IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW MEXICO

ISAAC LEGARETTA, and JOHN or JANE DOES 1-20, Plaintiffs, vs. FERNANDO MACIAS, Dona Ana County Manager, DIRECTOR BRYAN BAKER, an Official with the Dona Ana County Detention Center, CAPTAIN BEN MENDOZA, an official with the Dona Ana County Detention Center, CAPTAIN JOSHUA FLEMING, an official with the Dona Ana County Detention Center, and JOHN or JANE DOES 1-20, Defendants.	)	Case No.: _____ COMPLAINT

COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF

The Plaintiff states:

GENERAL ALLEGATIONS

1. He is a resident of the state of New Mexico, County of Dona Ana, City of Las Cruces. Defendant Fernando Macias is a governmental official within the state of New Mexico. Defendants Director Bryan Baker, Captain Ben Mendoza and Captain Joshua Fleming are supervisors to Plaintiff, any of which have the authority from Defendant Macias to terminate Plaintiff from his employment or otherwise enforce the illegal mandate for compulsory injection.

2. This Court has jurisdiction under Article III because the Plaintiff alleges that Defendant Macias has violated Plaintiff's rights by issuing a mandate requiring him to take a vaccine for COVID-

19 which mandate is in direct conflict with federal law which states that the unapproved vaccine cannot be mandatory.

3. The Plaintiff is an employee at the Dona Ana Detention Center which is administered by the Defendants. On or about February 1, 2021, County Manager Fernando Macias issued a "Mandatory COVID-19 Vaccination Directive," requiring first-responders in Dona Ana County to receive COVID-19 vaccination as a condition of ongoing employment. **Exhibit A.**

4. On or about February 18, 2021, Plaintiff received a 5 day notice to comply with the mandate to receive the COVID vaccine. Plaintiff has received a "coaching and counseling" write up for not complying with the directive. **Exhibit B.**

5. Plaintiff is in imminent danger of being terminated from his job for refusing to accept the vaccine.

6. The Mandatory COVID-19 Vaccination Directive issued by Defendant Macias is in direct violation of Federal law, specifically 21 U.S. Code § 360bbb–3 - *Authorization for medical products for use in emergencies*. That law states that where a medical product is "unapproved" then no one may be mandated to take it. At Section (e)(1)(A) of the aforementioned statute it states:

> "With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:
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> (i) Appropriate conditions designed to ensure that health care professionals administering the product are informed--
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> (I) that the Secretary has authorized the emergency use of the product;
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> (II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and
>
> (III) of the alternatives to the product that are available, and of their benefits and risks.
>
> (ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed--

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and

(III) **of the option to accept or refuse administration of the product,** of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks. (emphasis added)

7. The Defendants have violated the last two quoted sections (II and III). They did not advise Plaintiff of the "known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown" of the COVID-19 vaccine.

8. Most importantly for purposes of the injunctive and declaratory relief requested, the Defendants did not inform Plaintiff that he had an option to refuse the vaccine. Quite the opposite, he was advised that he would be fired if he did so.

9. That the vaccine being forced upon Plaintiff is "unapproved" cannot be disputed. Even though the FDA granted emergency use authorizations for the Pfizer/BioNTech and Moderna vaccines in December, 2020, the clinical trials the FDA will rely upon to ultimately decide whether to license these vaccines are still underway and are designed to last for approximately two years to collect adequate data to establish if these vaccines are safe and effective enough for the FDA to license. The abbreviated timelines for the emergency use applications and authorizations means there is much the FDA does not know about these products even as it authorizes them for emergency use, including their effectiveness against infection, death, and transmission of SARS-CoV-2, the virus that is allegedly the cause of the COVID disease. Given the uncertainty about the two vaccines, their EUAs (emergency use authorizations) are explicit that each is "an investigational vaccine not licensed for any indication" and require that all "promotional material relating to the Covid-19 Vaccine clearly and conspicuously ... state that this product has not been approved or licensed by the FDA, but has been authorized for emergency use by FDA". See **Exhibit C, EUA letter for Pfizer.**

10. The FDA on their website has stated the following:

> FDA believes that the terms and conditions of an EUA issued under section 564 preempt state or local law, both legislative requirements and common-law duties, that impose different or additional requirements on the medical product for which the EUA was issued in the context of the emergency declared under section 564 … In an emergency, it is critical that the conditions that are part of the EUA or an order or waiver issued pursuant to section 564A — those that FDA has determined to be necessary or appropriate to protect the public health—be strictly followed, and that no additional conditions be imposed."

11. On August, 2020 at a Centers for Disease Control and Prevention published meeting of the Advisory Committee on Immunization Practices the Committee's Executive Secretary and Chief Medical Officer of the National Center for Immunizations and Respiratory Diseases, Dr. Amanda Cohn stated (@1:14:40):

> "I just wanted to add that, just wanted to remind everybody, that under an Emergency Use Authorization, an EUA, vaccines are not allowed to be mandatory. So, early in this vaccination phase, individuals will have to be consented and they won't be able to be mandated."

FEDERAL PREEMPTION

12. The Supremacy Clause of the United States Constitution, Art. VI, which is the basis of the federal preemption doctrine, states:

> "This Constitution, and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding."

A federal requirement preempts a state requirement if the state requirement actually conflicts with the federal requirement because compliance with both is impossible. *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143 (1963). Preemption will also be applicable if the state requirement "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67, 61 S.Ct. 399, 404, 85 L.Ed. 581 (1941). Finally, federal exemption applies if a scheme of federal regulation is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230 (1947).

A more attenuated analysis of the doctrine of federal preemption including express and implied preemption is succinctly articulated in *Frei v. Taro Pharm. United Statesa*, Inc., 443 F.Supp.3d 456 (S.D. N.Y. 2020):

> "Express preemption is present when Congress's intent to preempt state law is explicitly stated in the statute's language." In re PepsiCo., Inc., Bottled Water Mktg. & Sales Practices Litig., 588 F. Supp. 2d 527, 530 (S.D.N.Y. 2008). "Implied preemption arises when, in the absence of explicit statutory language, ... Congress intended the Federal Government to occupy a field exclusively, or when state law actually conflicts with federal law." Air Trans. Ass'n of Am., Inc. v. Cuomo, 520 F.3d 218, 220 (2d Cir. 2008) (citing English v. Gen. Elec. Co., 496 U.S. 72, 79, 110 S.Ct. 2270, 110 L.Ed.2d 65 (1990)).
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> The latter type of implied preemption, called "conflict preemption," "comes in two forms—impossibility preemption and obstacle preemption." McDaniel v. Upsher-Smith Labs., Inc., 893 F.3d 941, 944 (6th Cir. 2018). The first, impossibility preemption, arises as its title suggests: when compliance with both federal and state law is impossible. Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98, 112 S.Ct. 2374, 120 L.Ed.2d 73 (1992). "The proper question for impossibility analysis is whether the private party could independently do under federal law what state law requires of it." PLIVA, Inc. v. Mensing, 564 U.S. at 620, 131 S.Ct. 2567. The second form, obstacle preemption, exists "when a state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Wis. Pub. Intervenor v. Mortier, 501 U.S. 597, 605, 111 S.Ct. 2476, 115 L.Ed.2d 532 (1991).

Frei v. Taro at 465-466

13. It is evident that the federal law at issue in this case preempts the Defendants' directive which completely disregards it, because compliance with both is impossible. In addition, Defendants' failure to comply with the federal law clearly is an obstacle to the purpose of the federal law which to allow people to not be compelled to take an unapproved drug or vaccine. Moreover, Plaintiff contends that the FDA, an agent of the Department of Health and Human Services, intends to exclusively occupy the field of approval of drugs and the manner in which unapproved drugs may be administered. This would seem to be self-evident. States simply do not venture into the area of drug approval. This is the FDA's field. The Defendants deciding to violate federal law by not giving employees the right to not take the vaccination clearly violates the doctrine of federal preemption. *See generally, Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 570-71 (2001) (overturning a state public health law because it was already the subject of a comprehensive federal scheme to manage public health).

RELIEF REQUESTED

COUNT ONE – DECLARATORY RELIEF

14. Plaintiff requests the Court issue declaratory relief that:

(a.) 21 U.S. Code § 360bbb–3, Section (e)(1)(A) does not permit Defendants to coerce an employee to accept an unapproved vaccine on penalty of termination or other sanctions.

(b.) The doctrine of federal preemption invalidates and voids the "Mandatory COVID-19 Vaccination Directive" of Defendant Macias.

COUNT TWO – INJUNCTIVE RELIEF

15. Plaintiff has been threatened with termination for choosing not to take an unapproved vaccine which federal law states cannot be mandated because insufficient trials have been conducted and its long-term effects are not known. Already there are many news reports of adverse effects and even deaths resulting from the vaccine. If Plaintiff were to be terminated for refusing a vaccine which federal law requires *not* to be mandated, it would be a retaliatory discharge under New Mexico law. The New Mexico Supreme Court has defined a retaliatory discharge as follows:

"For an employee to recover under this new cause of action, he must demonstrate that he was discharged because he performed an act that public policy has authorized or would encourage, or because he refused to do something required of him by his employer that public policy would condemn."

Shovelin v. Central New Mexico Elec. Co-op., Inc., 850 P.2d 996, 115 N.M. 293, 1993 NMSC 15 (N.M. 1993)

16. Plaintiff could not sue for damages for the tort of retaliatory discharge because New Mexico's sovereign immunity would not allow it and such immunity for a retaliatory discharge has not been waived in the New Mexico Tort Claims Act. New Mexico's sovereign immunity protects Defendants from suits for monetary damages but not suits for injunctions. Lacking the ability to sue for damages for retaliatory discharge, Plaintiff will be irreparably harmed absent injunctive relief.

17. If the Defendants were to terminate Plaintiff for refusing to take a vaccine it would be a

violation of his due process right to life and liberty under the 14th Amendment and an invasion of the zone of privacy and right to bodily integrity which have been held to emanate from various Bill of Rights amendments, including the first, fourth and fifth as well as the ninth amendment which speaks of essential but unenumerated rights. The constitutionally protected zone of privacy and right to bodily integrity have been articulated is many Supreme Court cases, including *Mapp v. Ohio*, 367 U.S. 643 (1961), *Griswold v. State of Connecticut*, 381 U.S. 479, 85 S.Ct. 1678, 14 L.Ed.2d 510 (1965); *Roe v. Wade,* 410 US 113 (1973).

In *Griswold,* the Court said:

> The foregoing cases suggest that specific guarantees in the Bill of Rights have penumbras, formed by emanations from those guarantees that help give them life and substance. See Poe v. Ullman, 367 U.S. 497, 516—522, 81 S.Ct. 1752, 6 L.Ed.2d 989 (dissenting opinion). Various guarantees create zones of privacy. The right of association contained in the penumbra of the First Amendment is one, as we have seen. The Third Amendment in its prohibition against the quartering of soldiers 'in any house' in time of peace without the consent of the owner is another facet of that privacy. The Fourth Amendment explicitly affirms the 'right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures.' The Fifth Amendment in its Self-Incrimination Clause enables the citizen to create a zone of privacy which government may not force him to surrender to his detriment. The Ninth Amendment provides: 'The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.'
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> The Fourth and Fifth Amendments were described in Boyd v. United States, 116 U.S. 616, 630, 6 S.Ct. 524, 532, 29 L.Ed. 746, as protection against all governmental invasions 'of the sanctity of a man's home and the privacies of life.'* We recently referred in Mapp v. Ohio, 367 U.S. 643, 656, 81 S.Ct. 1684 1692, 6 L.Ed.2d 1081, to the Fourth Amendment as creating a 'right to privacy, no less important than any other right carefully and particularly reserved to the people.' See Beaney, The Constitutional Right to Privacy, 1962 Sup.Ct.Rev. 212; Griswold, The Right to be Let Alone, 55 Nw.U.L.Rev. 216 (1960).
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> More recently in *Planned Parenthood v. Casey,* 505 U.S. 833(1992), referencing the Roe v. Wade decision the Court states stated:
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> > *Roe*, however, may be seen not only as an exemplar of *Griswold* liberty but as a rule (whether or not mistaken) of personal autonomy and bodily integrity, ***with doctrinal affinity to cases recognizing limits on governmental power to mandate medical treatment or to bar its rejection. If so, our cases since Roe accord with Roe's view that a State's interest in the protection of life falls short of justifying any plenary override of individual liberty claims***. *Cruzan v. Director, Mo. Dept. of Health*, 497 U.S. 261, 278, 111 L. Ed. 2d 224, 110 S. Ct. 2841 (1990); cf., *e. g., Riggins v. Nevada*, 504 U.S. 127, 135, 118 L. Ed. 2d 479, 112 S. Ct. 1810

(1992); *Washington v. Harper*, 494 U.S. 210, 108 L. Ed. 2D 178, 110 S. Ct. 1028 (1990); see also, *e. g., Rochin v. California*, 342 U.S. 165, 96 L. Ed. 183, 72 S. Ct. 205 (1952); *Jacobson v. Massachusetts*, 197 U.S. 11, 24-30, 49 L. Ed. 643, 25 S. Ct. 358 (1905). (emphasis added)

18. It is worth noting that in *Planned Parenthood, supra*, the Court includes *Jacobson v. Massachusetts* as a case "*recognizing limits on governmental power to mandate medical treatment or to bar its rejection."* because *Jacobsen* has often been cited for the opposite proposition since its holding was that a state law requiring vaccination was valid. However, the Jacobsen court said: "Before closing this opinion, we deem it appropriate, in order to prevent misapprehension as to our views, to observe -- perhaps to repeat a thought already sufficiently expressed, namely -- that the police power of a State, whether exercised by the legislature or by a local body acting under its authority, may be exerted in such circumstances or by regulations so arbitrary and oppressive in particular cases as to justify the interference of the courts to prevent wrong and oppression." (*Id*, 197 US 38).

Moreover, *Jacobsen* was decided 116 years ago when many of our most sacred and fundamental rights were still being sorted out. Suffrage had not yet occurred, civil rights barely existed, critical cases on fundamental rights such as interstate travel and bodily privacy had not come into play and the administrative state that we live in today simply did not exist. Since *Jacobsen* the court has decided many critical cases which expanded the conceptual and practical reach of the Bill of Rights as outlined in the preceding paragraphs.

19. Plaintiff contends that in light of the facts and the law hereinabove, success on the merits is likely, the balance of equities argues for granting injunctive relief and the public interest will not be harmed by the injunctive relief requested.

20. There is no need for a bond since Defendants will not suffer economic harm from injunctive relief.

COUNT THREE – INJUNCTION OR MANDAMUS REQUIRING DEFENDANTS TO REINSTATE PLAINTIFF

21. Plaintiff fears that the Defendants may, by the time this Complaint is filed and the Court can enter injunctive relief preventing termination of his employment, have already terminated him.

22. If such does occur, Plaintiff requests that the Court issue an affirmative injunction or Writ of Mandamus requiring the Defendants to reinstate him.

WHEREFORE, Plaintiff respectfully requests that the Court:

1. Enter declaratory relief as requested in Count One.

2. Enter an immediate TRO and a preliminary injunction enjoining the Defendants from terminating, demoting, or taking any negative action against Plaintiff for refusing to take a non-mandatory unapproved vaccine.

3. If need be, enter an injunction or Writ of Mandamus requiring Defendants to reinstate Plaintiff to his position of employment.

4. Order any other appropriate relief.

Respectfully submitted,

/s/ N. Ana Garner

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DECLARATION UNDER PENALTY OF PERJURY

The undersigned declares under penalty of perjury that he is the Plaintiff in the above action, that he has read the Complaint and hat the information contained therein is true and correct. 28 U.S.C. §1746. 18 U.S.C. 1621.

Executed at Las Cruces, New Mexico on February 26, 2021.

Isaac Legarreta

DOÑA ANA COUNTY
COUNTY MANAGER'S OFFICE

MEMORANDUM

To: **All Doña Ana County First Responders**

From: **Fernando R. Macias**

Date: **January 29, 2021**

Subject: **Mandatory COVID-19 Vaccination Directive**

On March 11, 2020, the novel coronavirus (COVID-19) was declared a pandemic by the World Health Organization. Due to the severity of illness and risk of death or serious harm that may result from becoming infected with COVID-19, this pandemic rises to the level of a direct threat as defined by the Occupational Safety and Health Administration (OSHA). As required by OSHA and in accordance with the County's duty to provide and maintain a workplace that is free of known hazards, we are adopting a mandatory COVID-19 vaccination directive to safeguard the health of our employees, their families, the customers we serve, and the community at large from this highly contagious, infectious disease. This directive takes into account all applicable laws and guidance from local health authorities.

All first responders will be required to receive the COVID-19 vaccination unless a reasonable accommodation is approved. Vaccines will be available for first responders on February 2, 3 and 4, 2021. First responders include certified law enforcement officers, detention officers and other staff who have face-to-face contact with inmates, firefighters, emergency medical technicians and paramedics. Volunteer firefighters and EMT's are strongly encouraged to be vaccinated next week as well.

There are certain conditions where receiving the COVID-19 vaccination is not advisable such as a history of adverse reactions to vaccines or other qualifying conditions. General information about the COVID vaccine can be found at https://cv.nmhealth.org/covid-vaccine/. If you believe that you have a qualifying condition that requires an accommodation, contact the Human Resources department to obtain the accommodation request form and guidance regarding the process. An accommodation may be granted if it does not cause an undue hardship or pose a direct threat to the health and safety of others. If you have an EEO or ADA related concern regarding the vaccination requirement, you will need to speak directly to a Human Resources Administrator to see if an accommodation can be made. Questions and concerns related to an accommodation should not be taken to your supervisor or department head as this type of information is generally private and protected.

EXHIBIT A

According to the New Mexico Department of Health, the COVID-19 vaccine rollout is in phase 1b which includes first responders. To register for the vaccine, go to www.vaccinenm.org and follow the steps below:

1. Login to the New Mexico Department of Health vaccination website – www.vaccinenm.org
2. Submit basic contact information and select the employment category **First Responder** or **Corrections** and list any medical conditions.
3. Once you have completed registration with the State, contact the Designated Infection Control Officer (DICO) for your department to notify them. The DICO will then provide you with additional information about how to register for a specific appointment.

Please note that first responder vaccination events taking place on February 2, 3 and 4, 2021 may be the final opportunity for you to receive priority status for the vaccination. It is required that, if you have not already started your vaccinations, that you be vaccinated with your first dose on one of these days, or contact Human Resources for accommodation. Being vaccinated is a requirement and a condition of on-going employment with the County due to the significant health and safety risks posed by contracting or spreading COVID-19.

Once you receive your vaccination, you must provide the proof of vaccination to the Human Resources Department and your department's DICO for tracking purposes.

Thank you for your commitment to our community. And, thank you for your ongoing service in this critical role to protect our residents!

IL

Coaching/Counseling Acknowledgement

I acknowledge that I have had the policy, procedure, or execution of a specific work process demonstrated or explained to me regarding the following:

Officer Legarreta, on January 29, 2021, a Mandatory COVID-19 Vaccination Directive was given by Dona Ana County Manager Fernando Macias via email. The directive specifically states that all first responders will be required to receive the COVID-19 vaccination unless a reasonable accommodation is approved by Human Resources. Additionally, on January 29,2021, Detention Center Director Bryan Baker sent a follow-up email to all detention center staff with a requirement that all individuals with access to the secure area of the facility are mandated to have received their first dose of their vaccination by February 5th, 2021 unless there is a documented ADA or EEO exception granted by Human Resources.

Officer Legarreta, as of today's date you have not provided proof of receiving the COVID-19 Vaccination or having registered for the vaccination. You are being required to follow the attached directives from Fernando Macias and Bryan Baker, which requires you to receive the COVID-19 Vaccination. You have 5 business days from today's date to comply with the directives and provide your registration number. Please keep in mind that you may request a reasonable accommodation by Human Resources. Please provide proof or notification to the Detention Center's Designated Infection Control Officer (DICO) Lieutenant Matthew Cordova within 5 business days of today's date.

with the purpose of bringing my work performance in line with Doña Ana County Detention Center standards and expectations.

I understand and acknowledge that coaching/mentoring is not considered a form of discipline and is solely used as a tool for performance management and is intended to proactively enhance the employee's performance through feedback and re-direction as per Doña Ana County Human Resources Policy 9-1 "Coaching and Counseling".

Isaac Legarreta 2793 — Print Name and ID #

2/17/21 — Date

Signature

EXHIBIT B

J. LUJAN
Coach / Counselor / Supervisor Print Name and ID #

2/17/2021
Date

Coach / Counselor / Supervisor Signature

December 23, 2020

Pfizer Inc.
Attention: Ms. Elisa Harkins
500 Arcola Road
Collegeville, PA 19426

Dear Ms. Harkins:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of 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 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, 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 Coronavirus Disease 2019 (COVID-19) for individuals 16 years of age and older, as described in the Scope of Authorization (Section II) of this letter, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act) (21 U.S.C. 360bbb-3). On December 23, 2020, 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 December 11, 2020 letter in its entirety with revisions incorporated to remove reference to the number of doses per vial after dilution, to clarify instructions for vaccination provider reporting to VAERS, and to provide other technical corrections. The Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) is being revised 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 are being revised to include additional information on safety monitoring and to clarify information about the availability of other COVID-19 vaccines.

Pfizer-BioNTech COVID-19 Vaccine is for use for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16

[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 Federal Food, Drug, and Cosmetic 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).

EXHIBIT C

years of age and older. The vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. It is an investigational vaccine not licensed for any indication.

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 has 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 confirm 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, it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective. Additionally, 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.

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.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Pfizer-BioNTech COVID-19 Vaccine 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:

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

2. 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

3. There is no adequate, approved, and available alternative to the emergency use of Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19.[3]

This is false and needs to be disclosed

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)[4], to emergency response stakeholders[5] 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[6] and used only to prevent COVID-19 in individuals ages 16 and older; and
- Pfizer-BioNTech COVID-19 Vaccine may be administered by a vaccination provider without an individual prescription for each vaccine recipient.

Product Description

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

[4] "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.

[5] 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.

[6] 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. 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).

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 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 two doses of 0.3 mL each, 3 weeks apart.

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)

- Fact Sheet for Recipients and Caregivers: Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 16 Years of Age and Older

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, 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 16 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 Pfizer-BioNTech COVID-19 Vaccine, that do not alter the analysis of benefits and risks that underlies this authorization and FDA may determine that such changes may be permitted without amendment of this EUA. That determination must be made by joint decision of the Office of Vaccines Research and Review (OVRR)/Center for Biologics Evaluation and Research (CBER), 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/Office of the Commissioner (OCS).

F. Pfizer Inc. will report to Vaccine Adverse Event Reporting System (VAERS):
- 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; 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, within 15 days after the last day of a month, 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.
- 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 the Agency.

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 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. The first report is due July 2021.

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 study(ies) to evaluate the association between Pfizer-BioNTech COVID-19 Vaccine and a pre-specified list of adverse events of special interest, 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 (16 years of age and older), populations of interest such as healthcare workers, pregnant women, immunocompromised individuals, subpopulations with specific comorbidities. The study(ies) 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 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 Fact Sheet for Recipients and Caregivers to each individual receiving vaccination and provide the necessary information for receiving their second dose.

T. Vaccination providers administering Pfizer-BioNTech COVID-19 Vaccine must report the following information associated with the administration of Pfizer-BioNTech COVID-19 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 16 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.

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,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures