sites.

C. Pfizer Inc. will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., emergency response stakeholders, authorized distributors, and vaccination providers) involved in distributing or receiving authorized Pfizer-BioNTech COVID-19 Vaccine. Pfizer Inc. will provide to all relevant stakeholders a copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized labeling.

D. Pfizer Inc. may develop and disseminate instructional and educational materials (e.g., video regarding vaccine handling, storage/cold-chain management, preparation, disposal) that are consistent with the authorized emergency use of the vaccine as described in the letter of authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs during an emergency. Any instructional and educational materials that are inconsistent with the authorized labeling are prohibited.

E. Pfizer Inc. may request changes to this authorization, including to the authorized Fact Sheets for the vaccine. Any request for changes to this EUA must be submitted to Office of Vaccines Research and Review (OVRR)/Center for Biologics Evaluation and Research (CBER). Such changes require appropriate authorization prior to implementation.[24]

F. Pfizer Inc. will report to Vaccine Adverse Event Reporting System (VAERS):
   - Serious adverse events (irrespective of attribution to vaccination);
   - Cases of Multisystem Inflammatory Syndrome in children and adults; and
   - Cases of COVID-19 that result in hospitalization or death, that are reported to Pfizer Inc.

[24] The following types of revisions may be authorized without reissuing this letter: (1) changes to the authorized labeling; (2) non-substantive editorial corrections to this letter; (3) new types of authorized labeling, including new fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing processes, including tests or other authorized components of manufacturing; (7) new conditions of authorization to require data collection or study. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), or (7), review and concurrence is required from the Preparedness and Response Team (PREP)/Office of the Center Director (OD)/CBER and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS).

These reports should be submitted to VAERS as soon as possible but no later than 15 calendar days from initial receipt of the information by Pfizer Inc.

G. Pfizer Inc. must submit to Investigational New Drug application (IND) number 19736 periodic safety reports at monthly intervals in accordance with a due date agreed upon with the Office of Biostatistics and Epidemiology (OBE)/CBER beginning after the first full calendar month after authorization. Each periodic safety report is required to contain descriptive information which includes:
   - A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest;
   - A narrative summary and analysis of vaccine administration errors, whether or not associated with an adverse event, that were identified since the last reporting interval;
   - Newly identified safety concerns in the interval; and
   - Actions taken since the last report because of adverse experiences (for example, changes made to Healthcare Providers Administering Vaccine (Vaccination Providers) Fact Sheet, changes made to studies or studies initiated).

H. No changes will be implemented to the description of the product, manufacturing process, facilities, or equipment without notification to and concurrence by FDA.

I. All manufacturing facilities will comply with Current Good Manufacturing Practice requirements.

J. Pfizer Inc. will submit to the EUA file Certificates of Analysis (CoA) for each drug product lot at least 48 hours prior to vaccine distribution. The CoA will include the established specifications and specific results for each quality control test performed on the final drug product lot.

K. Pfizer Inc. will submit to the EUA file quarterly manufacturing reports, starting in July 2021, that include a listing of all Drug Substance and Drug Product lots produced after issuance of this authorization. This report must include lot number, manufacturing site, date of manufacture, and lot disposition, including those lots that were quarantined for investigation or those lots that were rejected. Information on the reasons for lot quarantine or rejection must be included in the report.

L. Pfizer Inc. and authorized distributor(s) will maintain records regarding release of Pfizer-BioNTech COVID-19 Vaccine for distribution (i.e., lot numbers, quantity, release date).

M. Pfizer Inc. and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

N. Pfizer Inc. will conduct post-authorization observational studies to evaluate the association between Pfizer-BioNTech COVID-19 Vaccine and a pre-specified list of

adverse events of special interest, including myocarditis and pericarditis, along with deaths and hospitalizations, and severe COVID-19. The study population should include individuals administered the authorized Pfizer-BioNTech COVID-19 Vaccine under this EUA in the general U.S. population (5 years of age and older), individuals who receive a booster dose, populations of interest such as healthcare workers, pregnant women, immunocompromised individuals, subpopulations with specific comorbidities. The studies should be conducted in large scale databases with an active comparator. Pfizer Inc. will provide protocols and status update reports to the IND 19736 with agreed-upon study designs and milestone dates.

Emergency Response Stakeholders

O. Emergency response stakeholders will identify vaccination sites to receive authorized Pfizer-BioNTech COVID-19 Vaccine and ensure its distribution and administration, consistent with the terms of this letter and CDC's COVID-19 Vaccination Program.

P. Emergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of this letter of authorization, and the terms herein and any subsequent amendments that might be made to the letter of authorization, instruct them about the means through which they are to obtain and administer the vaccine under the EUA, and ensure that the authorized labeling [i.e., Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Vaccine Information Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website).

Q. Emergency response stakeholders receiving authorized Pfizer-BioNTech COVID-19 Vaccine will ensure that appropriate storage and cold chain is maintained.

Vaccination Providers

R. Vaccination providers will administer the vaccine in accordance with the authorization and will participate and comply with the terms and training required by CDC's COVID-19 Vaccination Program.

S. Vaccination providers will provide the Vaccine Information Fact Sheet for Recipients and Caregivers to each individual receiving vaccination and provide the necessary information for receiving their second dose and/or third dose.

T. Vaccination providers administering the vaccine must report the following information associated with the administration of the vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):
- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome in children and adults
- Cases of COVID-19 that result in hospitalization or death

Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. The VAERS reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report. More information is available at vaers.hhs.gov or by calling 1-800-822-7967. To the extent feasible, report to Pfizer Inc. by contacting 1-800-438-1985 or by providing a copy of the VAERS form to Pfizer Inc.; Fax: 1-866-635-8337.

U. Vaccination providers will conduct any follow-up requested by the U.S government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.

V. Vaccination providers will monitor and comply with CDC and/or emergency response stakeholder vaccine management requirements (e.g., requirements concerning obtaining, tracking, and handling vaccine) and with requirements concerning reporting of vaccine administration data to CDC.

W. Vaccination providers will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to CDC, and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising, and Promotion

X. All descriptive printed matter, advertising, and promotional material, relating to the use of the Pfizer-BioNTech COVID-19 Vaccine shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in Section 502(a) and (n) of the FD&C Act and FDA implementing regulations.

Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Pfizer-BioNTech COVID-19 Vaccine clearly and conspicuously shall state that:

- This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use either in individuals 12 years of age and older, or in individuals 5 through 11 years of age, as appropriate; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

Condition Related to Export

Z. If the Pfizer-BioNTech COVID-19 Vaccine is exported from the United States, conditions C, D, and O through Y do not apply, but export is permitted only if 1) the regulatory authorities of the country in which the vaccine will be used are fully

informed that this vaccine is subject to an EUA and is not approved or licensed by FDA and 2) the intended use of the vaccine will comply in all respects with the laws of the country in which the product will be used. The requirement in this letter that the authorized labeling (i.e., Fact Sheets) be made available to vaccination providers, recipients, and caregivers in condition A will not apply if the authorized labeling (i.e., Fact Sheets) are made available to the regulatory authorities of the country in which the vaccine will be used.

Conditions With Respect to Use of Licensed Product

AA. COMIRNATY (COVID-19 Vaccine, mRNA) is licensed for individuals 16 years of age and older. There remains, however, a significant amount of Pfizer-BioNTech COVID-19 Vaccine that was manufactured and labeled in accordance with this emergency use authorization. The authorization remains in place with respect to the Pfizer-BioNTech COVID-19 Vaccine for this population.

BB. This authorization also covers the use of the licensed COMIRNATY (COVID-19 Vaccine, mRNA) product when used to provide: (1) a two-dose primary regimen for individuals 12 through 15 years of age;[25] (2) a third primary series dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise; (3) a single booster dose at least 6 months after completing the primary series to individuals 65 years of age or older, 18 through 64 years of age at high risk of severe COVID-19, and 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2; and (4) a heterologous booster dose to certain individuals who have completed primary vaccination with a different authorized COVID-19 vaccine as described in the Scope of Authorization (Section II) under this EUA. Conditions A through W in this letter apply when COMIRNATY (COVID-19 Vaccine, mRNA) is provided for the uses described in this subsection III.BB., except that product manufactured and labeled in accordance with the approved BLA is deemed to satisfy the manufacturing, labeling, and distribution requirements of this authorization.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

[25] As noted above, this includes the first dose of a two-dose primary regimen for individuals who are 11 years old and will turn 12 years of age between their first and second dose in the primary regimen.

Sincerely,

--/S/--

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosures

combat COVID. hhs.gov

EXHIBIT E

COVID-19 Information

x

Get the latest public health information from CDC
Get the latest research information from NIH | Español
Learn more about COVID-19 and you from HHS

NEWS: DailyMed Announcements

SEPTEMBER 13, 2021

Pfizer received FDA BLA license for its COVID-19 vaccine

Pfizer received FDA BLA license on 8/23/2021 for its COVID-19 vaccine for use in individuals 16 and older (COMIRNATY). 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.

At present, Pfizer does not plan to produce any product with these new NDCs and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution. As such, the CDC, AMA, and drug compendia may not publish these new codes until Pfizer has determined when the product will be produced with the BLA labels.

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